Guida pratica

MALAYSIA

THE PHARMACEUTICAL INDUSTRY IN MALAYSIA

(December 2012)
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INTRODUCTION

The pharmaceutical industry is one of the new growth areas targeted for promotion and development by the Government. The products manufactured by the Malaysian pharmaceutical industry are broadly categorised into four categories, i.e. prescription medicines, over-the-counter (OTC) products, traditional medicines and health/food supplements. The pharmaceutical companies are mainly small and medium-sized companies engaged in the production of generic drugs, traditional medicines and herbal supplements as well as contract manufacturing for foreign multinational corporations (MNCs).

According to the Drug Control Authority (DCA) of the Ministry of Health, currently there are 234 pharmaceutical companies licensed by the DCA comprising 167 traditional medicine companies and 67 modern medicine companies.

Among the major local companies are Pharmaniaga Manufacturing Berhad, Hovid Berhad, CCM Duopharma Biotech Sdn Bhd, and Kotra Pharma (M) Sdn Bhd. These companies focus mainly on generic drugs, particularly antibiotics, painkillers, health supplements and injectables. Some of the foreign-owned companies with manufacturing presence in the country include Y.S.P. Industries (M) Sdn Bhd (Taiwan), Sterling Drug (M) Sdn Bhd (the manufacturing arm of GlaxoSmithKline from UK), Ranbaxy (M) Sdn Bhd (India), Xepa-Soul Pattinson (M) Sdn Bhd (Singapore) and SM Pharmaceutical Sdn Bhd (India).

The large MNCs such as Pfizer, Schering Plough, Novartis, Eli Lilly, Astra Zeneca are mainly licensed importers. Their products, which are mostly branded drugs, are distributed by locally incorporated companies.

The Malaysian pharmaceutical industry has the capability to produce almost all dosage forms, including sterile preparations such as eye preparations, injections, soft gelatine capsules and time release medications. In January 2002, Malaysia was admitted as a member of the Pharmaceutical Inspection Cooperation/Scheme (PIC/S). This would facilitate exports of Malaysian pharmaceutical products to the member countries which include EU, Australia and Canada.

Investment Opportunities

Formulation Services

A number of top products from the world’s leading pharmaceutical companies will lose patent protection in the next five years. This will result in vast opportunities for local pharmaceutical companies which have well established expertise in formulation technologies to produce the generic version of these products or to provide formulation services to overseas pharmaceutical companies that wish to produce the generic version of these products for the local and regional markets.

Formulation services would cover pre-formulation studies, product development studies, bioavailability and bioequivalence studies, clinical trials, efficacy studies, quality control and sample production. The actual production could be carried out by other pharmaceutical companies.

Contract Manufacturing

The current trend among the major global drug companies is to outsource their manufacturing operations to enable them to concentrate on time consuming and costly ‘gene hunting’ methods of R&D for new drug discovery. The pharmaceutical industry in Malaysia could capitalise on this development by manufacturing the products of these companies on contract basis. A number of local companies are keen to provide contract manufacturing services to interested parties.
Generic Drugs
Foreign pharmaceutical companies are encouraged to set up facilities in Malaysia to manufacture off-patented drugs.

Herbal Drugs
Foreign pharmaceutical companies could enter into collaborations with local companies and research institutions to produce new medicinal drugs.

Manufacturing of Active Pharmaceutical Ingredients
There is huge demand for the active ingredients to be used in the manufacturing of local pharmaceuticals as well as for export.

Other higher value-added products and services
The products include innovator drugs, vaccines, inhalation products and novel delivery systems.
REGULATORY CONTROL IN PHARMACEUTICAL INDUSTRY

Regulatory Agency

National Pharmaceutical Control Bureau (NPCB) / Biro Pengawalan Farmaseutikal Kebangsaan (BPFK)

The regulatory control of pharmaceutical products and traditional medicines in Malaysia is carried out by the National Pharmaceutical Control Bureau (NPCB), an institution under the Pharmaceutical Services Division (PSD) Ministry of Health, which ensures the quality, efficacy and safety of pharmaceutical products as well as the quality and safety of traditional medicines and cosmetics marketed in the country.

The NPCB, formerly known as the National Pharmaceutical Control Laboratory, was set up in October 1978 to implement quality control on pharmaceutical products. The infrastructure and facilities were designed to meet the requirements for testing and quality control activities.

