Medical, Healthcare & Life Sciences

HSA Consults on Proposed Regulatory Controls on Active Ingredients under Health Products Act

Introduction

On 17 July 2023, the Health Sciences Authority ("**HSA**") announced a public consultation on new subsidiary legislation under the Health Products Act 2007 ("**HPA**"), namely the proposed Health Products (Active Ingredients) Regulations 2023 ("**Regulations**").

"Active ingredients" are defined as ingredients that contribute to the intended function of the product, and are pharmacologically active substances that may be used to manufacture health products. At present, active ingredients are regulated under the Poisons Act 1938 (which imposes a licensing requirement on importers and wholesalers), and the Medicines Act 1975 (on application for certification).

To ensure that active ingredients are consistently manufactured, stored and distributed in accordance with appropriate quality standards, HSA seeks to implement risk-based regulatory controls that will be streamlined and consolidated under the HPA by way of the Regulations. Further, the proposed Regulations will provide a fit-for-purpose and risk-based licensing framework for active ingredients that will be aligned with international standards.

Once the proposed Regulations are implemented, the regulatory controls under the Poisons Act 1938 and Medicines Act 1975 will no longer apply. Licensed importers and wholesalers will no longer need to hold a separate Form A Poisons Licence under the Poisons Act.

In this Update, we examine the scope, overview, and licensing framework proposed in the draft Regulations.

Scope

The proposed Regulations will regulate active ingredients listed in The Schedule of the Regulations and which are useable as pharmacologically active constituents in the manufacture of (i) therapeutic products; (ii) cell tissue or gene therapy products that are not a result of only minimal manipulation of cell or tissue; and (iii) medical devices.

At present, the list of active ingredients is yet to be confirmed.

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Overview

Broadly, the Regulations cover:

1. **Prohibitions** against the manufacture, import or supply of adulterated, counterfeit or unwholesome active ingredients. The importation or supply of an active ingredient that has been tampered with is also prohibited.

2. **Licensing**, encapsulating:

    a. activities for which licences are required;
    b. persons exempted from licensing requirements; and
    c. requirements for obtaining the relevant licence.

3. **Duties** relating to:
    a. storage and transport;
    b. import, export and supply; and
    c. specific licences.

4. **Issuing of certificates** stating that:
    a. an active ingredient intended for export is compliant with specified standards;
    b. the manufacturer of an active ingredient has conformed with the Good Manufacturing Practice ("**GMP**") standard; and
    c. A distributor of an active ingredient has conformed with the applicable Good Distribution Practice ("**GDP**") standard.

5. **Provisions for routine inspections** of premises used for the manufacture, supply and storage of active ingredients and conveyances used for the transport of active ingredients.

Licensing Framework – Risk-based Approach

With regard to licensing, the proposed Regulations take a risk-based approach by creating an activity-based licensing framework for manufacturers, importers and wholesalers of active ingredients based on their risk profiles.

Where active ingredients are used in health products for local clinical use, inspection and licensing controls will apply to all manufacturers, importers and wholesalers. Such companies will be inspected for compliance with the Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP Guide or HSA GDP standard.

Where active ingredients are intended for non-clinical purposes (e.g. clinical research or use in animals), less stringent requirements will be imposed. For instance, manufacturers, importers and wholesalers

will be exempted from licensing requirements where the active ingredient is solely for use in a relevant health product that is intended to be used only in clinical research. However, HSA will reserve the rights to inspect as required.

Concluding Words

In response to the increasing complexity in the manufacturing and supply chain of active ingredients, the proposed Regulations seek to safeguard public health by streamlining and enhancing the relevant regulatory controls. The consultation will run from 17 July to **17 August 2023**, and feedback may be provided to HSA here.

If you have any queries on the above developments, please feel free to contact our team below.

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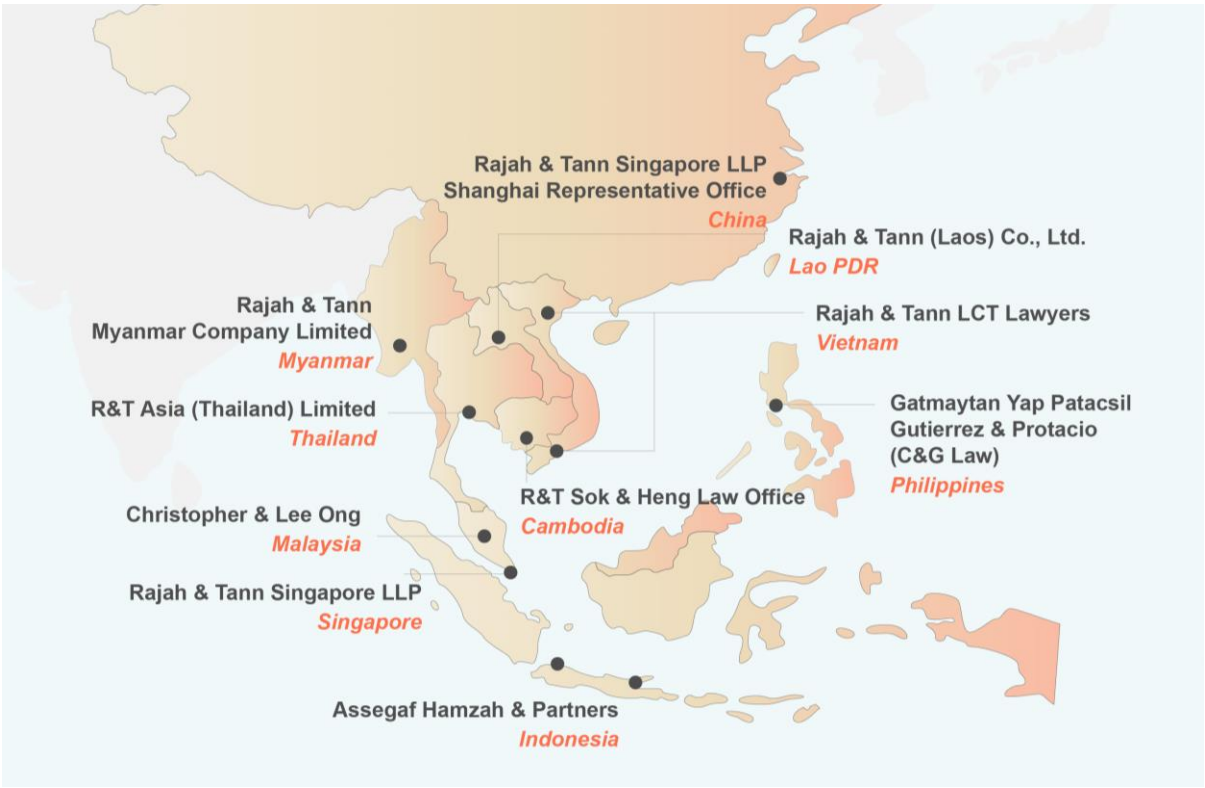

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