Ministry of Health Malaysia
National Pharmaceutical Regulatory Agency (NPRA)
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46200 Petaling Jaya, Selangor

GUIDELINE

APPLICATION OF MANUFACTURER'S LICENSE, IMPORT LICENSE AND WHOLESALER'S LICENSE FOR REGISTERED PRODUCTS

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PART A

INTRODUCTION

OBJECTIVE OF GUIDELINE

This guideline provides information to the industry and government agency intending to apply for a Manufacturer's Licence, Import Licence and Wholesaler's Licence under the Control of Drugs and Cosmetics Regulations 1984, as well as to assist applicants in understanding the application requirements and preparing complete supporting documents.

PART B

LICENSING REQUIREMENTS

LEGAL PROVISIONS

Sale of Drugs Act 1952.
Control of Drugs and Cosmetics Regulations 1984.

OBJECTIVE OF LICENSING

To regulate the activities of manufacturing, importing and wholesale dealing or supplying of products registered with the Drug Control Authority (DCA), Ministry of Health Malaysia (MOH).

LICENSE APPLICANTS

All companies involved in manufacturing, importing, wholesale or supplying registered products. Applications for the relevant licence shall be submitted before any of these activities are carried out.

METHOD OF APPLICATION

Online	Via QUEST System. Link: https://quest3plus.bpfk.gov.my/
Manual	Application Form for Manufacturer's Licence, Import Licence and Wholesaler's Licence for Registered Products (for Government Agencies only) can be downloaded from the Official Portal of the National Pharmaceutical Regulatory Agency (NPRA).

CLIENT CHARTER (LICENCE ISSUANCE TIMELINE)

Manufacturer's Licence, Import Licence and Wholesaler's Licence for Registered Products will be issued within 15 working days upon receipt of a complete application and complies with the requirements of Good Manufacturing Practice (GMP) and/ or Good Distribution Practice (GDP).

PART C

CONDITIONS PRIOR TO LICENCE APPLICATION

A. COMPANY APPLYING FOR A MANUFACTURER'S LICENSE

(i) A company registered in Malaysia.

(ii) The company shall be the Product Registration Holder (PRH) or be appointed by the PRH as the contract manufacturer for the registered product.

(iii) The product to be manufactured shall be registered with the DCA.

(iv) The company shall operate at manufacturing premises and store premises (if any) that are valid and licensed by the Local Authority (PBT).

(v) The manufacturing premises and store premises (if any) shall have been inspected and comply with the requirements of GMP and GDP.

(vi) Where scheduled poison registered products are handled, the company shall appoint a Pharmacist who holds a Type A (Wholesale) Licence issued under the Poisons Act 1952.

B. COMPANY APPLYING FOR AN IMPORT LICENSE

(i) A company registered in Malaysia.

(ii) The company shall be the PRH or be appointed by the PRH as the importer of the registered product.

(iii) The product to be imported shall be registered with the DCA.

(iv) The company shall operate at import premises and store premises (if any) that are valid and licensed by the PBT.

(v) The import premises and store premises (if any) shall comply with the requirements of GDP.

(vi) Where scheduled poison registered products are handled, the company shall appoint a pharmacist who holds a Type A (Wholesale) Licence issued under the Poisons Act 1952.

C. COMPANY APPLYING FOR WHOLESALER'S LICENSE

(i) A company registered in Malaysia.

(ii) The products to be sold by wholesale or supplied shall be registered with the DCA.

(iii) The company shall operate at wholesale premises and store premises (if any) that are valid and licensed by the PBT.

(iv) The wholesale premises and store premises (if any) shall comply with the requirements of GDP.

(v) Where scheduled poison registered products are handled, the company shall appoint a pharmacist who holds a Type A (Wholesale) Licence issued under the Poisons Act 1952.

PART D

LICENSE APPLICATION PROCEDURE

1. Licence applications shall be submitted online through the QUEST System. Applicants are required to register as QUEST System users. Information relating to registration as a QUEST System user (first time user) is available on the Official NPRA Portal.