The NPCB has in place a well-structured and comprehensive regulatory system. This system handles the registration of pharmaceutical products and traditional medicines as well as the notification of cosmetic products under the Control of Drug and Cosmetics Regulations 1984.

The introduction of these regulations in June 1984 was an important milestone in the history of drug regulatory activities in Malaysia as it provides for the establishment of the Drug Control Authority (DCA) to regulate the pharmaceutical industry. The DCA, an executive committee which is responsible for product registration and licensing of manufacturers, importers and wholesalers was established in 1985, whereby the NPCB functions as the operational arm and the secretariat to the DCA.

Since 1985, the NPCB has been given the task of ensuring the quality, efficacy and safety of pharmaceuticals through the registration and licensing scheme. This is achieved through evaluation of scientific data and laboratory tests on all products before they are marketed. A system to monitor products in the market was also setup. In addition, the Adverse Drug Reactions (ADR) monitoring program was launched in Malaysia in 1987 to carry out pharmacovigilance activities. Under the surveillance program, registered products are routinely sampled to ensure compliance with regulatory requirements.

Under the ASEAN Technical Co-operation among Developing Countries (ASEAN TCDC) Program, the NPCB has been chosen and recognised by the ASEAN countries as the regional training centre for quality control of pharmaceuticals. NPCB has been the host for various training programs in quality control and has successfully conducted such trainings since 1986. In addition, the NPCB has also been receiving trainees from ASEAN countries as well as various other countries such as Bangladesh, Iran, Sri Lanka and some African countries.

In view of the technical expertise and training capabilities of NPCB, it received the recognition as a "WHO Collaborating Centre in the Regulatory Control of Pharmaceuticals" on 10th May 1996. As a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals, the NPCB will continue to provide training in pharmaceutical quality assurance and regulatory affairs to fellows from other countries. This recognition was redesignated on 1st August 2007, for a period of 4 years.

Drug Control Authority (DCA)

The Drug Control Authority (DCA) is the executive body established under the Control of Drugs and Cosmetics Regulations 1984. The main task of this Authority is to ensure the safety, quality and efficacy of pharmaceuticals, traditional medicines, health supplements, veterinary products and personal care products that are marketed in Malaysia.
This objective is being achieved through the following:
- Registration of pharmaceutical products, natural products (traditional medicines) and veterinary products
- Control of cosmetic products via the notification process
- Licensing of premises for importers, manufacturers and wholesalers
- Monitoring the quality of registered products in the market
- Adverse Drug Reaction Monitoring

Product Registration

Introduction
The guidelines outlined in the Drug Registration Guidance Document (DRGD) primarily drawn up in accordance with the legal requirements of the Sale of Drugs Act 1952 and the Control of Drugs and Cosmetics Regulations 1984. Although the legal requirements of other related legislations have been included, applicants are reminded that it is their responsibility to ensure that their products comply with the requirements of these legislations, namely:
- Dangerous Drugs Act 1952;
- Poisons Act 1952;
- Medicine (Advertisement & Sale) Act 1956;
- Patent Act 1983; and
- any other relevant Acts.

Definition of a Product
Under the Control of Drugs and Cosmetics Regulations 1984, a ‘product’ as defined in the Regulations, means a ‘drug’ in a dosage unit or otherwise, for use wholly or mainly by being administered to one or more human beings or animals for a medicinal purpose. Under the Sale of Drugs Act 1952, ‘drug’ includes any substance, product or article intended to be used or capable, or purported or claimed to be capable of being used on humans or any animal, whether internally or externally for a medicinal purpose used in humans (and animals).

Drug Registration
- Under Regulation 7(1) of the Control of Drugs and Cosmetics Regulations 1984, no person shall manufacture, sell, supply or import any product unless the product is a registered product; and the person holds the appropriate licence issued under this regulation.
- Any ‘product’, as defined under the Control of Drugs and Cosmetics Regulations 1984, is required to be registered with the DCA.
- Medicinal purpose means any of the following purposes:
  - Alleviating, treating, curing or preventing a disease or a pathological condition, or symptoms of a disease
  - Diagnosing a disease or ascertaining the existence, degree or extent of a physiological or pathological condition;
  - Contraception;
  - Inducing anaesthesia;
  - Maintaining, modifying, preventing, restoring or interfering with, the normal operation of a physiological function;
  - Controlling body weight;
  - General maintenance or promotion of health or well-being
- The Regulations do not apply to the following products:
  - Diagnostic agents and test kits for laboratory use;
  - Non-medicated medical and contraceptive devices;
  - Non-medicated bandages, surgical dressings, plaster, dental fillings;
- Food, (as defined under Food Act 1983 and Food Regulations 1985, includes every article manufactured, sold or represented for use as food or drink for human consumption or which enters into or is used in the composition, preparation, preservation, of any food or drink and includes confectionery, chewing substances and any ingredient of such food, drink, confectionery or chewing substances. This includes food for special dietary use for persons with a specific disease, disorder or medical condition, and food which contain quantities of added nutrients allowable under the Food Act and Regulations).

