Intellectual Property

Pharmaceutical Product Registration and Cosmetic Product Notification in Malaysia

Introduction

As the global COVID-19 cases continue to rise, researchers around the world are racing to understand the virus and working to roll out an effective vaccine. In this article, we look at the general requirements and procedure for pharmaceutical product registration and also cosmetic product notification in Malaysia.

Introduction of Pharmaceutical Product Registration

A company must obtain appropriate approval from the National Pharmaceutical Regulatory Agency ("**NPRA**") (formerly known as National Pharmaceutical Control Bureau) to manufacture, sell, supply, import or possess or administer any drug or pharmaceutical products in Malaysia, unless specifically exempted by the Regulations.

The applicant for product registration for pharmaceutical products is known as the Product Registration Holder ("**PRH**"). A PRH must be a locally incorporated company, corporate or legal entity, with permanent address and registered with Companies Commission of Malaysia (with the scope of business related to the health/pharmaceutical product).

Since only Malaysian companies may apply for such product registration, a foreign company will have to appoint a local agent (a company registered in Malaysia) as their local representative to obtain product registration. The appointed agent would then be responsible for all matters relating to product quality, safety and efficacy.

If the applicant is not the product owner, the PRH should have an authorization in writing by the product owner to be the holder of the product registration and be responsible for all matters pertaining to quality, safety and efficacy of the product. This shall include updating any information relevant to the product/ application.

Pharmaceutical Products that Must be Registered

To determine whether a product has to be registered, we refer to Regulation 2 of the Control of Drugs and Cosmetics Regulations 1984 ("**CDCR**"), which defines "product" as a drug in a dosage unit or

otherwise, for use wholly or mainly by being administered to human beings or animals for a medicinal purpose or a drug to be used as an ingredient of a preparation for a medicinal purpose.

Under Section 2 of the Sale of Drugs Act 1952, "medicinal purpose" means any of the following purposes:

(a) alleviating, treating, curing or preventing a disease or a pathological condition or symptoms of a disease;
(b) diagnosing a disease or ascertaining the existence, degree or extent of a physiological or pathological condition;
(c) contraception;
(d) inducing anaesthesia;
(e) maintaining, modifying, preventing, restoring, or interfering with, the normal operation of a physiological function;
(f) controlling body weight; and
(g) general maintenance or promotion of health or wellbeing.

Registrable products include, but are not limited to the following:

(a) Pharmaceutical products containing scheduled poisons;
(b) Pharmaceutical products containing non-scheduled poisons; and
(c) Natural products, including herbal and traditional products.

Products which are not registrable include the following:

(a) Diagnostic agents and test kits for laboratory/in-vitro use;
(b) Medical Devices;
(c) Food;
(d) Sports Nutrition, such as body-building products containing protein/whey/soya bean;
(e) Raw herbs used in extemporaneous preparations, including those that are dried & cut into pieces, without dosage instructions and indications;
(f) Insect repellents, insecticides, pesticides and parasiticides; and
(g) Detergents/disinfectants for domestic use.

Although the products are not registrable under the Sales of Drugs Act 1952, they might be regulated by different authorities, for example, medical devices are regulated by the Medical Device Authority governed under the Medical Device Act 2012.

Categorisation of Product

The applicant must determine the category of product before applying for product registration. Products are categorised as follows:

(a) New Drug Products;
(b) Biologics;
(c) Generics;
(d) Health Supplements; and
(e) Natural Products.

Applicants may apply to the NPRA for product classification if they are unsure of the product category.

Criteria for Registration of Pharmaceutical Products

Products to be registered must fulfil the registration requirements determined by the NPRA, especially from the aspect of safety, quality and efficacy of the product.

The method of evaluation depends on the category of product. The product will be required to undertake either full evaluation or an abridged evaluation subject to the product category. The applicant is required to comply with the conditions applied on product registration applicable according to the type of product such as the special conditions for registration for a particular product or group of products, the list of permitted, prohibited and restricted substances, labelling requirements, guideline on patient dispensing pack for pharmaceutical products in Malaysia.

Cosmetic Products

As for cosmetic products, a company shall not manufacture, sell, supply, import, possess or administer any cosmetics unless the cosmetic is a notified cosmetic. The company must notify the NPRA of the cosmetic products.

The CDCR defines cosmetic as any substance or preparation intended to be placed in contact with the various external parts of the human body or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance or correcting body odours, protecting them or keeping them in good condition.

A cosmetic product placed on the market must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use. Notified products shall meet all stipulated regulations and guidelines for cosmetic products.

Labelling Requirement

Further, the company must fulfil the labelling requirements for the registered product imposed by the NPRA. The registered product shall be affixed with the security device approved by the NPRA. A security device (hologram) (known as "**MeditagTM label**"), which is serialized, shall be used to authenticate and verify that the product is registered with the NPRA, and will be affixed to each unit pack of the product, whether locally manufactured or imported. All products without MeditagTM label will be considered as unregistered products. The requirement for the affixation of this security device to product labels, is applicable to all registered pharmaceuticals products, traditional products and health supplements.

Currently the requirement for security label does not apply to cosmetics. It is not recommended that cosmetic products carry the MeditagTM label as it may lead to confusion. However, the company shall also ensure that the label of a cosmetic product complies with the labelling requirements as defined in the Cosmetic Labelling Requirements.

Food – Drug Interphase Products

There are many products on the market that claim to promote good health and are even for the maintenance, prevention and treatment of chronic disease. To protect the interest of the consumers, the Ministry of Health monitors and regulates the marketing and sale of these products.

