MALAYSIA’S PHARMACEUTICAL INDUSTRY: A FAST-GROWING FORCE
GEARED FOR MOVING UP THE VALUE CHAIN
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Taking a thematic approach in addressing the COVID-19 pandemic and its impact on the economy and society, the Malaysian Government, under the 12th Malaysia Plan (12MP), is focusing on the revitalisation of the healthcare system. This endeavour includes supporting growth along the pharmaceutical value chain through the production of high value-added and complex products and an educated workforce. It also involves encouraging efforts to increase domestic investment in the pharmaceutical industry through commercialisation of research and development (R&D) projects.

The Malaysian Government values the pharmaceutical industry as a catalytic industry and has the relevant policies and regulations to support its growth under the Industry4WRD framework, including ensuring that policies will be reviewed and roadmaps developed to cater to changing market and technological trends.

Malaysia is a regional manufacturing hub with a growing and vibrant services sector. The 12MP builds on the nation’s solid economic fundamentals and history of facilitating fundamental and history of facilitating investments to push for restructuring and new priorities towards economic sustainability. The role of the pharmaceutical industry is critical in this push as increasing the preparedness of the healthcare sector has become a priority in the wake of the pandemic. Towards this end, the Malaysian Government is prioritising the strengthening of the healthcare system with better pharmaceutical services, including securing sufficient medical supply and its distribution to all healthcare facilities.

Government spending on healthcare is expected to increase with the growing GDP. As of December 2019, the Malaysian Government allocated RM34.2 billion under its 2022 Budget for healthcare, with specific funding for vaccines, personal protective equipment and consumables for managing the COVID-19 pandemic. Government spending on healthcare is expected to increase with a growing population, longer life expectancy as well as the commitment to provide better healthcare facilities and services.

A POWER DUO-TIER HEALTHCARE SYSTEM

Malaysia has a two-tier healthcare system comprising a tax-funded public healthcare sector providing universal healthcare and a thriving private healthcare sector. Both sectors co-exist at the primary, secondary and tertiary levels of the healthcare system enabling the delivery of pharmaceutical products, including originator, generic and over-the-counter (OTC) medicines, to the public. The federal Government has allocated RM4.2 billion under its 2022 Budget for healthcare, with specific funding for vaccines, personal protective equipment and consumables for managing the COVID-19 pandemic. Government spending on healthcare is expected to increase with a growing population, longer life expectancy as well as the commitment to provide better healthcare facilities and services.
The pharmaceutical industry in Malaysia has seen steady growth for a decade and has been identified as a key growth area. The industry is regulated by the National Pharmaceutical Regulatory Agency (NPRA), which is under the purview of the MOH. Under the NPRA is the Drug Control Authority (DCA), whose main task is to ensure the safety, quality and efficacy of pharmaceuticals, and health and personal care products that are marketed in Malaysia.

Products manufactured by the industry include new drug products, biologics, generics (prescription and OTC products), traditional medicines, and health and food supplements. Domestic pharmaceutical companies produce generic drugs, traditional medicines and herbal supplements as well as contract manufacturers for foreign multinational corporations (MNCs). Whether producing for their own brands or for MNCs, industry manufacturers have the capability and capacity to produce all dosage forms, including sterile preparations such as eye preparations, injections, soft gelatine capsules and time release medications.

There are more than 269 licensed pharmaceutical manufacturers, of which 179 or 66.54 per cent produce traditional medicine and health supplements; 78 or 29 per cent are producers of pharmaceuticals and; 12 or 4.4 per cent manufacture veterinary products. Among the major domestic pharmaceutical companies are Pharmaniaga Manufacturing Berhad, Duopharma Biotech Berhad, Ktara Pharma (M) Sdn. Bhd. and Hovid Berhad. These companies focus mainly on generic drugs, particularly antibiotics, painkillers, health supplements and injectables.

MNCs with a manufacturing presence in the country include Biocon Sdn. Bhd. (part of India’s Biocon Ltd.), Oncogen Pharma (Malaysia) Sdn. Bhd., Y.S.P. Industries (M) Sdn. Bhd. (Taiwan), Sterling Drug (M) Sdn. Bhd. (the manufacturing arm of the UK’s GlaxoSmithKline plc), Ranbaxy (M) Sdn. Bhd. (part of India’s Sun Pharmaceutical Industries Ltd.), Xepa-Soul Pattinson (M) Sdn. Bhd. (Singapore) and SM Pharmaceutical Sdn. Bhd. (India). The prominent players in the global pharmaceutical industry function mainly as licensed importers, and distribute their branded drugs through locally incorporated companies. These companies include US-based Pfizer Inc, Schering-Plough, Eli Lilly & Co, the UK’s AstraZeneca plc, and Switzerland’s Novartis International AG.

