# 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 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** that in the year 1992, the ASEAN Heads of Government declared that an ASEAN Free Trade Area (AFTA) shall be established in the region and that in 1995, they agreed to accelerate its implementation to the year 2003;

**NOTING** the Agreement on the Common Effective Preferential Tariff (CEPT) Scheme for the AFTA signed on 28 January 1992 and its amending Protocols of 1995 and 2003, which provide for cooperation to supplement and complement the liberalisation of trade including, among others, the harmonisation of standards, reciprocal recognition of test reports and certification of products;

**MINDFUL** that the Declaration of ASEAN Concord II (Bali Concord II) adopted by the ASEAN Heads of Government during the 9th ASEAN Summit in Bali, Indonesia on 7 October 2003, commits ASEAN to deepen and broaden its

internal economic integration and linkages, with the participation of the private sector, so as to realise an ASEAN Economic Community;

**MINDFUL** that the establishment of the ASEAN Economic Community has been accelerated from 2020 to 2015 which will create ASEAN as a single market and production base;

**REITERATING** their commitments to the Agreement on Technical Barriers to Trade of the World Trade Organization, which encourages Contracting Parties to enter into negotiations for the conclusion of agreements for the mutual recognition of results of each other's conformity assessment and mandates, among other matters, the elimination of unnecessary obstacles to trade including those relating to technical regulations;

**RECALLING** the ASEAN Framework Agreement on Mutual Recognition Arrangements signed on 16 December 1998 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; and

**DESIRING** to establish a Sectoral Mutual Recognition Arrangement for Good Manufacturing Practice (hereinafter referred to as "GMP") Inspection of Manufacturers of Medicinal Products (hereinafter referred to as "Sectoral MRA"), to facilitate the movement of medicinal products in ASEAN,

**HAVE AGREED** as follows:

## Article 1
## Definitions

General terms concerning conformity assessment used in this Sectoral MRA shall have the meaning given in the glossary contained in the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (hereinafter collectively referred to as "PIC/S") Guide to GMP for Medicinal Products, the ASEAN Glossary of Terms as adopted by the ASEAN Consultative Committee on Standards and Quality - Pharmaceutical Product Working Group and in the ASEAN Framework Agreement on Mutual Recognition Arrangements, as may be amended from time to time, with the exception of the following terms which shall contain the definitions provided herein:

"***Accept***" means the use of GMP certifications and/or inspection reports as a basis for regulatory actions such as the granting of approvals or licenses, and post-market assessments of conformity;

"***Certification***" means a procedure by which a Party gives written or other formal assurance that a process or service conforms to specified requirements;

"***Contact Point***" means a person, position or body with and through whom Parties shall exchange information and communicate in accordance with requirements of this Sectoral MRA;

"***Designating Body***" means a National Drug Regulatory Authority designated by a Party to this Sectoral MRA, with the responsibility among others for designating a GMP Inspection Service for that Party;

"***Equivalent GMP Code***" means any GMP standard recognised by the Joint Sectoral Committee (hereinafter

referred to as "JSC") to be equivalent to the PIC/S Guide to GMP for Medicinal Products;

***"Good Manufacturing Practice"*** or "***GMP***" means that part of quality assurance which ensures that medicinal products are consistently produced and controlled in accordance with quality standards appropriate for their intended use and as required by the applicable marketing authorisations or product specifications;

***"Inspection Service"*** in relation to a Party, means the conformity assessment body of the National Drug Regulatory Authority of that Party as referred to in Article 7 which has the responsibility of inspecting manufacturers of medicinal products for the purpose of assessing if the manufacturer conforms to the GMP standards of this Sectoral MRA, and to issue inspection reports and/or GMP certificates in this regard;

"***Listed Inspection Service***" means an Inspection Service which has been accepted by the JSC pursuant to paragraph 2 of Article 7;.

