ASEAN PHARMACEUTICAL REGULATORY FRAMEWORK AGREEMENT

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");

MINDFUL of the purpose of ASEAN to create a single ASEAN market and production base which is stable, economically integrated with effective facilitation for trade and investment with the intention to enhance the well-being and livelihood of the peoples of ASEAN by providing them with equitable access to opportunities for human development, social welfare and justice envisaged in the ASEAN Charter signed by the ASEAN Leaders on 20 November 2007 in Singapore, and the ASEAN Economic Community Blueprint 2025 and the ASEAN Socio-Cultural Community Blueprint 2025 adopted by the ASEAN Leaders on 22 November 2015 in Kuala Lumpur, Malaysia;

NOTING 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;

RECOGNISING that ongoing ASEAN cooperation towards regional integration on pharmaceutical development and regulation have been implemented under the respective

purviews of the ASEAN Economic Ministers (AEM) and ASEAN Health Ministers (AHM);

NOTING the ASEAN Pharmaceutical Regulatory Policy (APRP) and the ASEAN Pharmaceutical Regulatory Framework (APRF) respectively were adopted by the AEM and AHM Meetings in 2022 and 2023 respectively;

RECOGNISING that cooperation in the area of pharmaceutical regulation including pharmaceutical development in the economic and socio-cultural sectors will facilitate the development of an integrated market in pharmaceutical products that ensures the well-being of peoples of ASEAN;

RECOGNISING that enhanced ASEAN cooperation on pharmaceuticals will greatly enhance security and self-reliance in pharmaceutical products, including vaccines in the region;

RECOGNISING that effective regulation of the pharmaceutical sector in ASEAN requires a structured, coherent, and comprehensive approach that links the initiatives in a legal framework and ensures that pharmaceutical regulations are implemented across product life cycle;

UNDERSTANDING the desire and the need for the development and optimal use of existing ASEAN scientific, technical, and regulatory resources;

HAVE AGREED AS FOLLOWS:

Article 1
Definitions

For the purposes of this Agreement, the following definitions shall apply:

(a) **National Regulatory Authority** means the National Regulatory Authority responsible for regulation of pharmaceutical products in the Member State.

(b) **pharmaceutical operators** means government or non-governmental entities involved in development pre-clinical and clinical testing, manufacture, laboratory testing, distribution, and import or export of pharmaceutical products;

(c) **pharmaceutical product** means:

(i) any substance or combination of substances presented for treating or preventing diseases in human beings; or

(ii) any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting, or modifying physiological function in human beings;

(d) **Protocol** means a document defining obligations and rights of the Member States with respect to the implementation of pharmaceutical regulatory requirements, including associated arrangements, agreed upon and signed by the Member States.

Article 2
Objectives

The objective of the ASEAN Pharmaceutical Regulatory Framework Agreement (hereinafter referred to as "Agreement") is to establish a comprehensive and coherent overall approach towards an integrated market for pharmaceuticals in ASEAN that:

(a) provides a basis and a framework for Member States to facilitate the development of harmonised strategies that enhance national regulatory systems and enable the implementation of market integration initiatives;

(b) facilitates the removal of unnecessary technical barriers to intra-ASEAN trade in pharmaceutical products by Member States;

(c) ensures timely access to high quality, safe, and efficacious pharmaceutical products to peoples of ASEAN through transparent and accountable procedures;

(d) enhances efficiency of regulatory practices in ASEAN through strengthened collaboration among National Regulatory Authorities in the regulation of pharmaceuticals marketed in ASEAN, based on regulatory and technical standards, practices, and guidelines jointly agreed by National Regulatory Authorities;

(e) facilitates arrangements as required, for information sharing, work-sharing, and coordination and cooperation in regulatory positions and decisions, on pharmaceutical products and pharmaceutical operators; and

(f) strengthens cooperation among National Regulatory Authorities in combating pharmaceutical products and pharmaceutical operators non-compliant with relevant legislation and regulatory requirements, as appropriate.

Article 3
Scope

1. This Agreement shall apply to the development of initiatives to enhance the integration of the market in the pharmaceutical sector based on the APRP so as to address the quality, safety, and efficacy requirements throughout the life-cycle of pharmaceutical products and controls of pharmaceutical operators.

2. This Agreement shall not apply to:

(a) veterinary pharmaceuticals and other categories of health products such as medical devices, traditional medicines, health supplements, and cosmetics; and

(b) regulation of pricing of pharmaceutical products.

Article 4
Principles

1. Member States shall develop and apply appropriate pharmaceutical regulations towards attaining the objectives of the APRP to ensure timely access of high quality, safe, and efficacious pharmaceutical products to peoples of ASEAN, also taking into consideration concerns on substandard and falsified pharmaceuticals.

2. Member States shall facilitate the integration of supply chains of pharmaceuticals across ASEAN to ensure Member States' secure access to pharmaceutical products through alignment of regulatory pathways.

