2017 ASEAN MUTUAL RECOGNITION ARRANGEMENT FOR BIOEQUIVALENCE STUDY REPORTS OF
GENERIC MEDICINAL PRODUCTS

Signed in Manila, the Philippines on 2 November 2017

[2017 ASEAN MUTUAL RECOGNITION ARRANGEMENT FOR BIOEQUIVALENCE STUDY REPORTS OF GENERIC MEDICINAL PRODUCTS 2](#_Toc514922252)

[ARTICLE 1 DEFINITIONS 3](#_Toc514922253)

[ARTICLE 2 OBJECTIVE 4](#_Toc514922254)

[ARTICLE 3 GENERAL PROVISIONS 4](#_Toc514922255)

[ARTICLE 4 SCOPE 4](#_Toc514922256)

[ARTICLE 5 JOINT SECTORAL COMMITTEE (JSC) 4](#_Toc514922257)

[ARTICLE 6 MUTUAL RECOGNITION OBLIGATIONS 5](#_Toc514922258)

[ARTICLE 7 NATIONAL DRUG REGULATORY AUTHORITY (NDRA) 5](#_Toc514922259)

[ARTICLE 8 LISTING OF BIOEQUIVALENCE CENTRES 5](#_Toc514922260)

[ARTICLE 9 TRANSPARENCY 6](#_Toc514922261)

[ARTICLE 10 IMPLEMENTATION 6](#_Toc514922262)

[ARTICLE 11 ANNEXES TO THE SECTORAL MRA 6](#_Toc514922263)

[ARTICLE 12 PRESERVATION OF NATIONAL DRUG REGULATORY AUTHORITY 6](#_Toc514922264)

[ARTICLE 13 CONFIDENCE BUILDING 7](#_Toc514922265)

[ARTICLE 14 CONFIDENTIALITY 7](#_Toc514922266)

[ARTICLE 15 SETTLEMENT OF DISPUTES 7](#_Toc514922267)

[ARTICLE 16 RIGHTS AND OBLIGATIONS UNDER EXISTING INTERNATIONAL AGREEMENTS AND CONVENTIONS 7](#_Toc514922268)

[ARTICLE 17 REVIEW 7](#_Toc514922269)

[ARTICLE 18 AMENDMENTS 8](#_Toc514922270)

[ARTICLE 19 ENTRY INTO FORCE 8](#_Toc514922271)

[ARTICLE 20 RESERVATIONS 8](#_Toc514922272)

[ARTICLE 21 DEPOSITARY 8](#_Toc514922273)

[ANNEX A 10](#_Toc514922274)

# 2017 ASEAN MUTUAL RECOGNITION ARRANGEMENT FOR BIOEQUIVALENCE STUDY REPORTS OF GENERIC MEDICINAL PRODUCTS

Signed in Manila, the Philippines on 2 November 2017

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

**MINDFUL** of the goals of establishing ASEAN as a single market and production base characterised by free flow of goods, services, investment, skilled labour and freer flow of capital envisaged in the ASEAN Charter, the Declaration on the ASEAN Economic Community Blueprint signed by the Leaders on 20 November 2007 in Singapore and the ASEAN Economic Community Blueprint 2025 adopted by the Leaders on 22 November 2015 in Kuala Lumpur, Malaysia;

**RECALLING** that the ASEAN Trade in Goods Agreement ("ATIGA") signed on 26 February 2009 in Cha-am, Thailand has the objective of achieving 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 towards the realisation of the ASEAN Economic Community;

**RECALLING** the ASEAN Framework Agreement on Mutual Recognition Arrangements signed on 16 December 1998 in Hanoi, Viet Nam to facilitate the elimination of technical barriers to trade and to enhance trade in ASEAN;

**RECALLING** the ASEAN Framework Agreement for the Integration of Priority Sectors and the ASEAN Sectoral Integration Protocol for Healthcare signed on 29 November 2004 in Vientiane, Lao PDR;

**RECOGNISING** that mutual recognition of results of conformity assessment procedures is an important means of reducing technical barriers to trade and that such mutual recognition is of particular interest to businesses in ASEAN;

**MINDFUL** of the different levels of infrastructure for technical regulation, standards, certification, inspection and analysis and of the different levels of economic development of Member States;