- Cosmetics, (in conformance with the harmonisation of cosmetic regulations in the ASEAN region and in compliance to the ASEAN Cosmetic Directive, cosmetics are regulated via the notification process starting 1 January 2008).

- Instruments, apparatus, syringes, needles, sutures, catheters.

- Products which are not registered with the DCA and are intended to be imported for the purpose of clinical trial shall have a Clinical Trial Import Licence (CTIL).

- Products which are not registered with the DCA and are intended to be manufactured locally for the purpose of clinical trial should apply for exemption by the DCA (Clinical Trial Exemption) from the provisions of Regulation 7(1) of the Control of Drugs and Cosmetics Regulations 1984.

- Any person who wishes to manufacture any product solely for the purpose of producing a sample for the sole purpose of registration should apply for an exemption for manufacture of sample (Applies to locally manufactured products only).
New Application Processing Procedures

A. Application Type

<table>
<thead>
<tr>
<th>Application for a new product registration may be categorised as follows:</th>
</tr>
</thead>
<tbody>
<tr>
<td>i. Application for an innovator product (NCE/Biotech)</td>
</tr>
<tr>
<td>ii. Application for a generic product (Controlled Poisons &amp; Non-Controlled Poisons)</td>
</tr>
<tr>
<td>[a generic product is a product that is essentially similar to a currently registered product in Malaysia. The term generic is not applicable to biological and biotech products]</td>
</tr>
<tr>
<td>iii. Application for product registration via the abridged procedure (for certain categories of OTC products and traditional medicines)</td>
</tr>
</tbody>
</table>

B. Data Requirements

<table>
<thead>
<tr>
<th>The data required to support an application is divided into:</th>
</tr>
</thead>
<tbody>
<tr>
<td>i. Administrative data (Part I)</td>
</tr>
<tr>
<td>ii. Data to support product quality (Part II)</td>
</tr>
<tr>
<td>iii. Data to support product safety (Part III)</td>
</tr>
<tr>
<td>iv. Data to support product efficacy (Part IV)</td>
</tr>
</tbody>
</table>

Applicants are advised to read the explanatory notes in Section 2 of Drug Registration Guidance Document, and also the relevant ASEAN or ICH Guidelines (www.ich.org) and checklists, for full information on product data requirement. The DCA may request for supplementary information.

C. Data Submission

<table>
<thead>
<tr>
<th>Data to be submitted will be based on the application type:</th>
</tr>
</thead>
<tbody>
<tr>
<td>i. Innovator product – Parts I to IV (For existing chemical or biological entity(s) in a new dosage form, only Parts I and II, together with pharmacokinetic data will be required)</td>
</tr>
<tr>
<td>ii. Generic product – Parts I &amp; II only</td>
</tr>
<tr>
<td>iii. Abridged procedure – Part I only</td>
</tr>
</tbody>
</table>

The applicant should make available the requested information within the specified period. Failure to do so may result in the rejection of the application.

Application Formalities

The DCA accepts only web-based online submission using Quest 2* via www.bpfk.gov.my except for products categorised as new chemical entity (NCE) and biotech. The applicant must be a locally incorporated company with a permanent address. The applicant (if the said company is not the product owner) should be authorised in writing by the product owner to be the holder of the product registration certificate and be responsible for all matters pertaining to the registration of the product.

a. Responsibility of Marketing Authorisation Holder
   (i.e. the applicant for product registration)

- The applicant shall be responsible for the product and all information supplied in support of his application. He shall be responsible for updating any information relevant to the product/application during the course of evaluation and after product registration.
• Any person who knowingly supplies any false or misleading information in connection with his application commits an offence under the Control of Drugs and Cosmetics Regulations 1984. The applicant is responsible for the quality, safety and efficacy of his products.

b. Application Fee

Every application for registration shall incur a processing fee:

