

Guidelines of Entering Health Supplement, Traditional Medicine or OTC Market in Malaysia

The sales of Health Supplement, Traditional Medicine and Over-the-Counter products is accessed by the National Pharmaceutical Regulatory Agency (NPRA), where stringent ruling is imposed. Before being marketed, the products under the above category must be registered with the NPRA. Otherwise, a breach of the ruling by the company will result in a heavy penalty.

Here are **three (3) steps** to consider during registration:

01 Product Classification

To identify the product category, product classification must be submitted to NPRA. Classification of the products is based on its active ingredients as well as product claims.

Eg: Tongkat Ali capsules is categorized under traditional medicine.

02 Setting Up a Company

Whether for product registration or business operation, Product owner needs to access if he/she is required to set up a company. Product owner can also appoint their OEM manufacturer or consultant's company to be the holder. In addition to product owners, wholesalers and importers are also required to comply strictly with NPRA ruling for businesses.

Some companies prefer the products to be manufactured locally (under OEM) than importing it, as local products have a higher advantage in compliance with Product Registration, usually consisting of product formulation, documentation, labelling requirement, GMP certificates, and QC tests.

03 Product Registration

The next step after product classification is registering the products. Each category varies in indications, labeling requirements, recommended dosage, testing parameters, registration process, documentation, fee, and durations. Following the procedure, registered products will be required to affix a Hologram on the outer packaging, and registration number given to the product upon approval.

Having a predominantly Muslim population, having a Halal certificate for your product is important. The manufacturers whether local or overseas, must be Halal certified and recognized by JAKIM (the local Halal authority) to obtain a Halal certificate for the products.

For more information on the do's and don'ts of Product Registration on medicinal products, please visit: <http://np.ra.moh.gov.my/index.php/faq/product-registration>

