Frequently Asked Questions on the ASEAN Mutual Recognition Arrangement (MRA) on

GMP INSPECTION of MANUFACTURERS of MEDICINAL PRODUCTS

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Frequently Asked Questions on the ASEAN Mutual Recognition Arrangement (MRA) on GMP Inspection of Manufactures of Medicinal Products

The ASEAN Secretariat
Jakarta

The Association of Southeast Asian Nations (ASEAN) was established on 8 August 1967. The Member States of the Association are Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand and Viet Nam. The ASEAN Secretariat is based in Jakarta, Indonesia.

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1. What is the ASEAN Sectoral MRA on GMP Inspection for Medicinal Products?

The ASEAN Sectoral MRA on GMP Inspection is an agreement signed by the ASEAN Economic Ministers which aims to facilitate the movement of medicinal product in ASEAN through the mutual exchange and recognition of GMP inspection reports and certificates. The scope and coverage of the Sectoral MRA, the criteria for listing the Inspection Service, a description of the mutual recognition obligations, implementation and dispute settlement are stipulated in the Agreement.

2. What was the background to the ASEAN Sectoral MRA on GMP Inspection for Medicinal Products?

An ASEAN Mutual Recognition Arrangement (MRA) on Good Manufacturing Practice (GMP) Inspection is included as one of the measures in the Roadmap for Integration of ASEAN Healthcare Sector. It was decided at the 9th ACCSQ-PPWG meeting held on 22 – 24 February 2005, in Makati City, Philippines that a MRA on GMP Inspection in ASEAN be signed. The ASEAN Sectoral MRA was signed on 10 April 2009 in Pattaya, Thailand by the ASEAN Economic Ministers.

3. What is the scope of the ASEAN Sectoral MRA on GMP Inspection for Medicinal Products?

The scope of the MRA is applies to the GMP inspection and certification of manufacturers of medicinal products

in finished dosage forms. It includes both prescription and non-prescription medicinal products for human use, but excludes biopharmaceuticals, radiopharmaceuticals, traditional medicines and investigational medicinal products intended for clinical trials.

4. Does the scope of the ASEAN Sectoral MRA on GMP inspection applies to all categories of medicinal products?

No. For a start, the scope of the MRA would be restricted only to medicinal 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 intended for clinical trials. The scope of the MRA may be extended to include biologics and traditional / complementary medicines at a later stage.

5. What benefits can ASEAN Member States gain by being a Party to the MRA on GMP Inspection?

Benefits would include:

a. Recognition and acceptance of the GMP inspection reports / certificates issued by the other Party's Inspection Service.

b. No need for other Parties of the MRA to re-audit / re-assess a drug manufacturing facility located within the territories of a

Party to the MRA. This results in savings in terms of time and resources for both regulators and industry.

c. Overall facilitation of access of medicinal products across the 10 ASEAN Member States.

d. Greater recognition and acceptance of GMP inspections by PIC/S members and other countries of the world.

e. Leveling up of ASEAN Inspection Services to the international PIC/S standard.

f. Possibility of working towards an MRA on GMP Inspection with other non-ASEAN countries collectively as an ASEAN economic bloc.

6. What are the requirements and criteria to be included as a Listed Inspection Service under the ASEAN Sectoral MRA?

The Listed Inspection Service shall operate a Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) GMP inspection and manufacturer's licensing system, as evident by PIC/S membership or other alternative approaches to determine equivalence.

The following requirements need to be in place

i) Inspection Service has adopted or adhered to the PIC/S Guide to GMP for Medicinal

Product and relevant Annexes or equivalent GMP code, including the inspection report format;

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

iii) There is an adequate legal framework for inspection and licensing of manufacturers of pharmaceutical products in finished dosage forms.