**REITERATING** that Member States' commitments under the World Trade Organization (WTO) Agreement on Technical Barriers to Trade ("TBT Agreement") are reaffirmed in ATIGA and that Members are encouraged to enter into negotiations or consultations on mutual recognition of conformity assessment procedures which include, inter alia, procedures for sampling, testing, inspection, certification, registration, accreditation and for recognition of equivalence of technical regulations;

**DESIRING** to establish a Sectoral Mutual Recognition Arrangement for Bioequivalence Study Reports of Generic Medicinal Products (hereinafter referred to as "Sectoral MRA") to facilitate the movement of generic medicinal products in ASEAN.

HAVE AGREED AS FOLLOWS:

# ARTICLE 1 DEFINITIONS

For the purposes of this Sectoral MRA, the terms "standard" and "conformity assessment procedures", shall, when used in this Sectoral MRA, have the same meaning as given in the definitions in the TBT Agreement. In addition, the following definitions shall apply:

a. "**accept**” means the use of bioequivalence study reports from listed Bioequivalence Centres as part of the requirements for the registration of generic medicinal products by the National Drug Regulatory Authority of a Member State taking into consideration that the review and assessment is under the jurisdiction of the respective Member States;

b. "**Bioequivalence Centre**" or "**BE Centre**" means any independent organisation located in the territory of the Member State which conducts the bioequivalence study and issues the bioequivalence study report;

c. "**Bioequivalence Study**" or "**BE Study**" means a comparative bioavailability study designed to establish equivalence between a generic medicinal product and a comparator product. Both the clinical and bioanalytical parts of the study must be conducted in Member States;

d. "**Bioequivalence Study Report**" or "**BE Study Report**" means a report of the BE study issued by a Listed BE Centre according to the ASEAN BE Study Reporting Format;

e. "**comparator product**" means a pharmaceutical product selected based on the selection criteria of a ASEAN comparator product with which the generic medicinal product is intended to be interchangeable in clinical practice, and it does not refer to any harmonised list of comparator products;

f. "**generic medicinal product**" means a product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the comparator product, and whose bioequivalence with the comparator product has been demonstrated by appropriate bioavailability studies;

g. "**Listed Bioequivalence Centre**" or "**Listed BE Centre**" means a BE Centre which has been recognised by the Joint Sectoral Committee;

h. "**National Drug Regulatory Authority**" or "**NDRA**", in relation to each Member State, means the regulatory authority or entity of that Member State which exercises a legal right to control the import, manufacture, export, distribution, transfer, use and sale of medicinal products within that Member State's jurisdiction and which may take regulatory action to ensure that the products marketed within its jurisdiction comply with regulatory requirements;

i. "**Panel of Experts**" or "**PoE**", means a group of people with expertise in BE inspection who is appointed by the Joint Sectoral Committee. The PoE shall comprise the representatives from Member States' NDRA; and

j. "**Pharmaceutical Product Working Group**" means the working group that was set up in the 13th Meeting of the ASEAN Consultative Committee on Standards and Quality held on 18-19 March 1999 in Manila, Philippines.

# ARTICLE 2 OBJECTIVE

The objective of this Sectoral MRA is to enable the mutual recognition of BE Study Reports of generic medicinal products, issued by Listed BE Centres located in the territory of Member States in order to facilitate the movement of generic medicinal products within ASEAN.

# ARTICLE 3 GENERAL PROVISIONS

1. All Member States shall be eligible for participation in this Sectoral MRA.

2. Member States shall ensure that the BE Study Report which is produced in accordance with ANNEX B (ASEAN Guideline for the Conduct of Bioequivalence Studies) and issued by a Listed BE Centre, is accepted for review.

3. Each Member State may establish a list of comparator products as guided by ANNEX B (ASEAN Guideline for the Conduct of Bioequivalence Studies). Each Member State is encouraged to publish this list on its website.

# ARTICLE 4 SCOPE

This Sectoral MRA applies to BE Study Reports of generic medicinal products as defined in ANNEX A (Scope of Application of the Sectoral MRA), issued by Listed BE Centres located in the territory of Member States.

