Newsletter

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Singapore's Health Sciences Authority Streamlines Regulations of "Therapeutic Products" with Proposed Changes to the Health Products Act

The public consultation conducted by the Health Sciences Authority (HSA) on proposed changes to the *Health Products Act* (the "**HPA**") was concluded on 23 November 2014 (click here for the previous client alert).

Two sets of regulations were featured for public consultation, namely:

(a) the *Health Products (Advertisement of Therapeutic Products) Regulations 2015*; and

(b) the *Health Products (Licensing of Retail Pharmacies) Regulations 2015*.

Below is a summary of the key changes proposed in these regulations.

Proposed Health Products (Advertisement of Therapeutic Products) Regulations 2015

The key proposed changes include the removal of the existing permit system for advertising and sales promotion of pharmaceutical products, and the extension of the regulatory requirements to the Internet and corporate websites.

Presently, the *Medicines Act* requires any person who wishes to issue a medical advertisement or conduct a sales promotion to first obtain a permit. In line with international best practices, the proposed regulations replace the pre-publish permit system with broad principles for compliance by the industry. This move towards self-regulation will reduce the regulatory burden and costs for the industry.

Regulatory controls of advertisements will also extend to the Internet and social media platforms. In particular, registrants or licensees of therapeutic products will be prohibited from having discussion forums or similar platforms on their corporate websites, including blogs and Facebook pages.

Proposed Health Products (Licensing of Retail Pharmacies) Regulations 2015

Retail pharmacies are unlikely to be significantly affected by the proposed regulations. Most of the current controls under the *Medicines Act* will be laterally transferred to the HPA, with streamlining of the licensing requirements.

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Retail pharmacies registered under the existing regime need not re-apply for a Retail Pharmacy Licence under the HPA. The pharmacy would still have to be managed by a registered pharmacist holding an active practising certificate.

Pharmacy registration and the Form A Poisons Licence will be consolidated into the Retail Pharmacy Licence. In this regard, businesses dealing solely in the wholesaling of pharmaceutical products containing a listed poison under the HPA licensing regime will not need a Form A Poisons Licence. Businesses which handle active pharmaceutical ingredients, laboratory reagents and/or veterinary products containing listed poisons under the *Poisons Act* will still need a Form A Poisons Licence.

The proposed regulations also clarify the requirements to obtain approval for telepharmacy services. Retail pharmacies seeking to provide telepharmacy services will need to ensure that they possess:

(a) the necessary technological set-up and capability for the delivery of telepharmacy services;

(b) adequately trained personnel to provide telepharmacy services; and

(c) written procedures detailing how the telepharmacy services are to be provided.

The changes are expected to be finalised in the third quarter of 2015. More details and draft copies of the proposed regulations are available on the HSA's website, which can be accessed at this link.

Singapore's Ministry of Health to Strengthen Clinical Practice Guideline Framework

The Ministry of Health (MOH) will strengthen the clinical practice guideline ("**CPG**") framework to ensure that patients receive appropriate care.

The MOH has been publishing CPGs since 1998. The main aim of the CPGs is to guide primary care and hospital care providers, including both public and private sector doctors, on the current best practices. CPGs can also be used to guide the development of clinical programmes and audits.

The various CPGs cover a broad spectrum of clinical care, from asthma and heat injuries, to schizophrenia and even gambling disorders.

Unless otherwise specified in individual guidelines, the CPGs are considered withdrawn five years after publication.

Recent publications include CPGs on Attention Deficit Hyperactivity Disorder and Diabetes Mellitus. The current CPGs can be found on MOH's website here.