7. Why was the "PIC/S Guide to GMP for Medicinal Products" chosen to be the reference GMP Code for this Sectoral MRA?

The use of PIC/S GMP Code was decided during the 9th ACCSQ PPWG meeting held in Manila in early 2005. Selecting PIC/S as the reference standard is a good option because:

a. The PIC/S Guide to Good Manufacturing Practice for Medicinal Products is an internationally recognized standard for manufacturers of medicinal products.

b. PIC/S is a global organization. Currently, more than 30 countries are members of PIC/S, and these include countries from all 5 continents – Europe, Asia, America, Australia and Africa. Countries from the Middle East,

Indonesia, Thailand, Philippines and also the United States have recently submitted applications to join the PIC/S. Many other countries including China, Brunei, Russia and Japan have also shown interest.

c. The PIC/S works in close partnership with WHO, EMEA, EDQM, Unicef.

8. Why does the Inspection Service need to operate a PIC/S or equivalent Quality System?

All GMP Inspection Service should have a Quality System to help ensure transparency and consistency in the GMP inspection and manufacturer's licensing process.

The PIC/S Quality System Requirements for Pharmaceutical Inspectorates has an internationally recognised quality system guidelines for pharmaceutical inspectorates. This Quality System has also been adopted by World Health Organisation (WHO). It has an established GMP Inspection report format and quality system procedures. Therefore, there is no need to duplicate efforts to develop these processes.

9. What is the PIC/S GMP audit report format like? Can an equivalent format be used instead?

The PIC/S GMP audit report format can be found at www.picscheme.org. An equivalent format can be used, provided that the contents of the GMP audit report

should contain at least all the requirements as listed in the PIC/S GMP audit report format.

10. Is it a pre-requisite for an ASEAN Member State to become a PIC/S member in order to be a Listed Inspection Service?

No, it is not a pre-requisite for an ASEAN Member State to become a PIC/S member in order to be a Listed Inspection Service. There is an alternative approach to determine equivalence to the PIC/S GMP Inspection and Manufacturer's licensing System through the Panel of Experts as provided under the ASEAN Sectoral MRA. What is essential is for the interested Member States to operate a PICS GMP Inspection and Manufacturer's licensing System as evident by PIC/S membership or demonstrate an equivalent system as assessed by the Panel of Experts.

11. What are the criteria used by the Panel of Experts in determining equivalence to the PIC/S GMP Inspection and Manufacturer's licensing System.

The criteria used by the Panel of Experts in determining equivalence include:

- Legal requirements
- Quality system requirements
- GMP Standard used

Details may be found in the Operation Manual on the Panel of Experts and the 4 Annexes.

12. What are the obligations of the ASEAN Member States when the ASEAN Sectoral MRA enters into force?

The ASEAN Sectoral MRA on GMP Inspection will enter into force on 1 January 2011. Under this MRA, all ASEAN Member States shall accept and recognize the GMP Certificates and/or inspection reports of a Listed Inspection Service.

13. How can an Inspection Service apply to be listed under the ASEAN Sectoral MRA?

An Inspection Service which is ready to implement the Sectoral MRA should submit its application to the Joint Sectoral Committee via the ASEAN Secretariat for decision to be a Listed Inspection Service. An Inspection Service which has fulfilled the criteria (see Question 11) for implementation of the Sectoral MRA will be included as a Listed Inspection Service. A Joint Sectoral Committee would oversee the implementation of the Sectoral MRA.

14. What is a Listed Inspection Service?

A Listed Inspection Service is an Inspection Service which has met the criteria as stipulated in the Sectoral MRA and has been accepted by the Joint Sectoral Committee, and hence recognized by the ASEAN Member States. A GMP

inspection report / certificate issued by a Listed Inspection Service shall be accepted by other ASEAN Member States without the need for further GMP inspections.

15. Who comprise the Panel of Experts?

All members of the Panel of Experts shall be appointed by the JSC. The Panel of Experts shall not exceed five in number.

The Panel of Experts shall consist of representatives from the Listed Inspection Service who are experienced GMP inspectors in the NDRA and are knowledgeable of the PIC/S GMP inspection framework and international GMP standards.

The JSC may also appoint independent expert(s) when necessary to assist the Panel of Experts in the assessment process. In addition to their technical credentials and experience, these independent expert(s) should also be familiar with the PIC/S GMP inspection framework and international GMP standards. These independent expert(s) play an advisory role within the Panel of Experts.

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