THIRD DRAFT

As of 1 May 2015

(Revised by ASEC on Article 10.1 and 11.1 based on input from LSAD on 4 April 2015 and Singapore on 27 April 2015)

ASEAN SECTORAL MUTUAL RECOGNITION ARRANGEMENT FOR BIOEQUIVALENCE STUDY REPORTS

The Governments of Brunei Darussalam, the Kingdom of Cambodia, the Republic of Indonesia, the Lao People's Democratic Republic, Malaysia, the 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 (hereinafter referred to as "ASEAN");

MINDFUL of the goals of establishing ASEAN as a single market and production base characterised by the free flow of goods in the Declaration of the ASEAN Economic Community signed by the ASEAN Heads of Government in 2007;

RECALLING that the ASEAN Trade in Goods Agreement (ATIGA) of 26 February 2009 has the objective to achieve a free flow of goods in ASEAN as one of the principal means to establish a single market and production base for deeper economic integration of the region towards the realization of the ASEAN Economic Community by 2015;

RECOGNISING that mutual recognition of certification, inspection , analytical results are an important mean of reducing Technical Barriers to Trade which directly or indirectly affect trade and enhancing market access and that such mutual recognition are 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 ASEAN Member States;

DESIRING to establish a Sectoral Mutual Recognition Arrangement for mutual acceptance of Bioequivalence Study Reports for generic medicinal products

(hereinafter referred to as “Sectoral MRA") to facilitate the movement of generic medicinal products in ASEAN.

REITERATING Member States’ commitments under the World Trade Organization (WTO) Agreements on Technical Barriers to Trade (TBT Agreement) are reaffirmed in and noting that the TBT Agreement encourages Members 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.

HAVE AGREED AS FOLLOWS:

ARTICLE 1

DEFINITIONS

For purposes of this Sectoral MRA, **Definitions** for International Standards, Technical Regulations, and Conformity Assessment Procedures as stated in the Technical Barriers to Trade (TBT) Agreement shall apply. For other terms the following definitions shall apply:

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

Bioequivalence (hereinafter referred to as **BE**) ***Centre*** means any independent organisation located in ASEAN Member States which conducts the BE study and issues the BE study report. ***Bioequivalence Study*** means a comparative bioavailability study designed to establish equivalence between generic medicinal product and comparator product. Both clinical and bioanalytical parts of the study must be conducted in ASEAN Member States

Bioequivalence Study Reports means a report of BE study issued by a Listed BE Centre according to the ASEAN BE Study Reporting Format.

~~ASEAN~~ Comparator Product means a pharmaceutical product selected based on the ASEAN Selection Criteria of Comparator Product with which the generic medicinal product is intended to be interchangeable in clinical practice, and it does not refer to a harmonized list of comparator products.

Generic Medicinal Product means product which has same qualitative and quantitative composition in active substances and the same pharmaceutical form as the comparator product, and whose bioequivalence with the ~~ASEAN~~ comparator product has been demonstrated by appropriate bioavailability studies.

Listed Bioequivalence Centre means a BE Centre which has been recognised by the Joint Sectoral Committee.

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

Panel of Experts, hereinafter referred to as **PoE**, means a group of people with expertise in BE inspection who are appointed by the Joint Sectoral Committee. The PoE shall comprise the representatives from ASEAN NDRA.

Party/Parties means ASEAN Member State/s that is/are participating in this Sectoral MRA

ARTICLE 2

OBJECTIVE

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

ARTICLE 3

GENERAL PROVISIONS

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

2. Parties to this Sectoral MRA shall ensure that the BE Study Reports conducted as per the latest version of the 'ASEAN Guideline for the Conduct of BE Studies' (ANNEX XX) are accepted for review.

3. Each Party shall establish a list of comparator products as guided by the ASEAN Guideline for the Conduct of Bioequivalence Studies, wherever possible. Each Party is encouraged to publish this list on its website.

ARTICLE 4

SCOPE

The Sectoral MRA applies to BE Study Reports of generic medicinal products as defined in Annex A of this Sectoral MRA, from those Listed BE Centres located in ASEAN Member States

ARTICLE 5

JOINT SECTORAL COMMITTEE (JSC)

1. A JSC shall be established upon signing of this Sectoral MRA, which shall be responsible for the effective functioning of this Sectoral MRA.

2. The JSC shall comprise the Head of the NDRA of each Party or his/her official designate. For the purpose of membership of the JSC, a Member State shall, upon becoming a Party of this Sectoral MRA, notify the ASEAN Secretariat of the name of the Head of NDRA or his/her official designate.

3. The JSC shall be responsible for:

   a. Establishing a Panel of Experts (PoE), who shall consist of NDRA officials, and its terms of reference (ToR) which include competency and qualification of the PoE. The JSC member may also become a PoE member;

b. Establishing standards and training programmes to ascertain the competency of persons nominated to be a member of the PoE.

c. Preparing a procedure for the listing of BE Centres as well as the removal/de-listing of BE centres that are already listed.

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

e. Establishing, reviewing and amending any annexes referenced to this Sectoral MRA,and

~~f. Reviewing and approving amendments of the scope of this Sectoral MRA as defined in Annex 1 as proposed requested by Party/Parties to JSC~~

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

4. The JSC shall meet at least once a year as and when required, to discharge its duties; determine its own rules of procedures; and make its decision by consensus. Any disagreement shall be settled in accordance with Article 15.