Some of these products are not clearly classified as either "food" or "drugs". Such products include a variety of so-called health products and have been termed as "food-drug interphase (FDI) products". Generally, FDI products are products with a combination of food ingredients and active ingredients for oral consumption. Examples of food ingredients are fruit, vegetables, meat, poultry, milk, cocoa and cereal. Examples of active ingredients are vitamins, minerals, herbs, enzymes, probiotics, prebiotics, amino acids and other ingredients that are not traditionally consumed as food. FDI products may be presented in the form of powder, liquid, semisolid forms such as gel/jelly, chewable tablet, drops, granule, etc.

It is important to determine the category of a FDI product, and whether the product is regulated as drug (which would fall under the NPRA's purview) or, as food (which would fall under the Food Safety and Quality Division (FSQD)'s purview).

To address this issue, both the NPRA and FSQD, Ministry of Health Malaysia formed the Committee for the Classification of Food-Drug Interphase Products. There are guidelines provided to determine whether a product is a drug product or food or FDI. However, if it remains unclear whether a product falls under food or drug product or FDI, then an application can be made to the Committee to determine the type of product and subsequently obtain necessary approval, if necessary. When there is greater uncertainty regarding the safety of an FDI product, such product shall be regulated by NPRA.

Licenses & Certificates Required

A company that wishes to import an unregistered product for the purpose of clinical trial shall apply for a Clinical Trial Import Licence. Products which are not registered and are intended to be manufactured locally for the purpose of clinical trial shall require Clinical Trial Exemption from the NPRA. Any person who wishes to manufacture any product solely for the purpose of producing a sample for registration should apply for an exemption for manufacture of sample (applies to locally manufactured products only).

After the product is registered or notified, a company that wishes to manufacture, import and/or wholesale any registered/notified products needs to first apply for Manufacturer's Licence, Import Licence and/or Wholesaler's License.

Compliance to Good Manufacturing Practice ("**GMP**") and Good Distribution Practice ("**GDP**") is a prerequisite to application for a manufacturing license, as well as product registration/cosmetic notification. GMP is a standard which shall be followed by the manufacturers to ensure that the products manufactured are safe, efficacious and of quality. Meanwhile, importers and wholesalers are required to comply with the principles of GDP.

Conclusion

Note that depending on the nature of the products, the procedure to register a drug product or to notify a cosmetic product might differ and there might be more stringent requirements. It is prudent for businesses to consult legal advisors before rolling out drug and cosmetic products in the market.

Visit our COVID-19 Resource Centre for views from our lawyers across the region on common issues and legal implications brought about by COVID-19. For specific inquiries, please reach out to your relationship partner or send an email to our COVID-19 Legal Team.

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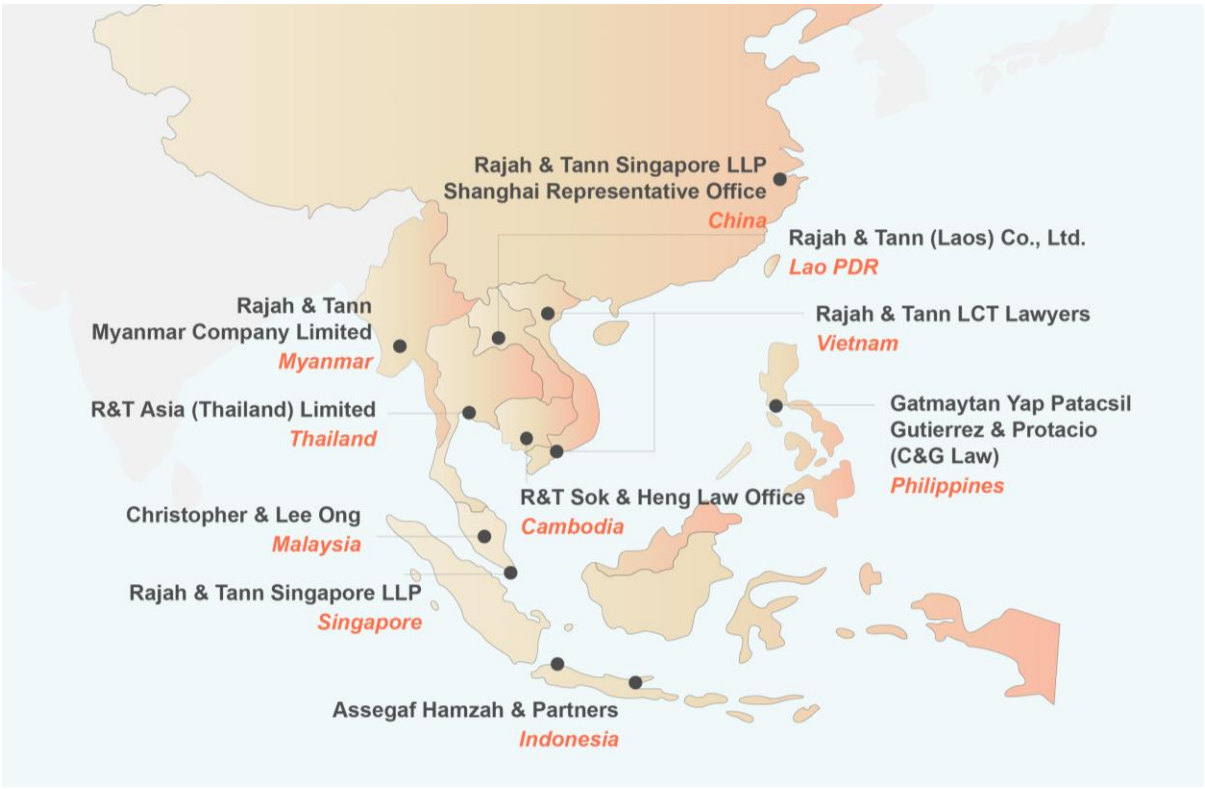

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