***"Mandatory Requirements"*** means the technical requirements, legislative and regulatory provisions, as well as administrative arrangements imposed by a Party in relation to medicinal products, and which pertain to the GMP inspection or the certification of manufacturers of medicinal products, in respect of which compliance is mandatory;

"***Manufacture***" means all operations starting from the purchase of materials and products through to production, quality control, release, storage, and shipment (from storage related to the manufacturing site) of finished products, and the related controls. Manufacture includes re-packaging and re-labelling operations;

"***Medicinal Product***" means pharmaceutical products in finished dosage forms, and includes both prescription and non-prescription medicinal products for human use, but

excludes biopharmaceuticals, radiopharmaceuticals, traditional medicines and investigational medicinal products;

***"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 the 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***" means a group of people with expertise in GMP who are appointed by the JSC. The Panel of Experts comprises of the representatives from the NDRA of Member States whose Inspection Service has been listed in accordance with the criteria in Article 10;

"***Parties***" means Member States that are participating in this Sectoral MRA;

***"Party"*** means a Member State that is participating in this Sectoral MRA;

"***Quality System***" means an appropriate infrastructure, encompassing the organisational structure, procedures, processes and resources necessary to ensure adequate confidence that a product (or service) will satisfy given requirements for quality (reference: World Health Organisation Technical Report Series 902 Annex 8).

## Article 2
## Objectives

This Sectoral MRA sets out the arrangements under which each Party shall accept:

(a) the GMP certificates for manufacturers of medicinal products, where the GMP Certificates are issued by a Listed Inspection Service; and

(b) the GMP inspection reports which verify conformity of a manufacturer of medicinal products with the mandatory requirements, where such inspection reports are issued by the Listed Inspection Service.

## Article 3
## General Provisions

1. Each Party shall, upon the request of another Party, provide the requesting Party with a copy of the GMP certificate and/or GMP inspection report in respect of a facility manufacturing medicinal products in its territory, provided that the request is only made in respect of a manufacturing facility whose products are exported to the territory of the requesting Party. Information furnished to a requesting Party under this paragraph shall be restricted to information relating to GMP Inspection that is routinely collected by the other Party, and shall include the information specified under paragraph 2 of Article 8.

2. A Party shall accept the GMP certificates and/or GMP inspection reports issued by the Listed Inspection Service of another Party in accordance with the provisions of this Sectoral MRA referred to in Article 2.

3. The technical requirements that the Parties shall apply to the Listed Inspection Service in the inspection and certification of manufacturers of medicinal products to GMP are specified in Article 10 of this Sectoral MRA.

4. All documents issued for the purpose of information exchange, verification, provision of evidence and other activities arising from the obligations of this Sectoral MRA

shall be accompanied by an English translation certified by the NDRA if they are not written in English.

## Article 4
## Scope and Coverage

The scope of this Sectoral MRA applies to the GMP inspection and certification of manufacturers of medicinal products as defined in Article 1.

## Article 5
## Designating Body

1. Parties shall ensure that their Designating Bodies have the authority and competence in their respective territories to carry out the obligations required of them under this Sectoral MRA.

2. Designating Bodies shall regularly monitor their respective Inspection Services to ensure that the latter are capable and remain capable of properly assessing manufacturers of medicinal products in their respective territories whether they conform to the applicable standards.

3. Designating Bodies shall, where necessary, consult with their counterparts in the other Parties, to ensure the maintenance of confidence in the GMP inspection system. This consultation may include joint participation in audits or inspections involving their respective Inspection Services, where appropriate.

## Article 6
## Joint Sectoral Committee

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

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

2. The JSC shall be responsible for:

(a) listing, verification and termination of Inspection Services in accordance with this Sectoral MRA;

(b) providing a forum for discussion of issues that may arise concerning the implementation of this Sectoral MRA;

(c) the formation of the Panel of Experts and the appointment of independent experts. An independent expert shall not be a member of the Panel of Experts, and shall only be engaged when necessary;

(d) reviewing and proposing amendments to the scope and coverage of this Sectoral MRA; and

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

3. The JSC shall:

(a) endeavour to meet at least once a year or, as and when required, to discharge its duties;

(b) determine its own rules of procedures; and

(c) make its decision by consensus. Any disagreement amongst the JSC shall be settled in accordance with Article 17.