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Processing Fee</th>
<th>Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traditional Product/ Traditional Health Supplement</td>
<td>RM500.00 (each product)</td>
<td>RM700.00 for laboratory tests</td>
</tr>
<tr>
<td>Pharmaceutical Product/ Pharmaceutical Health Supplement</td>
<td>RM1000.00</td>
<td>RM1200.00 (1 active ingredient) or RM2000.00 (&gt;1 active ingredient) as fee for analytical validation evaluation method</td>
</tr>
<tr>
<td>New Chemical Entities/Biotech</td>
<td>RM1000.00</td>
<td>RM3000.00 (1 active ingredient) or RM4000.00 (&gt;1 active ingredient) as fee for analytical validation evaluation method</td>
</tr>
<tr>
<td>Veterinary Product</td>
<td>RM1500.00 (each poison / OTC product, inclusive of laboratory tests)</td>
<td>Not applicable</td>
</tr>
<tr>
<td></td>
<td>RM1200.00 (each natural product, inclusive of laboratory tests)</td>
<td></td>
</tr>
<tr>
<td>Cosmetic Product</td>
<td>RM50.00 (each product)</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

* The DCA will charge the applicant such costs as it may incur for the purpose of carrying out laboratory investigation relating to the registration of any product. (Any payment made is not refundable once an application has been submitted and payment confirmed)

** Exchange rate EUR 1 = RM 3.9

c. Accompanying Documents

i) The following documents are to be submitted together with the application:
   • Authorisation from the product owner
• Letters of authorisation of contract manufacture and acceptance as well as from the manufacturer and also each sub-contractor, where a product is contract manufactured, if applicable (e.g. repacker).

ii) The letter of authorisation or acceptance from the manufacturer should be on the product owner’s original letterhead and be dated and signed by the Managing Director, President, CEO or an equivalent person who has overall responsibility for the company or organisation.

iii) The letters should state the name of the product concerned, name and actual plant address of the manufacturer(s) involved in the manufacture of the product.

iv) Imported products will also need to be accompanied with either:
• Certificate of Pharmaceutical Product (CPP) from the competent authority in the country of origin; OR
• Certification for Free Sales (CFS) and Good Manufacturing Practice (GMP) from the relevant authorities for the following groups of products:
  - Traditional medicines and dietary supplements;
  - External personal care products for medicinal purpose i.e. acne, antidandruff
  - Oral care, antibacterial soaps, talc and skin protectants.

Application Process

a. Initiation of Review

Review of applications will follow a queue system. There will be separate queues for the different categories of products:

- New Chemical Entity (NCE)
- Biotech
- Generics (full evaluation procedure)
- Abridged Evaluation Procedure Pharmaceuticals (OTC, Health supplements)
- Traditional Products

b. Stop Clock

The clock starts once payment has been confirmed for a submitted application and will stop whenever NPCB needs to seek further information from the applicant. The clock restarts when NPCB receives complete responses from the applicant. A period of four (4) months will be given within which the applicant should submit the additional information required by NPCB. The clock stops when DCA informs the applicant of its regulatory decision. An application will be closed if the time taken by the applicant to respond to enquiries exceeds 6 months after issuance of 2 reminders, and a new application will need to be submitted if the applicant wishes to pursue registration for the product in question.

c. Time Frame

The time frame for registration of products excludes stop-clock time.

<table>
<thead>
<tr>
<th>Full Evaluation</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription Drugs (Poison)</td>
<td>12 months</td>
</tr>
<tr>
<td>Non-prescription (Non-poison) Drugs</td>
<td>12 months</td>
</tr>
<tr>
<td>NCE</td>
<td>12 months</td>
</tr>
</tbody>
</table>
Abridged Evaluation

<table>
<thead>
<tr>
<th>Product</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-prescription (Non-poison) Drugs</td>
<td>6 months</td>
</tr>
<tr>
<td>Health Supplement Products</td>
<td>6 months</td>
</tr>
<tr>
<td>Natural Products (Traditional)</td>
<td>6 months</td>
</tr>
<tr>
<td>Cosmetic Products (Notification Note)</td>
<td>3 days</td>
</tr>
</tbody>
</table>

- The time frame for each product is calculated from the date of final and complete submission.
- Priority review may be granted where the product is intended for treatment of a serious or life-threatening disease (where the likelihood of death is high unless the course of the disease is interrupted).