Pharmaceutical products manufactured in Malaysia are sold to EU member countries, Australia and Canada, with Malaysia admitted as the 26th member of the Pharmaceutical Inspection Cooperation/Scheme (PIC/S) in January 2022. PIC/S ensures member countries conform to good manufacturing practices and guidelines and mutually recognise the inspection standards of members.
INVESTMENT OPPORTUNITIES

BIOPHARMACEUTICALS / BIOGENERICs (BIOSIMILARS)
The Malaysian Government is focusing on investors who want to move up the value-chain in biosimilars as the country has the ecosystem to be a cost-competitive location and offers a good value proposition. Currently, domestic and foreign biopharmaceutical companies are already engaged in activities like biopharmaceutical (APIs), FDA/EMEA cGMP compliant services, specialising in monoclonal antibodies and recombinant proteins, and there is also ongoing R&D for the commercialisation of biopharmaceutical products. The potential expansion of biosimilars is expected to have major implications for biopharmaceuticals, which are considerably more expensive than conventional medication while the impact of biosimilars to the biopharmaceutical industry will be even greater than the impact of generics to the pharmaceutical industry.

MANUFACTURING OF ACTIVE PHARMACEUTICAL INGREDIENTS (API)
There is a huge demand for the use of API in the manufacturing of local pharmaceuticals as well as for export.

PRODUCTS AND SERVICES
The products include innovator drugs, vaccines, biopharmaceuticals, inhalation products, drug discovery activities or new chemical entities (NCE) and novel delivery systems.

CONTRACT MANUFACTURING
The Malaysian pharmaceutical industry is interested to provide contract manufacturing services for the major foreign MNCs who have been outsourcing manufacturing operations to enable them to concentrate on time-consuming and costly 'gene-hunting' methods of R&D for new drugs discovery.

GENERIC DRUGS
Foreign pharmaceutical companies are encouraged to set up facilities in Malaysia to manufacture off-patented drugs.

HERBAL MEDICINES
There is wide interest among Malaysian pharmaceutical companies to collaborate with foreign pharmaceutical companies and research institutions to produce new medicinal drugs.

WHY MALAYSIA

Supportive Government Policies
- Pro-business policies
- Responsive government
- Liberal investment policies
- Attractive tax and other incentives
- Liberal exchange control regime
- Intellectual property protection

Vibrant Business Environment
- Market-oriented economy
- Well-developed financial and banking sector, including the Labuan International Financial Exchange
- Wide use of English, especially in business, legal and accounting practices based on the British system
- Large local business community with a long history in international business links
- Large foreign business community in all business sectors
- Extensive trade links - country’s total trade was valued at RM1.8 trillion in 2019

Developed Infrastructure
- Network of well-maintained highways and railways
- Well-equipped seaports and airports
- High-quality telecommunications network and services
- Fully developed industrial parks, including free industrial zones, technology parks and the Multimedia Super Corridor (MSC)
- Advanced MSC Malaysia Cybercities and Cybercentres

Educated Workforce
- Talented, young, educated and productive workforce
- Multilingual workforce speaking two or three languages, including English
- Comprehensive system of vocational and industrial training, including advanced skills training
- Harmonious industrial relations with minimal trade disputes

Quality of Life
- Friendly and hospitable Malaysians
- Safe and comfortable living environment
- Excellent housing, modern amenities, good healthcare and medical facilities
- Excellent educational institutions including international schools for expatriate children
- World-class recreational and sports facilities
- Excellent shopping with goods from all over the world

Malaysia’s Pharmaceutical Industry: A Fast-Growing Force
APPLICATION FOR THE REGISTRATION OF A FOREIGN COMPANY UNDER SECTION 562 OF THE ACT:

a) WITH SHARE CAPITAL
   i. not more than RM 1,000,000.00 5,000
   ii. exceeding RM 1,000,000.00 but not exceeding RM 10,000,000.00 20,000
   iii. exceeding RM 10,000,000.00 but not exceeding RM 50,000,000.00 40,000
   iv. exceeding RM 50,000,000.00 but not exceeding RM 100,000,000.00 60,000
   v. exceeding RM 100,000,000.00 70,000
b) WITHOUT SHARE CAPITAL 70,000

For the full range of fees, please visit www.ssm.com.my

Source: Companies Act 2016 (Act 777)

Malaysia’s Pharmaceutical Industry: A Fast-Growing Force

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b) WITHOUT SHARE CAPITAL 70,000

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Source: Companies Act 2016 (Act 777)
Available infrastructure support

