2009 ASEAN Sectoral Mutual Recognition Arrangement for Good Manufacturing Practice Inspection of Manufacturers of Medicinal Products

1.This Sectoral MRA sets out the arrangements under which each Party shall accept the GMP certificates for manufacturers of medicinal products, where the GMP Certificates are issued by a Listed Inspection Service; and 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.

2.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.

3.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.

4.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.

5.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.

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

7.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.

8.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.

9.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.

10.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.

11.The JSC shall be responsible for listing, verification and termination of Inspection Services in accordance with this Sectoral MRA; providing a forum for discussion of issues that may arise concerning the implementation of this Sectoral MRA; 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; reviewing and proposing amendments to the scope and coverage of this Sectoral MRA; and considering any other matters and taking appropriate technical decisions relating to the implementation of this Sectoral MRA.

12.The JSC shall endeavour to meet at least once a year or, as and when required, to discharge its duties; determine its own rules of procedures; and make its decision by consensus. Any disagreement amongst the JSC shall be settled in accordance with Article 17.

13.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.

14.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.

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

16.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: is licensed or authorised to manufacture that medicinal product or is licensed to carry out a manufacturing operation in question; has been regularly inspected for compliance with GMP standards by its Listed Inspection Service; and complies with the PIC/S Guide to GMP for Medicinal Products or equivalent GMP code .

17.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.

18.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.

19.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.

20.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.

21.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).

22.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.

23.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.

24.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.

25.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.

26.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.

27.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.

28.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.

29.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: 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; 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; whether there is an adequate legal framework for the inspection and licensing of manufacturers of Medicinal Products.

30.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.

31.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.

32.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.

33.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.

34.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.

35.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.

36.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.

37.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.

38.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.

39.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: compromise the health or safety of persons in its territory; not meet the legislative, regulatory or administrative provisions within the scope of this Sectoral MRA; or otherwise fail to satisfy a requirement within the scope of this Sectoral MRA.

40.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.

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

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

43.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.

44.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

45.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.

46.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.

47.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.

48.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.

49.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.

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

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

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

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

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