**Regulatory Outcome**

a. Decisions of the DCA

An application may be approved or rejected and the DCA decision will be sent via e-mail to the marketing authorisation holder.

b. Product Registration Number

- A Registration Number, which is specific for the product registered, will be given via e-mail when an application is approved by the DCA. Registration is valid for a period of 5 years.
- Product Notification Number will be given to a cosmetic product after the notification process.

c. Rejection, Cancellation, Suspension of Registration

The DCA may reject, cancel or suspend the registration of any product if there are deficiencies in safety, quality or efficacy of the product or failure to comply with conditions of registration.

d. Appeal against DCA decisions

Any applicant aggrieved by the decisions of the DCA may make a written appeal to the Minister of Health. Appeals MUST be made within fourteen days from the date of the DCA notification. A period of 180 days from the date of appeal is given for submission of any supporting data or documents for NCE and biotechnology products and 90 days for other products. The appeal is closed if all the required information is not submitted within the stated time given.

e. Decision of the Minister

The decision made on any appeal is final.
Registration Maintenance

a. Conditions for Registration

The affixing of the security device, one of the conditions for product registration, to product labelling has been identified as a means to verify and authenticate that the product has been duly registered with the DCA.

The DCA may specify certain conditions for registration for a particular group, amend any conditions for registration and may lay down specific product labelling requirements.

The DCA may cancel the registration of any product if the conditions for registration are not complied with.

b. Validity Period

The registration of a product is valid for 5 years or such period as specified in the registration certificate.

For cosmetic products, the Notification Note is valid for 2 years or such period as specified in the Notification Note.

Renewal of product registration should be done six months prior to the expiry of the validity period of product registration. Upon expiry of the validity period of registration, the module for renewal of product registration will no longer be accessible and application for re-registration of the product can no longer be submitted.

c. Change In Particulars of Registered Products

Changes in particulars of a Registered product require DCA approval. Changes refer to any changes in product name, product specifications, packing, indications, contents of product label, package insert, or product literature, or any relevant particulars of the registered product.

• Any changes in excipients, such as change in lubricant, preservative, solvent in film coating, etc to improve product formulation requires prior approval of the DCA.
• Explanation/reason for the changes should be given. All relevant supporting data related to the above changes should be updated accordingly.
• The registration of a product may be cancelled if changes are made without prior approval of the DCA.
• The marketing authorisation holder must ensure that all the necessary validation has been conducted to demonstrate that the change does not reduce the quality, safety or efficacy of the product and submit all necessary documents.

d. Reporting Problems with Registered Products

i. Adverse Drug Reactions (ADR)

• The Malaysian Adverse Drug Reactions Advisory Committee (MADRAC), sub committee of the DCA, reviews Malaysian reports of ADR.
• The marketing authorisation holder should inform the DCA of any ADR to the product as the product registration can be cancelled if the marketing authorisation holder fails to inform the DCA of any serious adverse reactions upon receipt of such reports.
• All labels and package inserts must be amended to include any new ADR, warning, precautions, etc. within the time frame given by the DCA.

ii. Market Surveillance of Registered Products
Samples of registered products may be tested for compliance with standards or specifications and if they fail to meet adequate specifications, the marketing authorisation holder will be issued a warning and has up to 30 days to identify the source of quality defect(s) and actions taken to improve quality unless the failure is serious enough to justify recall of the product.

iii. Product Complaints
- The market authorisation holder should notify the DCA of any product quality related problems that the holder is aware of.
- Complaints submitted to the DCA by health care professionals, consumers, and patients will be investigated. Based on the outcome of these investigations, appropriate action will be taken which may include product/batch recalls, cancellation/suspension of product registrations or other regulatory action as deemed necessary.

iv. Product Recalls
- Recalls of unsafe/defective products are instituted by the DCA, if deemed necessary, and the marketing authorisation holder is responsible for conducting recalls of these products after informing/consulting the DCA.

e. Termination of Registration by Marketing Authorisation Holder
The marketing authorisation holder shall inform the DCA of decision to terminate the registration of a product before the end of the validity of such registration and surrender the product registration certificate immediately to the DCA.