# ARTICLE 5 JOINT SECTORAL COMMITTEE (JSC)

1. A JSC shall be established and shall be responsible for the effective functioning of this Sectoral MRA.

2. The JSC shall comprise one official representative from each Member State's NDRA. The representative may be accompanied by his/her delegation at meetings of the JSC. For the purpose of membership of the JSC, a Member State shall notify the ASEAN Secretariat of the name of the official representative or his/her official designate.

3. The JSC shall be responsible for:

a. establishing a PoE, that shall consist of NDRA officials, and establishing its terms of reference including the competencies and qualifications of individuals in the PoE;

b. establishing requirements for the competencies and qualifications of independent experts, who shall not be members of the PoE, and who shall be appointed when necessary;

c. preparing the requirements and procedures for the listing, verification and removal/de-listing of BE Centres in accordance with this Sectoral MRA;

d. providing a forum for discussion of issues that may arise concerning the implementation of this Sectoral MRA,

e. proposing amendments to this Sectoral MRA, including its annexes, and proposing additional annexes; and

f. considering any other matters and taking appropriate technical decisions relating to the implementation of this Sectoral MRA.

4. The JSC shall endeavour to meet at least once a year as and when required, to discharge its duties and determine its own rules of procedures. Decisions of the JSC shall be made by consensus.

# ARTICLE 6 MUTUAL RECOGNITION OBLIGATIONS

1. Member States shall accept the BE Study Reports issued by Listed BE Centres for review by their respective NDRAs.

2. The review and assessment of the BE Study Reports remains within the jurisdiction of Member States' NDRAs.

# ARTICLE 7 NATIONAL DRUG REGULATORY AUTHORITY (NDRA)

1. Each Member State shall designate an NDRA which is responsible for the implementation of the Member State's obligations under this Sectoral MRA.

2. Member States shall notify the ASEAN Secretariat of the names of their NDRA official representatives or official designates and update the ASEAN Secretariat of any changes.

3. Each Member State shall ensure that its NDRA is authorised to implement the provisions of this Sectoral MRA.

4. The NDRA of each Member State shall be responsible for ensuring that any BE Centre within its jurisdiction that requests to be listed under this Sectoral MRA complies with all the requirements for listing before submitting the application to the JSC.

5. The NDRA of each Member State shall be responsible for monitoring the performance of its Listed BE Centres and shall notify the JSC of any non-compliance that it observes.

# ARTICLE 8 LISTING OF BIOEQUIVALENCE CENTRES

1. An application for the listing of any BE Centre shall be submitted to the JSC, by an NDRA where the BE Centre is located.

2. The inspection of the BE Centre shall be conducted by the PoE. The JSC will make its decision for listing of BE Centre based on the recommendations from the PoE.

3. The ASEAN Secretariat shall update and maintain the list of Listed BE Centres and publish it on the ASEAN website.

# ARTICLE 9 TRANSPARENCY

1. Each Member State shall designate a contact point for exchange of information and notify the ASEAN Secretariat of its designated contact point. The ASEAN Secretariat shall establish, update and maintain the list of contact points for all Member States.

2. Member States are encouraged to publish a list of their Listed BE Centres in their respective territories.

3. Each Member State may request information regarding a Listed BE Centre from the Member State where that Listed BE Centre is located.

# ARTICLE 10 IMPLEMENTATION

1. Member States shall undertake appropriate measures to fulfil their obligations arising from this Sectoral MRA.

2. Member States shall implement the mutual recognition obligations referred to in Article 6 no later than five (5) years after the entry into force of this Sectoral MRA.

# ARTICLE 11 ANNEXES TO THE SECTORAL MRA

1. Each Member State shall adhere to the following Annexes of this Sectoral MRA:

a. ANNEX A (Scope of Application of the Sectoral MRA); and

b. ANNEX B (ASEAN Guideline for the Conduct of Bioequivalence Studies)

2. The Annexes to this Sectoral MRA shall form an integral part of this Sectoral MRA.

# ARTICLE 12 PRESERVATION OF NATIONAL DRUG REGULATORY AUTHORITY

1. Subject to the provisions of this Sectoral MRA, nothing in this Sectoral MRA shall be construed to:

a. limit the authority of a Member State to determine, through its legislative and administrative measures, the level of protection it considers appropriate for the safety and protection of the health of persons in its territory; and

b. limit the authority of the NDRA to take any appropriate and immediate measures whenever it ascertains that a generic medicinal product may:

i. compromise the health and safety of persons in its territory;

ii. not meet the legislative or administrative provisions of this Sectoral MRA; or

iii. fail to satisfy a requirement of this Sectoral MRA.