4. A member of the JSC shall abstain from voting on any matter which concerns the Designating Body or Inspection Service of his or her Party.

**Article 7**
**Listing of Inspection Service**

1. Each Designating Body shall propose an Inspection Service, which shall be responsible for inspecting manufacturers of medicinal products for the purpose of assessing if the manufacturer conforms to the GMP standards of this Sectoral MRA, and to issue inspection reports and/or GMP certificates in this regard, for the purposes of this Sectoral MRA.

2. Each Designating Body shall submit written details of the conformity assessment body which it proposes to designate as its Inspection Service for the purposes of this Sectoral MRA to the JSC through the ASEAN Secretariat for the decision of the JSC, in accordance with the relevant procedures in Article 10 and the following procedures:

(a) Within ninety (90) calendar days following receipt of a Designating Body's submission, the JSC shall inform the ASEAN Secretariat whether they agree or oppose to the designation of the conformity assessment body in question as the Inspection Service of that Party. If there is no response within ninety (90) calendar days, the submission of the designation of the conformity assessment body by a Party shall be taken as having no objection by the JSC, and that conformity assessment body shall be added to the list of accepted Inspection Services under this Sectoral MRA;

(b) Upon the reasonable request of one or more Parties for the verification of the technical competence or compliance of a proposed

Inspection Service, the JSC may decide that the Inspection Service concerned be more fully verified in accordance with Article 10 of this Sectoral MRA before deciding for the acceptance of the proposed Inspection Service. Such a request for verification by a Party shall be submitted to the JSC through the ASEAN Secretariat for determination of equivalence in accordance with Articles 9 and 10; and

(c) A member of the JSC who fails to vote on the approval of a conformity assessment body proposed by a Designating Body within the time specified in sub-paragraph (a) shall not be regarded as having objected to the acceptance of that body as an Inspection Service of that Party.

3. The ASEAN Secretariat shall establish and maintain the list of accepted Inspection Services under this Sectoral MRA.

## Article 8
## Mutual Recognition Obligations

1. At the request of one NDRA to another NDRA, as the case may be, the Listed Inspection Service of the other NDRA shall assess and, where appropriate, certify that the manufacturer of a medicinal product in its Listed Inspection Service territory:

(a) is licensed or authorised to manufacture that medicinal product or is licensed to carry out a manufacturing operation in question;

(b) has been regularly inspected for compliance with GMP standards by its Listed Inspection Service; and

(c) complies with the PIC/S Guide to GMP for Medicinal Products or equivalent GMP code.

2. Certificates and/or inspection reports issued by an Inspection Service shall identify the site(s) of manufacture and/or contract testing laboratories (if any), the dosage forms manufactured at the facility, and whether the manufacturer complies with GMP. If there is any suspension or withdrawal of the GMP certificate, a Party is obliged to notify the Parties which the manufacturer has exported its medicinal products to.

3. Certificates shall be issued expeditiously, and the time taken shall not exceed sixty (60) calendar days from the date of receiving the request. In exceptional cases, such as when a new inspection has to be carried out, this period may be extended to ninety (90)calendar days from the date of receiving the request.

4. In addition, upon receiving a reasonable request from a Party, the relevant Inspection Service shall forward a copy of the latest inspection report of the manufacturing site or contract testing laboratory, in the case where analytical operations are contracted out. The format of the narrative GMP inspection report should be similar in format to the PIC/S GMP Inspection Report. The requesting Party shall treat these inspection reports and the associated GMP Certificates in accordance with its confidentiality obligations under Article 15 of this Sectoral MRA.

5. If the manufacturing operations of a medicinal product in question have not been inspected recently, a Party may request for a specific and detailed inspection to be conducted. The Inspection Service shall in such cases ensure that inspection reports are forwarded to the requesting Party in no later than sixty (60) calendar days from the date of receiving the request. Should a new inspection be carried out, this period may be extended to

ninety (90) calendar days from the date of receiving the request.

6. A manufacturing facility shall not be regarded as having been inspected recently if that inspection was conducted by the concerned Listed Inspection Service more than two (2) years before the date of a request for a specific and detailed inspection by a Party, or if that inspection did not cover the relevant dosage form(s).