f. Change in Manufacturing Site
- Applies to change of manufacturing site for part or all of the manufacturing process of the product but does not cover changes related to a new site where only batch release takes place or to a new packager as these changes are covered under applications for amendments to the particulars of a registered product (variation).
- The new manufacturing site should comply with the current Good Manufacturing Practice (GMP). Local manufacturing sites are subjected to pre-licensing inspections and for sites outside Malaysia, certification by a competent authority is sufficient. However, the DCA reserves the right to conduct an inspection on any manufacturing site.
- This procedure is applicable for:
  - Change in the manufacturing site for the same company, including rationalisation in the event of mergers; and
  - Where a company which previously contracts out the manufacture of its product transfers the manufacture to its own premises
- A change in manufacturing site between contract manufacturers is not routinely allowed but may be considered in a crisis situation.
- There are 5 different types of site change, hence require different sets of accompanying documents.
  - **Type I : Change of Manufacturing Site Within Malaysia**
    The equipment, standard operating procedures (SOP’s), environmental conditions and controls remain the same.
  - **Type II : Change of Manufacturing Site from Foreign Country to Malaysia**
    The equipment, SOP’s, environmental conditions remain the same.
  - **Type III : Change of Manufacturing Site Located Outside Malaysia**
    The equipment, SOP’s and environmental conditions the same.
  - **Type IV : Change of Manufacturing Site for Special Category Products**
    The categories of products can be found in www.bpfk.gov.my, in Drug Registration Guidance Document.
Type V: Crisis Situation
Change in location is deemed necessary due to certain circumstances, such as natural disasters, closure, or suspension of premise and matters related to breach of product quality, safety and efficacy. This may involve a new manufacturer.

g. Other Information

i) Products for Export Only
- The DCA may register the following locally manufactured products for export only:
  - Product(s) registered by the DCA but sold in a different colour (formulation), shape and strength;
  - Products which contain ingredients not allowed by the DCA for local use (terms and conditions apply), provided that confirmation in writing is obtained from the competent authority of the importing country that there is no objection to the importation and sale of the formulation in question. Evidence of registration of solid formulation with the competent authority in importing country may be accepted as supporting data.
- If there is no change in the formulation or appearance of the product, registration for export purposes is not necessary.
- An "export notification" procedure allows an applicant to apply for Free Sale Certification (CFS) of the product whereby the applicant need to declare to the DCA the differences in the product for export compared to the registered product marketed in Malaysia.
- A Certificate of Pharmaceutical Product will be issued to the applicant for the registered product.

ii) Combination Packs
- Products which are packed together in combination for a therapeutic regimen can be registered as a single product.
- Where the combination pack product consists of registered and unregistered products, the unregistered product needs to be registered before submitting the registration application for the combination pack.
- Where the combination pack consists of registered products which are sourced from different product owners, letters of authorisation from the product owners shall be submitted, together with the following product details:
  - Product Name;
  - Product Registration Number.

iii) Use of HALAL logo
The use of HALAL logo on the labels of pharmaceutical products will not be allowed except for traditional products, dietary supplements and also cosmetics provided that such products have been certified and approved as HALAL by Department of Islamic Development Malaysia (JAKIM)

iv) Product Labelling, Bioequivalence, New/Additional Indication
Please refer to the Drug Registration Guidance Document in NPCB website for details.

Online Registration System

Quest 2 is an online submission system for the product licence holder to conduct secured online transactions on registration, change request, market sampling, renewal and other transactions

<table>
<thead>
<tr>
<th>Quest 2 Customer Support Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>603-78835400</td>
</tr>
<tr>
<td>extension: 5560/ 5561/ 5562/ 5563</td>
</tr>
</tbody>
</table>
Quest 2

Online Membership Registration

Log on [www.bpfk.gov.my](http://www.bpfk.gov.my) and select Quest 2

Click on the “First Time User” menu to register your membership.

The membership registration form requires you to upload the following scan images/pictures (in JPEG or PDF format) as follows:
- Company Registration Form with the Malaysian Registration of Companies (R.O.C)
- Company Authorisation Letter for you to conduct transaction on behalf of the company
- Identity Card (front only)

NPCB offers three types of packages varying in terms of length of validity (either one or two years). The cost varies from RM145 – RM375

You should also purchase User Digital Certificate that comes in Smart Card System. All payments for the SMART CARD and DIGITAL CERTIFICATE are payable to DIGICERT SDN BHD. Payments can be made by money order, postal order or company’s cheque.