2. Applicants shall complete the licence application form with the correct information.

3. Applicants shall upload all supporting documents required for a new licence application as listed below:

   a) A copy of Company Registration Certificate.

   b) A copy of the Licence Holder's Identity Card or Passport (for non-Malaysian citizens).
      - The copy of the Identity Card or Passport and the Type A (Wholesale) Licence shall belong to the same Licence Holder if the application involves scheduled poison registered products.

   c) A copy of the valid PBT Business Licence for the business premises (manufacturer/ importer/ wholesaler).

   d) A copy of the valid PBT Business Licence for the store premises (if any). The store premises and business premises shall be located within the same state, except for the State of Selangor and the Federal Territories of Kuala Lumpur and Putrajaya.

   e) A copy of the valid Type A (Wholesale) Licence for activities involving scheduled poison registered products.

   f) Completed **Lampiran B** (Checklist) for a new Import Licence and Wholesaler's Licence applications. Please refer to the notification letter entitled Improvement of the Import License/ Wholesaler's License Issuance Process through Evaluation and Pre-licensing Inspection. The **latest Lampiran B** can be downloaded through this link.

4. For licence renewal applications, only the supporting documents 3 (c) to 3 (e) together with a copy of the previous Manufacturer's Licence, Import Licence or Wholesaler's Licence shall be submitted. Renewal applications shall be made according to the date announced by NPRA or before the licence expires.

5. The company shall appoint two (2) responsible persons for matters relating to the licence application, one of whom shall be a Malaysian citizen and can be contacted.

6. Each license application shall be submitted with the license processing fee.

Type of License	Processing Fee
Manufacturer's License	RM1,000.00/ application
Import License	RM500.00/ application
Wholesaler's License	RM500.00/ application

Note: License processing fees are non-refundable.

7. For government agencies, licence applications shall be submitted manually and the application form (including the list of supporting documents) can be downloaded from the Official NPRA Portal. No processing fee is imposed.

PART E

LICENSE APPLICATION PROCESS

1. Each licence application shall be processed in accordance to the Licence Processing Procedure.

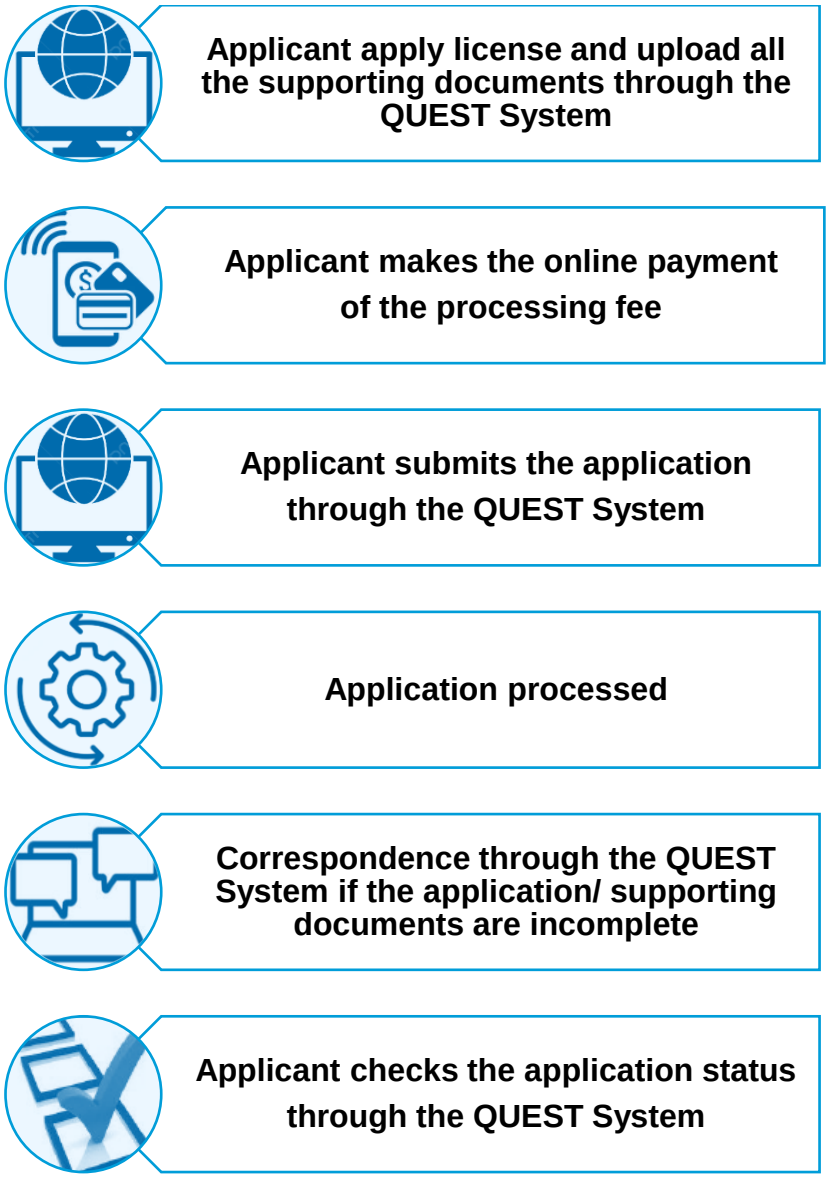
2. For incomplete application or unsatisfactory supporting documents, the applicant will be contacted and all correspondence shall be conducted through the QUEST System (and by email for government agencies). The license application may not be processed if the applicant fails to provide the feedback or additional supporting documents required.