2. If the NDRA of a Member State takes a measure pursuant to paragraph 1, it shall inform all other NDRAs of the measure taken and, provide reasons thereof.

# ARTICLE 13 CONFIDENCE BUILDING

Member States shall, through their contact points, strengthen and enhance existing cooperation through information exchange on regulatory requirements, conformity assessment procedures and regimes, and through confidence building measures.

# ARTICLE 14 CONFIDENTIALITY

1. Member States shall maintain, to the extent permitted under their laws and regulations, the confidentiality of information exchanged under this Sectoral MRA.

2. Member States shall take all precautions reasonably necessary to protect information exchanged under this Sectoral MRA from unauthorised disclosure.

# ARTICLE 15 SETTLEMENT OF DISPUTES

1. Member States shall at all times endeavour to agree on the interpretation or implementation of this Sectoral MRA and shall make any attempt through communication, dialogue, consultation and cooperation to arrive at a mutually satisfactory resolution of any matter that might affect the implementation of this Sectoral MRA.

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

# ARTICLE 16 RIGHTS AND OBLIGATIONS UNDER EXISTING INTERNATIONAL AGREEMENTS AND CONVENTIONS

This Sectoral MRA or any actions taken pursuant to this Sectoral MRA shall not affect the rights and obligations of any Member State under any existing international agreements or conventions to which it is also a signatory or party.

# ARTICLE 17 REVIEW

This Sectoral MRA may be reviewed five (5) years after its entry into force or otherwise as appropriate for the purpose of fulfilling the objective of this Sectoral MRA.

# ARTICLE 18 AMENDMENTS

1. The provisions of this Sectoral MRA may only be amended by mutual written agreement of all the Member States. Any amendment shall enter into force on such date as shall be mutually agreed upon by all Member States.

2. Notwithstanding paragraph 1 of this Article, amendments may be made to the 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.

3. Any amendment shall not prejudice the rights and obligations of the Member States arising from or based on this Sectoral MRA before the entry into force of such amendment.

# ARTICLE 19 ENTRY INTO FORCE

This Sectoral MRA shall enter into force on the date of its signature.

# ARTICLE 20 RESERVATIONS

No reservations shall be made with respect to any of the provisions of this Sectoral MRA.

# ARTICLE 21 DEPOSITARY

This Sectoral MRA 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 authorised by their respective Governments, have signed this ASEAN Sectoral Mutual Recognition Arrangement for Bioequivalence Study Reports of Generic Medicinal Products.

DONE at Manila, Philippines, this second day of November in the Year Two Thousand and Seventeen, in a single copy in the English Language.

For Brunei Darussalam:

**LIM JOCK SENG**

Minister at the Prime Minister's Office and Second Minister of Foreign Affairs and Trade

For the Kingdom of Cambodia:

**PAN SORASAK**

Minister of Commerce

For the Republic of Indonesia:

**ENGGARTIASTO LUKITA**

Minister of Trade

For the Lao People's Democratic Republic:

**KHEMMANI PHOLSENA**

Minister of Industry and Commerce

For Malaysia:

**MUSTAPA MOHAMED**

Minister of International Trade and Industry

For the Republic of the Union of Myanmar:

**KYAW WIN**

Union Minister for Planning and Finance

For the Republic of the Philippines:

**RAMON M. LOPEZ**

Secretary of Trade and Industry

For the Republic of Singapore:

**LIM HNG KIANG**

Minister for Trade and Industry (Trade)

For the Kingdom of Thailand:

**APIRADI TANTRAPORN**

Minister of Commerce

For the Socialist Republic of Viet Nam:

**TRAN THUAN ANH**

Minister of Industry and Trade

# ANNEX A

The ASEAN Mutual Recognition Arrangement for Bioequivalence Study Reports of Generic Medicinal Products applies only to the following:

• Immediate-release, oral, solid dosage forms, with systemic actions