



## **UPDATE ON ASEAN MRA ON GMP INSPECTION AND GMP CONFORMITY ASSESSMENT FOR MEDICINAL PRODUCT REGISTRATION IN SINGAPORE**

### **Dear Industry Stakeholders**

Under the ASEAN Sectoral Mutual Recognition Arrangement (MRA) on Good Manufacturing Practices (GMP) Inspection for Manufacturers of Medicinal Products all ASEAN Member States (AMS) are obliged to recognize and accept the inspection reports and certificates issued by Listed (Accepted) ASEAN Inspection Services without duplicating GMP inspection in each other's territory.

Singapore Health Sciences Authority, Malaysia National Pharmaceutical Control Bureau and Indonesia National Agency for Drug and Food Control are the first 3 Listed ASEAN Inspection Services. With effect from 13 March 2015, the Food and Drug Administration (FDA) of Thailand became the 4th Listed ASEAN Inspection Service, following the 22<sup>nd</sup> ACCSQ Pharmaceutical Products Working Group (PPWG) Meeting held on 12 – 13 March 2015 in Vientiane, Lao PDR.

### GMP Conformity Assessment for Medicinal Product Registration

A new finished product manufacturing site for an application for a medicinal product is subjected to GMP Conformity Assessment. Currently, HSA will accept documentary evidence of GMP conformance from overseas

competent agencies where HSA is satisfied with the system of GMP audit, which shall be equivalent to the standard adopted by Singapore:

- Agencies which are members of the Pharmaceutical Inspection Co-operation Scheme (PIC/S); and
- Agencies who are Listed ASEAN Inspection Services (for medicinal products in finished dosage forms excluding biologics and radiopharmaceuticals).

#### Impact to Industry

With the addition of the FDA of Thailand as the 4<sup>th</sup> Listed ASEAN Inspection Service, applications for medicinal products with new finished product manufacturing sites which are supported by GMP documentation (GMP Certificates/Inspection Reports) issued by the FDA of Thailand as the proof of GMP Compliance, may submit GMP evidence for evaluation as part of the regulatory requirement. Such manufacturers need not be audited by HSA if the submitted evidence is found to be acceptable.

#### Applications & Types of Products Involved

The above is applicable for all new and amendment product applications (NDA, GDA, MIV) for medicinal products in finished dosage form for human use, but excluding biologics and radio-pharmaceuticals.

#### Implementation

The above will be implemented with immediate effect.

**For enquiries, please contact:**

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