3. The issuance of a licence shall be considered only after the application received is complete and result of evaluation and inspection status for the premise and/ or store has to be satisfactory.

4. Applicants may check the license application status through the QUEST System from time to time.

PART F

LICENSE APPLICATION FLOWCHART



PART G

ISSUANCE, REVOCATION AND CANCELLATION OF LICENSE

1. Pursuant to the Control of Drugs and Cosmetics Regulations 1984, the Director of Pharmaceutical Services has the authority to approve or reject/ refuse applications for a Manufacturer's Licence, Import Licence and Wholesaler's Licence.

2. A licence shall be issued for approved application together with the Product List (except for a Wholesaler's Licence) and the licence conditions as stipulated by the Director of Pharmaceutical Services.

3. Every licence issued shall be valid only for the company's name of the licence holder and the address as specified in the licence.

4. The license issued shall be valid for one (1) year or until 31 December of the same year or such period as specified in the license.

5. Every licence holder shall be responsible for compliance with all licence conditions imposed and any guidelines or directives issued from time to time by the Director of Pharmaceutical Services or the DCA.

6. The Director of Pharmaceutical Services may amend any licence conditions imposed and may revoke a licence at any time if the licence holder fails to comply with the prescribed conditions or regulatory requirements.

7. The company shall notify NPRA in writing for cancellation of the existing license.

PART H

CHANGE OF INFORMATION IN THE LICENSE

1. Every license issued shall only be valid for the name and address of the particular company as stated on the license.

2. Every license issued shall not be amended or transferred to another person or company.

3. The company **shall apply for a new licence** if:

   a) The company name has changed. The applicant shall ensure that the change of the company name has been updated or approved in the QUEST System.

   b) The company premises have been relocated or there is a change in the company address. The applicant shall ensure that the change of address has been updated in the QUEST System (for Manufacturer's Licence and Import Licence only).

   c) There is a change to the store premises information (name and/ or address of the store premises including any change, addition or removal of store premises information).

   d) Addition or removal of the category of scheduled poison registered products.

   e) The company did not renew the license in the previous year.

   f) The handling of Time and Temperature Sensitive Products (TTSP)
   - Addition or removal of licence conditions; or
   - Changes to the information of the TTSP store premises since the last inspection by NPRA

4. The company shall provide **Lampiran B** for Import Licence and Wholesaler's Licence applications involving any changes as listed above [3 (a) to 3 (f)].

5. The company shall notify NPRA in writing if there is a need to update the information relating to the conditions annex of a Manufacturer's Licence. However, for changes to licence conditions annex that require GMP inspection, the relevant section shall be contacted in advance.

PART I

ADDITIONAL PRODUCT LIST APPLICATION FOR MANUFACTURER'S LICENSE AND IMPORT LICENSE

1. Additional Product List Application for Manufacturer's Licence and Import Licence shall be submitted if there are:

   a) new product has been registered or the product registration has been renewed.

   b) amendment to the information of a registered product (eg: product name or product manufacturer).

2. Additional Product List Application shall be submitted online through the QUEST System or by using the manual application form for Government Agencies which can be downloaded from the Official NPRA Portal [Application Form for Additional Product List of Licence for Registered Product for Government Agency]. Applicants must complete the Application Form together with the required supporting documents which are a copy of the Manufacturer's License or Import License for the current year and a copy of the approval from DCA.

PART J

RELATED REFERENCES

1. Sale of Drugs Act 1952.
2. Control of Drugs and Cosmetics Regulations 1984.
3. Poisons Act 1952 and Regulations.
4. Drug Registration Guidance Document (DRGD).
5. Guidelines on Good Manufacturing Practice (GMP).
6. Guideline on Good Distribution Practice (GDP).
7. Frequently Asked Questions.
8. Relevant directives issued by the Director of Pharmaceutical Services, MOH or the Drug Control Authority (DCA).

PART K

INFORMATION AND ENQUIRIES

For more information regarding licence applications, please contact:

Licensing & Certification Section
Centre of Regulatory Coordination & Strategic Planning
National Pharmaceutical Regulatory Agency (NPRA)
Ministry of Health Malaysia

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