

LEGAL  
ALERT

Cambodia  
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## Licensing Laws on the Management of Pharmaceuticals in Cambodia

The rapid growth of Cambodia's economy in the last few years has allowed its healthcare industry to be an emerging sector in Cambodia's growing economy. In 2011, the value of drugs imported into Cambodia increased by more than 10% from 2010, and the increase in 2010 from 2009 was around 11%.<sup>[1]</sup> Drug import figures are expected to be on an upward trend as the healthcare sector in Cambodia continues to grow.

Accordingly, legislation has been introduced to ensure that pharmaceutical services are safe and legal for use in Cambodia.

### Licensing laws

The Amendment of the Law on the Management of Pharmaceuticals, adopted by the National Assembly on 8 November 2007, established a requirement that any medical establishments must first be authorised or licenced by the Ministry of Health (MoH).

According to Article 10 of the Law on the Management of Pharmaceuticals, "those who produced, imported, exported or stored pharmaceutical materials without authorisation from the MoH shall be penalised with a fine from a range of KHR1 million (approximately USD250) to KHR10 million (approximately USD2500)." Unauthorised pharmaceutical activities that harm public health of humans and animals are punishable by a suspension of enterprise or imprisonment up to a maximum of 10 years.

**Drug Registration.** Drug registration in Cambodia comprises a range of processes that are overseen by the MoH. New drugs must undergo clinical trials to test for safety through a series of tests on volunteers to ensure its effectiveness on humans. Application forms, supported by documents such as a pharmaceutical diploma recognized by the MoH, the applicant's health certificate, criminal record clearance and establishment drawings (including maps of the location, storage and office building), are then directly submitted to the technical department.

Besides the application, officers may be required to ask for any further information regarding the application and the required licensing fee.

**Import and Export of Pharmaceuticals.** Primarily, Article 8 of the Law on Management of Pharmaceuticals, states that the "importation of addictive drugs, drugs affecting the nervous system, raw materials and ingredients containing addictive substances which have been specified in the addictive drug control law" must be authorised by MoH. Therefore, the legalised import-export of foreign pharmaceutical products into Cambodia requires licensing from the MoH (known as the "Pharmaceutical Importer-Exporter licence").

The licencing fee to import and export pharmaceutical products in and out of Cambodia is approximately KHR1.2 million (approximately USD300) and is valid for 2 years. However, fees for subsequent licencing renewals cost 30% less. If a primary approval on the application is given, the applicant will be required to pay the licensing fee. A recognised Pharmaceutical Importer-Exporter licence may be issued after all the procedures and conditions are met. Furthermore, before the pharmaceutical products may be distributed, imported and exported, it is also required that the pharmaceutical products be registered and receive a registration number from MoH.



**Conclusion.** Cambodia is working with international experts to improve its sustainable healthcare facilities. In particular, disease control initiatives are being implemented and immunisation methods are being expanded, which is showing to be a big part of the pharmaceutical market. As a result, this new innovation is beginning to rapidly reduce the rates of major infectious diseases, saving the lives of many.

[1] Sophal, Chun. “Drug import data digested.” The Phnom Penh Post 10 February 2011. Web. 26 October 2017.

If you have any questions or require any additional information, please contact [Nith Niteyana](#), [Sin Soromnear](#) or the ZICO Law Partner you usually deal with.

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