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GUIDELINE

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

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SECTION A

INTRODUCTION

OBJECTIVE AND SCOPE OF GUIDELINE

This guideline provides information to the industry regarding license requirements to carry out activities related to manufacturing, importation and supply or wholesale of products registered with the Drug Control Authority (DCA), Ministry of Health Malaysia (MOH). This guideline also explains the procedures for applications of Manufacturer's License, Import License and Wholesaler's License for registered products.

SECTION B

LICENSING REQUIREMENTS

LEGAL PROVISIONS

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

OBJECTIVE OF LICENSING

To control activities related to manufacturing, importation and sale or wholesale supply of products registered with DCA.

LICENSE APPLICANTS

All companies involved in activities related to manufacturing, importing and wholesale of products registered with DCA, MOH. Company needs to apply for a license before carrying out any manufacturing, importing and supplying or wholesale activities.

METHOD OF APPLICATION

Online	Via QUEST System. Link: https://quest3plus.bpfk.gov.my/
Manual	License Application Form for Manufacturer's License, Import License, Wholesaler's License for Registered Products (for use by Government Agencies only) and can be downloaded from NPRA's Official Portal.

CLIENT CHARTER (LICENSE APPROVAL TIMELINE)
Complete applications of license will be approved within four (4) working days.

SECTION C

CONDITIONS BEFORE APPLYING LICENSE

A. COMPANY APPLYING FOR MANUFACTURER'S LICENSE

(i) A company registered in Malaysia.

(ii) The company is a Product Registration Holder (PRH) or appointed by PRH as a contract manufacturer for registered products.

(iii) Manufactured products are registered with DCA, MOH.

(iv) Operate on premises (including store premises) that are valid and licensed by the Local Authority (PBT).

(v) Manufacturer's premises (including store premises) meet the requirements of Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP).

(vi) Appoint a Pharmacist who has a Type A Poison License (Wholesale) if handling Scheduled Poisons.

B. COMPANY APPLYING FOR IMPORT LICENSE

(i) A company registered in Malaysia.

(ii) The company is a Product Registration Holder (PRH) or appointed by PRH as an importer for registered product.

(iii) Imported products are registered with DCA, MOH.

(iv) Operate on premises (including store premises) that are valid and licensed by the Local Authority (PBT).

(v) Importer's premises (including store premises) meet all the requirements of Good Distribution Practice (GDP).

(vi) Appoint a Pharmacist who has a Type A Poison License (Wholesale) if handling Scheduled Poisons.

C. COMPANY APPLYING FOR WHOLESALER'S LICENSE

(i) A company registered in Malaysia.

(ii) Products supplied or sold by wholesale are registered with DCA, MOH.

(iii) Operate on premises (including store premises) that are valid and licensed by the Local Authority (PBT).

(iv) Wholesaler's premises (including store premises) meet all the requirements of Good Distribution Practice (GDP).

(v) Appoint a Pharmacist who has a Type A Poison License (Wholesale) if handling Scheduled Poisons.

SECTION D

LICENSE APPLICATION PROCEDURE

1. The license application shall be submitted via the QUEST System. Applicants must register as a NPRA's QUEST System User. Information related to registration as a first time user can be accessed through NPRA's Official Portal (http://www.npra.gov.my).

2. The applicant must complete the license application form with the correct information.

3. To upload all supporting documents required in the system as listed below:

   a) A copy of Company Registration Certificate.

   b) A copy of the License Holder's Identity Card or Passport (for non-Malaysian).
      - A copy of Identity Card or Passport and the Type A Poison License (Wholesale) should be from the same person if the application involves the Scheduled Poison products.

   c) A copy of valid Business License from the Local Authority for business premises.

   d) A copy of valid Business License from the Local Authority for the store (if any). Stores and business premises must be in the same state except for the state of Selangor and the Federal Territory of Kuala Lumpur & Putrajaya.

   e) A copy of valid Type A Poison License (Wholesale) for activity involves the Scheduled Poison products.

   f) Completed **Lampiran B** for new Import and Wholesaler's License application. Kindly refer to the notification letter via the link below. (https://www.npra.gov.my/easyarticles/images/users/1110/Makluman-Penambahbaikan-Proses-Pengeluaran-Lesen-Mengimport--Pemborong-2025.pdf)

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

5. The company needs to appoint two (2) responsible persons related to license applications and one of whom is a Malaysian and can be contacted.

6. Each license application must be submitted with a license processing fee.

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

Note: The license processing fee shall not be refundable.

7. For government agencies, the license application is submitted manually and the application form (including a list of supporting documents) can be downloaded from the NPRA Official Portal.

SECTION E

LICENSE APPLICATION PROCESS

1. Each license application will be processed in accordance to the License Processing Procedure.

2. For incomplete applications or unsatisfactory supporting documents, the applicant will be contacted and all correspondence will be 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. License will be issued upon receiving complete applications 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.

SECTION F

LICENSE APPLICATION FLOWCHART

Applicants apply license and upload all the supporting documents through the QUEST System

Applicants make online processing fee payment

Applicants submit the application through the QUEST System

Application processed

Correspondence through the QUEST System if the application/ supporting documents are incomplete

Applicants check the application status through the QUEST System

SECTION G

ISSUANCE, REVOCATION AND CANCELLATION OF LICENSE

1. The Director of Pharmaceutical Services, MOH may **ISSUE** any licenses or **REFUSE** any application for a licence (Manufacturer's License, Import License and Wholesaler's License).

2. A license will be issued for approved application together with the product list (except for Wholesaler's License) and license condition annex as stipulated by the Director of Pharmaceutical Services, MOH.

3. Every license issued shall be valid and only applicable to the licensee company's name and address as specified in the license.

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

5. License holder is responsible for compliance with all conditions of the license and any guidelines or directives issued from time to time by the Director of Pharmaceutical Services, MOH or the DCA.

6. The Director of Pharmaceutical Services, MOH may amend the conditions of the license imposed and may revoke the license issued at any time if the license holder fails to comply with the conditions or regulations stipulated.

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

SECTION 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 exchangeable or transferable to another person or company.

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

   a) Company name of the license holder has changed or the premise moved to another location/ change of address. The applicant needs to ensure these information changes have been updated or approved in the QUEST System.

   b) Changes of store information (store name and/ or address as well as changing or adding store).

   c) Addition or removal of Scheduled Poison product category.

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

   e) Handling of Time and Temperature-Sensitive Products (TTSP)
      - Addition/ Removal of the condition or
      - Changes in the details of TTSP stores after latest inspection by NPRA.

4. Company shall provide **Lampiran B** for the Import and Wholesaler's License application involving changes as listed above [3 (a) to 3 (e)].

5. The company shall inform NPRA if there is a need to update the information in the Manufacturer's License condition annex. However, for changes to license condition annex that require GMP inspection, the relevant section need to be contacted in advance.

SECTION I

ADDITION OF REGISTERED PRODUCTS INTO MANUFACTURER'S LICENSE AND IMPORT LICENSE

1. Manufacturer's license and import license holder can apply to add registered product(s) to the existing List of Products. Application for an additional product can be submitted if there are:

   a) new product registered or renewal of product registration.

   b) amendments to the registered product information (eg: product name, product manufacturer).

2. Applications for Additional Product List are submitted through the QUEST System or an application form that can be downloaded from the NPRA Official Portal (Application for Additional Product List of License for Registered Product for Government Agency). Applicants must complete the Application Form provided and submit 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.

SECTION J

RELATED REFERENCES

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

SECTION K

INFORMATIONS AND INQUIRIES

For more information on license 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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