7. A list of contact points shall be forwarded to the ASEAN Secretariat. The ASEAN Secretariat shall establish and maintain the list of contact points for each of the Parties participating in this Sectoral MRA.

## Article 9
## Verification of Technical Competency and Compliance of the Inspection Service

1. The Parties shall ensure that the Inspection Services proposed or designated by their Designating Bodies shall be available for verification, by the JSC, of their technical competency and compliance with applicable requirements of their respective Inspection Services.

2. Written justification shall be submitted to the ASEAN Secretariat for any request for verification of technical competency or compliance of the Inspection Service, which shall promptly forward it to the JSC for a decision.

3. Where the JSC decides that the verification of technical competency and compliance is required, it shall be carried out in a timely manner based on the procedures and criteria set forth in Article 10 of this Sectoral MRA.

4. The results of a verification exercise shall be discussed by the JSC, with a view to resolving the disagreement (if any) amongst the Parties as soon as possible.

## Article 10
## Technical Competence of Listed Inspection Service

1. Each Party shall ensure that its Listed Inspection Service maintains a Quality System in compliance with the current PIC/S Quality System Requirements for Pharmaceutical Inspectorates.

2. Each Party shall ensure that its Listed Inspection Service operates a PIC/S GMP inspection system, as demonstrated by PIC/S membership or adherence to any other equivalent standard as the JSC may determine based on the recommendations of the Panel of Experts.

3. In deciding whether an Inspection Service adheres to a standard equivalent to the PIC/S GMP inspection system for the purposes of acceptance under paragraph 2 of Article 7 or otherwise, the JSC shall consider, among others, the following criteria:

(a) whether the Inspection Service has adopted or adheres to the PIC/S Guide to GMP for Medicinal Products and relevant Annexes or equivalent GMP code, including the format for inspection reports;

(b) whether the Inspection Service has adopted or adheres to the PIC/S Quality System Requirements for Pharmaceutical Inspectorates, and the competency of the inspectors in this regard;

(c) whether there is an adequate legal framework for the inspection and licensing of manufacturers of Medicinal Products.

4. For the purposes of paragraph 3, the Panel of Experts shall make recommendations to the JSC, which shall then deliberate on the confirmation of, or objection to, the inclusion of the Inspection Service into the list of accepted Inspection Services for this Sectoral MRA, or the technical competence of the Inspection Service in question, as the case may be.

## Article 11
## Implementation

1. This Sectoral MRA is intended to be a multilateral arrangement in which all Member States are required to participate. However, taking into consideration paragraph 3 of Article 1 of the Framework Agreement on Enhancing ASEAN Economic Cooperation signed on 28 January 1992 in Singapore and paragraph 7 of Article 3 of the ASEAN Framework Agreement on Mutual Recognition Arrangements signed on 16 December 1998 in Ha Noi, Viet Nam, a Member State which is not ready to fully implement this Sectoral MRA may withhold from proposing a body to be designated as its Inspection Service for listing pursuant to paragraph 2 of Article 7.

2. Notwithstanding paragraph 1, a Party whose Inspection Service has not been listed in this Sectoral MRA shall accept the GMP certificates and/or the inspection reports in respect of a facility manufacturing medicinal products in the territory of those Parties which have their Inspection Services listed under this Sectoral MRA.

3. If a Party decides not to accept the 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 inspection report. Any dispute arising from the non-acceptance of an 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.

4. Parties shall enjoy full and equal benefits and responsibilities as set out in the provisions of this Sectoral MRA at the date that the JSC accepts the body which it proposes for designation as its Listed Inspection Service under this Sectoral MRA.

## Article 12
## Termination of the Listed Inspection Service

1. Any Party, through its Designating Body, may withdraw its Inspection Service from the list of accepted Inspection Services by notifying the JSC through the ASEAN Secretariat with relevant written justifications. All other Parties have a right not to accept the GMP Certificates and/or inspection reports of the withdrawn Inspection Service. The effective date of withdrawal shall be six (6) months from receipt of the notification.

