



# ENSURING SAFE PHARMACEUTICAL PRODUCTS IN ASEAN

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Divergences in national product standards often act as impediments to trade in goods. In order to promote deeper economic integration between economies towards the realisation of the ASEAN Economic Community by 2015, harmonisation of product standards and technical regulations, and mutual recognition of test reports and certification are necessary.

In the area of healthcare, which is one of the priority sectors identified to accelerate the economic integration process, the ASEAN Sectoral Mutual Recognition Arrangement (MRA) for Good Manufacturing Practice (GMP) Inspection of Manufacturers of Medicinal Products was signed by the ASEAN Economic Ministers at the 14<sup>th</sup> ASEAN Summit and Related Summits on 10 April 2009 in Pattaya, Thailand.

## MRA for GMP Inspection of Manufacturers of Medicinal Products

The MRA for GMP Inspection of Manufacturers of Medicinal Products calls for the mutual recognition of GMP certifications and/or inspection reports issued by inspection bodies that are parties to this MRA through their listing as the authorised bodies to issue such certificates and/or test reports. These certificates and/or inspections reports will be used as the basis for regulatory actions such as the granting of approvals or licences to the manufacturer, supporting post-market assessments of conformity of these products, and providing information on the manufacturer's facilities including the testing laboratories, if any, or its contracted laboratory. The reports also will include information on the dosage forms manufactured at the facility and whether the manufacturer complies with the GMP requirements.

Under this MRA, a facility manufacturing medicinal products shall ensure that it is licensed or authorised to manufacture medicinal products or carry out a manufacturing operation in question. The facility shall be regularly inspected for compliance with GMP standards. The facility shall also demonstrate that it complies with the Pharmaceutical Inspection Cooperation Scheme (PIC/S) Guide to GMP for Medicinal

Products or equivalent GMP code to fulfill the obligations under this MRA.

The MRA will be fully implemented by all ASEAN Member States by 1 January 2011.

## Benefits

This MRA will benefit both manufacturers and consumers alike. For manufacturers of medicinal products, in particular pharmaceutical products, ensuring the safety, quality and efficacy of their products will become a priority. Compliance with the MRA demonstrates that the medicinal products in ASEAN are consistently produced and controlled in accordance with the agreed principles of good manufacturing practices and quality standards among ASEAN regulators. This will enhance the competitiveness of the manufacturers as well as the consumers' confidence in their products. Business costs will also be reduced since manufacturers do not need to undertake repetitive testing or certification process. For consumers, they will benefit from the assurance that the medicinal products they consume are safe for use.

*For more information on ASEAN activities on the integration of the healthcare sector through the reduction of technical barriers to trade, contact Ms. Shirley V. Ramesh ([shirley@asean.org](mailto:shirley@asean.org)) of the Bureau for Economic Integration and Finance at the ASEAN Secretariat.*

*Please visit [www.asean.org](http://www.asean.org) for the full text of the documents on ASEAN cooperation in these areas.*

FACT SHEET

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