Building the ASEAN Community

Medicinal Products

Ensuring Safety of Medicinal Products across ASEAN

Healthcare is one of the 12 priority sectors for ASEAN economic integration. In line with this, an ASEAN Mutual Recognition Arrangement (MRA) on Good Manufacturing Practices (GMP) Inspection for Manufacturers of Medicinal Products had been identified as a priority initiative. An ASEAN MRA Taskforce on GMP Inspection was formed in 2005 and on the 10th April 2009, an ASEAN Sectoral MRA on GMP Inspection for Manufacturers of Medicinal Products was signed by the Economic Ministers of all 10 ASEAN Member States (AMS). The international Pharmaceutical Inspection Co-operation Scheme (PICS) framework was used as the benchmark for this ASEAN MRA, which covers all medicinal products in finished dosage forms, including over-the-counter (OTC) medicinal products as well as prescription medicines.

To implement the ASEAN Sectoral MRA on GMP Inspection, a Joint Sectoral Committee (JSC) was formed in 2012. An ASEAN GMP Inspectorate which intends to be included in the list of accepted ASEAN Inspection Services can submit an official application to JSC via the ASEAN Secretariat. Any AMS which is a PICS member will be accepted for listing without any further technical assessment, while an AMS which is a not a PICS member will be subject to an assessment by an ASEAN Panel of Experts (PoE), to verify its technical competency against the PICS framework. ASEAN Secretariat shall maintain a List of Accepted Inspection Services.

Under the MRA, all 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 were the first 3 Listed ASEAN Inspection Services as they are members of PICS. The Food and Drug Administration (FDA) of Thailand became the 4th Listed ASEAN Inspection Service with effect from 13 March 2015.

TO LEARN MORE

1. ASEAN MRA on Good Manufacturing Practices (GMP) Inspection for Manufacturers of Medicinal Products

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