2. In the event of a complaint by an NDRA with relevant written justifications, regarding the technical competence of a Listed Inspection Service, the JSC shall proceed with the review of the complaint. The JSC may refer the matter to the Panel of Experts to conduct an assessment of that particular Listed Inspection Service if deemed necessary, specifying a timeframe to conclude the assessment. Based on the outcome of the assessment of the Panel of Experts, the JSC shall decide on the course of action to be taken against the Listed Inspection Service, including withdrawal or termination of the Inspection Service.

3. The JSC shall consider an application by a Party, through its Designating Body, to reinstate an Inspection Service whose participation has been withdrawn or terminated.

## Article 13
## Preservation of a National Drug Regulatory Authority

1. Nothing in this Sectoral MRA shall be construed to limit the authority of a Party to determine, through its legislative, regulatory and administrative measures, the level of protection it considers appropriate for safety and for protection of the health of persons in its territory.

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

(a) compromise the health or safety of persons in its territory;

(b) not meet the legislative, regulatory or administrative provisions within the scope of this Sectoral MRA; or

(c) otherwise fail to satisfy a requirement within the scope of this Sectoral MRA.

## Article 14
## Confidence Building

1. 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 such as:

(a) alignment of standards to, or acceptance of, the current PIC/S Guide to GMP for Medicinal

Products and the relevant Annexes or an equivalent GMP code, including the format for inspection reports;

(b) requiring an Inspection Service to establish a PIC/S Quality System, which shall include ensuring the competency of the inspectors;

(c) establishment of an appropriate legal framework for the conduct of inspections and the issue of GMP certificates and/or inspection reports to manufacturers;

(d) improving of infrastructure in inspection and certification to meet relevant international requirements for medicinal products; and

(e) actively participating in relevant arrangements undertaken by pertinent regional and international bodies, including collaboration in the assessment of manufacturing facilities located in non-ASEAN Member States.

2. A Party whose Inspection Service is not listed in this Sectoral MRA may submit a GMP Inspection Report to another Party, if it chooses to do so, for consideration by the other Party. The other Party may choose whether to accept or not to accept the report.

## Article 15
## Confidentiality

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

2. Parties shall take all reasonable and necessary precautions to protect information exchanged under this Sectoral MRA from unauthorised disclosure.

3. An importing Party shall not require the designated Inspection Service of an exporting Party to disclose a manufacturer's proprietary information, except to the extent necessary to demonstrate conformity with the importing Party's mandatory requirements.

4. Parties agree that the provisions of this Article shall continue to be binding between the Parties notwithstanding the withdrawal or termination of a Listed Inspection Service in accordance to Article 12.

## Article 16
## Rights and Obligations under Existing International Agreements or Conventions

This Sectoral MRA or any actions taken 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 a party.

## Article 17
## Dispute Settlement

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

## Article 18
## Deferral of Implementation

1. Any Member State that wishes to defer the discharge of its obligation as outlined in paragraph 2 of Article 11, shall notify the Secretary-General of ASEAN in writing of its

intention within three (3) months from the date of signature and the Secretary-General of ASEAN shall thereafter notify the rest of the Member States. The deferral shall be effective upon notification to the other Member States.

2. Pursuant to paragraph 1 of this Article, the Member State concerned shall notify the Secretary-General of ASEAN in writing when it is ready to implement this Sectoral MRA, provided that such date shall not be later than 1 January 2011. The Secretary-General of ASEAN shall thereafter notify the rest of the Member States.

3. Member States except those which have deferred the discharge of its obligation, shall accept and recognise the GMP certificates and/or inspection reports of a Listed Inspection Service.

## Article 19
## Final Provisions

1. The provisions of this Sectoral MRA may only be reviewed or amended by mutual written agreement of all the Member States.

2. Member States shall undertake appropriate measures to fulfill the agreed obligations arising from this Sectoral MRA.

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

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

5. This Sectoral MRA shall be deposited with the Secretary-General of ASEAN, who shall promptly furnish each Member State a certified copy thereof.

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

**DONE** at Pattaya, Thailand, this Tenth Day of April in the Year Two Thousand and Nine, in a single copy in the English Language.