

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 the License Holder's Identity Card/Passport (if foreigner). Copy of Identity Card/Passport and Type A License (wholesale) must belong to the same License Holder if the application involves Scheduled Poison A products
- c) A copy of Business License (Local Authority) for business premises
- d) A copy of Business License (Local Authority) for store (if any). All the stores must be in the same state as the business/ manufacturing premise. Exception is only for Selangor and Wilayah Persekutuan Kuala Lumpur
- e) A copy of the License Holder's Type A License (wholesale). This document is necessary if products manufactured/ imported/ wholesaled are Scheduled Poison A products or any other products that require a Pharmacist
- f) For renewal application, documents (c) to (e) together with a copy of previous Manufacturer's, Import and Wholesaler's License shall be submitted

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.

Application for Government Agencies shall be submitted using the 'Application for Licence for Registered Product for Government Agencies' form, which can be downloaded from the NPRA website.

Timeline for license approval is within 4 working days upon complete and satisfactory application. Hardcopy of license will be generated after the license has been approved. Each license is valid for one (1) year or until 31 December of the same year.

For more information on licensing, please refer to [Guideline on Application of Manufacturer's, Import and Wholesaler's Licenses for Registered Products](#), which can be downloaded from the NPRA website.

3. ADDITIONAL PRODUCT LIST OF LICENSES FOR REGISTERED PRODUCTS

Application of Additional Product List of a Manufacturer's License/ Import 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.)

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 from the Drug Control Authority (DCA) shall be provided as supporting documents.

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

Application for Government Agencies shall be submitted using the 'Application for Additional Product List of Licence for Registered Product for Government Agency' form, which can be downloaded from the NPRA website.