Once you have completed your membership registration and purchased your User Digital Certificate and Smart Card System, please take note following:
- Your password to log on to the system will be sent to your email at the email address specified in the membership registration form
- Your Digital Certificate and Smart Card System will be sent/mailed to you by POSLAJU at the company address given in the membership registration form (within 7 working days)
Licence Issued for Registered Products

NPCB processes the application and issues the following licences:

- Manufacturer’s Licence (Form BPFK-426.3_LK)
- Importer’s Licence (Form BPFK-424.3_LK)
- Wholesaler’s Licence (Form BPFK-422.3_LK)

Registration Fees

The registration fees for the application for the various licences are as follows:

<table>
<thead>
<tr>
<th>Licence</th>
<th>Registration Fee</th>
<th>Timeline</th>
<th>Validity</th>
<th>Renew Before</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer’s Licence</td>
<td>RM1000</td>
<td>1 month</td>
<td>1 year</td>
<td>December</td>
</tr>
<tr>
<td>Importer’s Licence</td>
<td>RM500</td>
<td>1 month</td>
<td>1 year</td>
<td>December</td>
</tr>
<tr>
<td>Wholesaler’s Licence</td>
<td>RM500</td>
<td>1 month</td>
<td>1 year</td>
<td>June</td>
</tr>
</tbody>
</table>

**Exchange rate EUR 1 = RM 3.9**

Licence Application

The Application for the above licences can be submitted manually or online through the NPCB QUEST 2 Online Submission System. Application forms must be accompanied with the following documents:

i) New Application:
- Organisation chart of the company (including names of the staff)
- Premises location plan (A4 size)
- Floor plan for premises (A4 size)
- List of storage facilities
- Products recall procedure
- List of other products (non-registered products) stored in the same premises
- Copy of Registration of Company (ROC) or Registration of Business (ROB) certificate
- Copy of Business Licence (Issued by the State Local Authority)
- Copy of identity card of applicant/licence holder
- Copy of Retention of Pharmacist Certificate*
- Copy of Annual Registration Certificate*
- Copy of Type A Licence*

ii) Application Renewal:
- Copy of Business Licence (Issued by the State Local Authority)
- Copy of identity card of applicant/licence holder
- Copy of Type A Licence*
- Copy of previous licence

*Note: If applicant is a registered pharmacist
Manufacturer’s Licence Application Procedures

The layout plan must be submitted to the Centre for Compliance and Licensing of National Pharmaceutical Control Bureau for evaluation. At the same time, an applicant may register the company with SSM.

The layout plan and design shall fulfil the following:

- Premise should be of suitable size, design, construction and its location.
- Have sufficient working area for the placement of equipment or machines and other materials for operational purposes.
- Able to avoid cross over between material flow personnel flow, and storage of materials.
- Once the plan has been approved, applicant shall seek additional advice/ approval from the Fire Department and Department of Environmental prior to construction.
- Applicant shall prepare a complete documentation system that comprises of directions, explanations, specifications and records pertaining to the operation.
- Once the construction of manufacturing facilities is completed, the applicant shall seek an appointment with the GMP auditor to inspect the premise for pre-licensing purpose.
- The report of the findings will be delivered 14 days after the date of inspection and Letter of Confirmation (LOC) will be issued by the Centre for Compliance and Licensing once approved.
- Once product has been registered applicant may apply for manufacturer’s licence.
- Applicant may also apply for business licence from the Local State Authority.
- During product registration, if the Centre for Product Registration requires samples for testing purposes, applicant may write an official letter to permit the manufacturing of that particular product.
- Application will only be processed once payment has been made to the Centre for Administration.
- Once approved, the manufacturer’s licence can be collected from Centre for Compliance And Licensing or it will be posted to the manufacturing address.

Bioavailability and Bioequivalence Study for Pharmaceutical Products

Introduction

Bioavailability (BA) testing of drug products in humans provides the most appropriate method available for determining bioequivalence. Demonstration of bioequivalence (BE) is generally the most appropriate method of substantiating therapeutic equivalence between medicinal products.

Bioavailability:

Bioavailability means the rate and extent to which the active substance or therapeutic moiety is absorbed from a pharmaceutical form and becomes available at the site of action.

Bioequivalence:

Two medicinal products are bioequivalent if they are pharmaceutical equivalents or alternatives and if their bioavailabilities (rate and extent) after administration in the same molar dose are similar to such degree that their effects, with respect to both efficacy and safety, will be essentially the same.
Generic Product List and Guidelines for Bioequivalence Studies

A list of drug substances which, when formulated in oral solid dosage forms, require BE data as a prerequisite for registration, has been established by the DCA. The list and guidelines can be found in the NPCB website at www.bpfk.gov.my.