3. Member States shall enhance regional collaboration and undertake institutional strengthening through the adoption and implementation of regulatory standards aligned with recognised international and World Health Organization standards.

4. Member States shall apply the principles of the APRP in the development of Protocols.

5. Member States may adopt specific measures in emergency and special situations as identified by and relevant to such Member States.

Article 5
General Provisions

1. Member States shall take all necessary measures to ensure that regulatory requirements for pharmaceuticals are comprehensive, up to date, and aligned with this Agreement.

2. Member States shall endeavour to keep regulatory requirements and standards in line with scientific and technical progress and international regulatory development.

3. Member States shall participate in the development and adoption of ASEAN harmonised regulatory requirements and standards that cover all essential elements related to regulation of quality, safety, and efficacy of pharmaceuticals throughout the life-cycle and reflect the standards established by recognised international organisations, initiatives, and platforms.

4. Member States shall prepare ASEAN roadmaps to define and monitor the adoption and implementation of ASEAN harmonised regulatory requirements and standards, and when appropriate, practices and guidelines. Member States shall individually prepare respective national plans as appropriate.

5. Member States shall endeavour to actively participate in the development of international technical regulatory standards, practices, and guidelines for pharmaceutical products when appropriate to ensure that the concerns of the region are considered.

6. When required to facilitate integration of the market for pharmaceutical products, Member States shall endeavour to develop and adopt common definitions and classifications of pharmaceutical products as appropriate.

7. Member States shall ensure that the National Regulatory Authorities are empowered and resourced to perform required regulatory and control functions through the life-cycle of pharmaceutical products.

8. Member States shall ensure the National Regulatory Authorities adopt the principles of the *ASEAN Guidelines on Good Regulatory Practice*.

9. The National Regulatory Authorities shall share, where appropriate, their regulatory decisions and reports among themselves to facilitate collaboration in implementation of regulations.

10. Member States shall develop and adopt arrangements and terms for activities on regulatory work performed in collaboration among Member States as needed.

Article 6
Regulatory Cooperation

1. Member States shall establish a process to generate a scientific or regulatory position when required to support regional cooperation initiatives.

2. Member States shall harmonise guidelines on good laboratory practice, good clinical practice, good manufacturing practice, and good distribution practice and shall apply the guidelines through an appropriate system of controls.

4. Member States shall establish an appropriate system of controls to ensure that importers of pharmaceutical products comply with regulatory requirements.

5. Member States shall subject a finished pharmaceutical product to marketing authorisation before its placement on the market and shall update the authorisations to reflect changes to the product, its manufacture and accompanying information taking into account scientific and technical progress.

6. Member States shall establish procedures to suspend or withdraw marketing authorisations of pharmaceutical products found to be non-compliant with regulatory requirements and standards. Information sharing on suspension or withdrawals of marketing authorisations among the National Regulatory Authorities shall be done based on agreed procedures.

7. Marketing authorisations and post-authorisation decisions shall be a Member State's sovereign regulatory decision.

8. Member States shall ensure that an effective pharmacovigilance system is implemented and regional collaborative arrangements are in place on collection of pharmacovigilance data and measures adopted to manage safety signals and concerns.

8. Member States shall expand existing collaboration among ASEAN pharmaceutical testing laboratories to facilitate pooling of laboratory testing resources as required.

9. Member States shall facilitate the exchange of information relevant to the use and availability of pharmaceutical products, such as treatment guidelines, antibiotic resistance, consumption volumes, shortages of essential pharmaceuticals, and access to antidotes, anti-toxins, and antivenoms when appropriate.

10. Member States shall adopt or establish appropriate

guidelines or regulations for safe disposal of substandard, falsified, and expired pharmaceutical products as required.

Article 7
Substandard and Falsified Pharmaceutical Products

1. Member States shall take the necessary measures at national level and, whenever required, through regional collaboration mechanism in order to prevent substandard or falsified pharmaceutical products from entering into circulation.

2. Member States shall ensure that:

(a) persons manufacturing, importing, distributing, and introducing substandard or falsified pharmaceutical products into circulation are held responsible; and

(b) pharmaceutical operators adopt measures to prevent substandard or falsified pharmaceutical products entering the market.

3. Member States shall regulate the recall and withdrawal of substandard and falsified pharmaceutical products in their respective laws and regulations.

Article 8
Traceability

Member States shall ensure that:

(a) pharmaceutical operators maintain traceability of finished pharmaceutical products throughout production, importation, and distribution;

(b) manufacturers of finished pharmaceutical products maintain traceability of supply chain of active pharmaceutical ingredients incorporated into the pharmaceutical products and other starting and packaging materials as appropriate; and

(c) pharmaceutical operators make traceability records concerning their supply and distribution available to the respective National Regulatory Authorities on demand.

Article 9
Medical Emergencies

Member States will consider existing ASEAN mechanisms in response to arising medical emergencies, where appropriate.