ARTICLE 6

MUTUAL RECOGNITION OBLIGATIONS

1. Parties to the Sectoral MRA shall accept the BE Study Reports for review by respective NDRA, from those Listed BE Centres

2. Assessment of the BE study report remains within the jurisdiction of Member States' NDRA.

ARTICLE 7

NATIONAL DRUG REGULATORY AUTHORITY (NDRA)

1. The NDRA shall be designated by each Party for the implementation of the obligations of the Sectoral MRA.

2. All Parties shall notify the ASEAN Secretariat of the name, address, contact details and name of the head of their NDRA and update of any changes.

3. All Parties shall ensure that the NDRA is authorised to implement the provisions of this Sectoral MRA as per obligations of this Sectoral MRA.

4. The NDRA shall be responsible to monitor the performance of its Listed BE Centres. It shall notify the JSC of any non-compliances that it observes.

5. The NDRA shall be responsible to ensure that any BE Centre within its jurisdiction that request to be listed under this Sectoral MRA complies with all the requirements for the listing of BE Centre before submitting the application to the JSC.

.

ARTICLE 8

LISTING OF BE CENTRES

1. Applications for the listing of BE Centres shall be submitted by any NDRA to JSC.

2. The inspection of the BE Centre will be conducted by PoE whereas JSC will recognize and list the BE Centre based on recommendation from PoE.

3. The removal of any listed BE Centres shall be in accordance with the procedure established by the JSC.

4. The ASEAN Secretariat shall update and maintain the list of BE Centres and publish it at the ASEAN website.

ARTICLE 9

TRANSPARENCY

1. Each Party shall designate the contact point for exchange of the information. A list of contact points shall be forwarded to the ASEAN Secretariat. The ASEAN Secretariat shall establish, update and maintain the list of contact points for each Party participating in the Sectoral MRA.

2. All Parties are encouraged to publish their BE Centres which are listed in their respective territories.

3. Each Party may request for information regarding the Listed BE Centre from respective Party where BE Centre is located.

ARTICLE 10

IMPLEMENTATION

1. This Sectoral MRA is a multilateral arrangement in which all ASEAN Member States are [required] to [participate]. [However, taking into consideration Paragraph 3 of Article 1 of Framework Agreement on Enhancing ASEAN Economic Cooperation signed on 28 January 1992 in Singapore and paragraph 7 of Article 3 of ASEAN Framework Agreement on Mutual Recognition Arrangements signed on 16 December 1998 in Hanoi, Viet Nam, a Member State which is not ready to fully implement this Sectoral MRA may withhold from

participating in Sectoral MRA from [proposing a body to be a listed BE Centre pursuant to Article 8]. The withholding period shall not exceed 5 (five) years after the entry into force of this Sectoral MRA].

2. A Party which does not require BE study reports for marketing authorisation of generic medicinal products or does not have any listed BE Centres within its territory shall not be prevented from participating in the Sectoral MRA.

3. Notwithstanding paragraph 1 of this article, a party whose NDRA has not listed any BE Centres shall accept BE study reports from those Listed BE Centres under this Sectoral MRA for review.

ARTICLE 11

ANNEXES TO THE SECTORAL MRA

1. The Parties shall adhere to the following, but not limited to, Annexes of this Sectoral MRA ~~[SG: as may be applicable]~~

   ~~i.~~ A. Scope of application of the Sectoral MRA

   ~~ii.~~ B. ASEAN Guideline for the Conduct of BE Studies, including Selection Criteria ~~for~~ of ASEAN Comparator Productand ASEAN BE Study Reporting Format.

   ~~iii.~~ C. ASEAN Inspection Criteria for BE Studies

2. A list and text of the latest version of the Annexes, indicating effective dates for implementation, shall be maintained on the website of the ASEAN Secretariat.

ARTICLE 12

PRESERVATION OF REGULATORY AUTHORITY

1. Subject to the provisions of this Sectoral MRA, nothing in this Sectoral MRA shall be construed to limit the authority of a Party 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.

2. Nothing in this Sectoral MRA shall be construed to limit the authority of the NDRA to take any appropriate immediate measures whenever it ascertains that a generic medicinal product may:

   a. compromise that health and safety of persons in its territory, or

   b. fails to satisfy a requirement within the scope of this Sectoral MRA.

ARTICLE 13

CONFIDENCE BUILDING

Parties 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. Parties shall maintain, to the extent permitted under its laws and regulations, the confidentiality of information exchanged under this Sectoral MRA.

2. Parties shall take all precautions reasonably necessary to protect information exchanged under this Sectoral MRA from unauthorized disclosure.

ARTICLE 15

SETTLEMENT OF DISPUTES

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

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

ARTICLE 16

RIGHTS AND OBLIGATIONS UNDER EXISTING INTERNATIONAL AGREEMENTS AND CONVENTIONS

The Sectoral MRA or any actions thereto shall not affect the rights and obligations of any party under any existing international agreements or conventions to which it is also a signatory or party.

ARTICLE 17

FINAL PROVISIONS

1. The provisions of this Sectoral MRA may be reviewed or amended by agreement of all Parties.

2. Parties shall undertake appropriate measures to fulfil the agreed obligations arising from this Sectoral MRA.

3. Parties shall make no reservations with respect to any of the provisions of this Sectoral MRA.

4. This Sectoral MRA shall be deposited with the Secretary General of ASEAN, who shall promptly furnish each Party a certified copy thereof.

5. This MRA shall enter into force upon the date of its signature

IN WITNESS WHEREOF the undersigned, being duly authorized by their respective Governments, have signed this ASEAN Sectoral Mutual Recognition Arrangement for Bioequivalence Study Reports.

Signing and Date. DONE at ……, ……, on the … day of ……. 20XX, in a single copy in the English Language.