

Independent Study Title	:	ASEAN Medical Device Directive (“AMDD”) Agreement should be beneficial to Thailand's medical device business and standards.
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ABSTRACT

Thailand has enacted the Medical Device Act 2008, which developed from the Medical Device Act 1988, to protect the public from substandard and dangerous medical devices, as well as advertisements for such devices. This Act has been established by the Thai Food and Drug Administration (hereinafter refer to as “TFDA”) in order to monitor, cover and control the manufacturers, importers, and distributors of medical devices within the territory of Thailand. The TFDA has duties under the law to enact regulations and monitor medical devices on their own initiative. Moreover, the TFDA also establishes and publishes the process by which entrepreneurs must register medical devices. The TFDA’s mission under the Act is to prevent circumstances that would result in harm to the public.

However, Thailand be part and parcel of the ASEAN Economic Community in the year 2015. ASEAN has set up a working schedule for the Medical Device Product Working Group (hereinafter referred to as “MDPWG”) and the ASEAN Consultative Committee for Standards and Quality (hereinafter refer to as “ACCSQ”) to brainstorm and draft the ASEAN Agreement on Medical Device Directive (hereinafter referred to as “AMDD”) to enforce and monitor medical devices in ASEAN member states. The objectives of this agreement are to promote cooperation, harmonization and mutual recognition of standards, and certification of medical devices. In 2015, the AMDD will be finalized and enforced, and the agreement will be honored and implemented by all ASEAN member states. Each member state may have to amend its internal laws, or enact new ones, to bring itself into compliance.

In conclusion, it can be asserted that the AMDD should be beneficial to Thailand. It can promote medical devices’ business, and enhance the devices’ standards. This will make the Thailand entrepreneurs more competitive, and this may be able to compete with other entrepreneurs in the world.