Article 10
Transparency

1. Each Member State shall ensure transparency of its respective laws, regulations, and administrative procedures which affect pharmaceutical regulation under this Agreement and its Protocols.

2. Each Member State shall ensure that the development of its laws and regulations relating to regulation of pharmaceutical products is undertaken in a transparent manner.

3. Member States shall share information on defective, substandard, or unsafe pharmaceutical products with other Member States through an agreed procedure.

Article 11

Capacity Building and Cooperation

1. Member States shall monitor regulatory competence, capacity, and resources and shall identify capacity building programmes that will strengthen each Member State's capacity for effective pharmaceutical regulation.

2. Member States are encouraged to cooperate in implementing capacity building programmes on mutually agreed terms.

Article 12
Institutional Arrangements

1. The ASEAN Pharmaceutical Regulatory Framework Coordinating Committee (APRFCC) shall be established under this Agreement.

2. The APRFCC shall be responsible for:

(a) overseeing, monitoring, and reviewing the implementation of this Agreement;

(b) coordinating with Pharmaceutical Product Working Group (PPWG) and ASEAN Health Cluster (AHC) 3 for development and implementation of initiatives for fulfilling objectives of this Agreement;

(c) making recommendations on any amendments to this Agreement to the PPWG and AHC 3;

(d) formulating its own rules and procedures; and

(e) reporting progress on the implementation of this Agreement and its Protocols to the PPWG and AHC 3.

3. The ASEAN Secretariat shall provide the support for coordinating and reviewing the implementation and monitoring of this Agreement and any other matters relating thereto.

Article 13
Implementation

Member States shall undertake appropriate measures to comply with the provisions of this Agreement.

Article 14
Contact Points

1. Each Member State shall designate a contact point to facilitate communication among the Member States on any matter covered by this Agreement, and shall notify the ASEAN Secretariat of its designated contact point.

2. The ASEAN Secretariat shall establish, update, and maintain the list of contact points for Member States in this Agreement.

Article 15
Protocols

1. The APRFCC shall coordinate the establishment of a series of Protocols under this Agreement.

2. ASEAN initiatives on pharmaceuticals, which are in existence prior to the coming into force of this Agreement may be considered for potential consolidation to become Protocols under this Agreement.

3. The PPWG and AHC 3 may at any time propose on the inclusion of additional protocols under this Agreement to the APRFCC.

4. The development of Protocols shall be undertaken by the PPWG and AHC 3 based on their field of competence, under coordination by the APRFCC.

5. Protocols to this Agreement shall form an integral part of this Agreement.

Article 16
Confidentiality

Each Member State shall maintain, to the extent permitted under its laws and regulations, the confidentiality of information exchanged under this Agreement. Any confidential information shall only be disclosed with the authorisation of the Member State providing such information.

Article 17
Dispute Settlement

The ASEAN Protocol on Enhanced Dispute Settlement Mechanism signed on 20 December 2019 in Manila, Philippines, or its successor, shall apply in relation to any disputes concerning implementation, interpretation, or application of this Agreement.

Article 18
Amendments

1. This Agreement may be amended by written agreement of the Member States.

2. 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 19
Review

This Agreement may be reviewed by the Member States, as deemed necessary, after its entry into force for the purpose of fulfilling the objectives of this Agreement.

Article 20
Rights and Obligations Under Existing International Agreements or Conventions

This Agreement or any action taken pursuant thereto shall not affect the rights and obligations of any Member State under any existing international agreements or conventions to which it is also a party.

Article 21
Reservation

No reservations shall be made to this Agreement.

Article 22
Entry into Force

This Agreement shall enter into force [XX] days after the Member States have notified the completion of their respective internal procedures for the entry into force of this Agreement, or where necessary, deposited instruments of ratification, approval, or acceptance with the Secretary-General of ASEAN.

5th APRF Workshop: Member States to suggest number of days for the Agreement to enter into force

Article 23
Depositary

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

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

DONE [City], [Country], this [Day] day of [Month] in the Year Two Thousand and [xx], in a single original copy in the English Language.

For the Government of Brunei Darussalam:

(NAME IN BOLD AND CAPS)
(Designation)

For the Government of the Kingdom of Cambodia:

(NAME IN BOLD AND CAPS)
(Designation)

For the Government of the Republic of Indonesia:

(NAME IN BOLD AND CAPS)
(Designation)

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

(NAME IN BOLD AND CAPS)
(Designation)

For the Government of Malaysia:

(NAME IN BOLD AND CAPS)
(Designation)

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

(NAME IN BOLD AND CAPS)
(Designation)

For the Government of the Republic of the Philippines:

(NAME IN BOLD AND CAPS)
(Designation)

For the Government of the Republic of Singapore:

(NAME IN BOLD AND CAPS)
(Designation)

For the Government of the Kingdom of Thailand:

(NAME IN BOLD AND CAPS)
(Designation)

For the Government of the Socialist Republic of Viet Nam:

(NAME IN BOLD AND CAPS)
(Designation)