Unified South Asian medical device regulations proposed

Source: Emergo Group

- *Southeast Asian governments setting up harmonized medical device regulatory scheme*
- *New regulatory system to be implemented in late 2014*

The Association of Southeast Asian Nations (ASEAN), a regional economic organization consisting of 10 member states (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam), is developing a harmonized regulatory system for medical devices that would cover all member countries.

The ASEAN Medical Devices Directive (AMDD) incorporates elements of both the European Medical Devices Directive (MDD 93/42/EEC), European guidelines (MEDDEVs), and Global Harmonization Task Force (GHTF) guidelines. Medical devices, active implantable medical devices as well as in vitro diagnostic devices would all fall under AMDD jurisdiction.

Elements of the AMDD

Major components of the proposed AMDD include a four-tier device classification system based on risk (Classes A, B, C and D) using criteria established by the GHTF. The AMDD also stipulates a Common Submission Dossier Template based on the GHTF Summary Technical Document (and already a requirement in place in Singapore and Malaysia), as well as compliance requirements relevant to Essential Principles (based on Essential Requirements). In addition, AMDD compliance will be evaluated via Conformity Assessments.

The AMDD also contains vigilance system requirements based on GHTF guidelines as well as European MEDDEV guidance.

In-country representation still required

Although AMDD will establish a harmonized regulatory system for medical devices throughout Southeast Asia, a local representative and registration in each member state would still be required. According to the draft AMDD document now in circulation, manufacturers would still need to have their authorized representatives manage their registration efforts in each ASEAN country.

Comment and implementation timelines

ASEAN directors have targeted an implementation deadline of December 2014 for the AMDD. In the meantime, comments on the proposed Directive are accepted until 31 August 2012.

What the AMDD means for your business

If established as planned, the AMDD will cover a market of roughly 600 million people. Medical device companies already in compliance with the European Medical Devices Directive may furthermore enjoy a faster route to AMDD compliance, given that the ASEAN directive borrows heavily from current EU regulations. And, the ASEAN member states will all adopt a harmonized medical device regulatory system.