

APPENDIX 28

LICENSING

1. TYPES OF LICENSES

Type of Licenses	Activity
Manufacturer's License	Licensee is authorized to manufacture the registered products in the premises specified in the license and to sell by wholesale or supply the products
Import License	Licensee is authorized to import and sell by wholesale or supply the registered products from the address of the premises specified in the license.
Wholesaler's License	Licensee is authorized to sell by wholesale or supply the registered products from the address of the business premises specified in the license

2. LICENSE APPLICATION FORM

The license application for registered products (Manufacturer's License, Import License and Wholesaler's License) shall be submitted via the QUEST system.

Applications must be submitted with the following supporting documents:

- a) A copy of Company/ Business Registration Certificate
- b) A copy of Business License (Local Authority) for business premises or store (if any)
- c) A copy of the Applicant's/ License Holder's Identity Card
- d) A copy of the License Holder's Type A License (This document is necessary if products manufactured/ imported/ wholesaled are Scheduled Poison A products or any other products that require a Pharmacist)
- e) A copy of previous license (For renewal application only)

An application shall only be processed if it is complete and payment has been approved.

The processing fee shall not be refundable. The processing fee of an application for a Manufacturer's License is RM 1,000.00 and RM 500.00 for an Import License or a Wholesaler's License.

Each license is valid for **one (1) year** or until 31 December, whichever earlier.

3. ADDITIONAL PRODUCT LIST OF LICENSES FOR REGISTERED PRODUCTS

Application of Additional Product List of a License is required when there is:

- a) Additional newly registered/ renewed products,
- b) Change in product registration details (E.g. Product name, product manufacturer, etc.), or
- c) Omission of registered products from the product list issued together with the Manufacturer's License or Import License.

When submitting the application for Additional Product List of License for Registered Products, a copy of the current Manufacturer's License/ Import License and a copy of approval letter from the Authority (The Authority's meeting result) shall be provided as supporting documents.

The application of additional list shall be submitted via the QUEST system.