Efficient logistics and world-class infrastructure

Malaysia’s network of roads, highways, seaports and airports together with the entire logistics supply chain is the backbone of the economy. This well-developed and efficient system is constantly being upgraded to ensure that goods, including pharmaceutical products, can reach markets across the world. The Malaysian Government is also pushing the rollout of 5G through the nation’s telecommunications network to enable the smooth operation of technologies of the Fourth Industrial Revolution.

availability of industrial estates and specialised parks

The diversified manufacturing sector is spread across the country, with the well-developed infrastructure ensuring that operations are smooth and efficient. Industrial estates and parks as well as the Free Industrial Zones (FIZs) are there to cater to the needs of export-oriented industries such as the pharmaceutical industry. Businesses located in the FIZs have certain incentives such as duty-free imports of raw materials, components, parts, machinery and equipment that are directly required in the manufacturing process. Where FIZs are not available, businesses can set up Licensed Manufacturing Warehouses (LMWs).

The Malaysian Government has long emphasised the need to move up the value chain and have set up fully integrated specialised parks with state-of-the-art infrastructure to cater to the needs of specific industries that focus on technology as well as R&D. Examples of these parks are the Technology Park Malaysia in Bukit Jalil, Kuala Lumpur and the Kulim Hi-Tech Park in the northern state of Kedah.

For further information on Bio-XCell, visit www.bio-xcell.my

For further information on Penang Science Park, visit www.pdc.gov.my

Other specialised parks developed by Malaysian government agencies are as follows:

Bio-XCell Malaysia

Bio-XCell is a premier biotechnology park and ecosystem dedicated to healthcare and industrial biotechnology developed by Malaysian Bio-XCell Sdn. Bhd. (a joint venture company formed between Bioeconomy Corporation and UEM Land Berhad).

Bio-XCell is strategically located on 160 acres in Nusajaya, within the Iskandar region of Johor, Malaysia, and close to the border with Singapore, providing global connectivity through a network of five seaports and two international airports, all within a 59 km radius. Bio-XCell offers an environment conducive for the development and manufacturing of biopharmaceuticals, bio-based/green chemicals and other solutions to heal, fuel and green the world. As a managed park, Bio-XCell provides its clients and investors with a range of value-added benefits including comprehensive infrastructure, high-speed internet access, strong commercial and business services, and core facilities to nurture the ecosystem.

For further information on Bio-XCell, visit www.bio-xcell.my

Enstek

Located within the township of Bandar Enstek, techpark@enstek is just 10 minutes away from Kuala Lumpur International Airport (KLIA) and only 58 minutes from downtown Kuala Lumpur via the Express Rail Link (ERL).

Bandar Enstek consists of 4 main components, a residential area, a technology land park, a commercial hub and institutional zones. techpark@enstek is envisaged to become a world-class technology hub catering to the needs of high technology and eco-conscious industries such as biotechnology, green technology and information technology (ICT) industries. It is also equipped with ready infrastructure and amenities to support such sectors.

For further information on Penang Science Park, visit www.pdc.gov.my

Penang Science Park

The Penang Science Park is designed with good infrastructure and amenities to cater for strategic industries such as high technology, biotechnology, halal industries and SME park.

Facilities / centres

<table>
<thead>
<tr>
<th>Distance / Driving Time</th>
<th>Penang Science Park</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penang International Airport</td>
<td>49 km (40 minutes)</td>
</tr>
<tr>
<td>Penang Port (Bentong)</td>
<td>25 km (20 minutes)</td>
</tr>
<tr>
<td>Butterworth</td>
<td>19 km (20 minutes)</td>
</tr>
<tr>
<td>Seberang Jaya</td>
<td>19 km (15 minutes)</td>
</tr>
<tr>
<td>Batu Kawan (new township)</td>
<td>5 km (5 minutes)</td>
</tr>
<tr>
<td>University Science Malaysia</td>
<td>10 km (15 minutes)</td>
</tr>
<tr>
<td>Singapore</td>
<td>within the park</td>
</tr>
</tbody>
</table>

For further information on Penang Science Park, visit www.pdc.gov.my
Meanwhile, the public sector complements these efforts with private entities also carrying out clinical trials. They include:

- Infokinetics Research Centre Sdn. Bhd.
- International Medical University
- NCI Hospital
- Sunway Medical Centre
- Mahkota Medical Centre
- Lam Wah Ee Hospital
- Mount Miriam Cancer Hospital
- Gleneagles Medical Centre
- Columbia Asia Medical Centre
- Island Hospital
- Penang Adventist Hospital
- Pantai Hospital Penang
- Loh Guan Lye Specialist Centre
- Monash University Sunway Campus & Johor Bahru Campus

**BIOEQUIVALENCE CENTRES**


For further information on CRC and BE centres in Malaysia, visit [www.crc.gov.my](http://www.crc.gov.my) and [www.clinicalresearch.my](http://www.clinicalresearch.my).

**KULIM HI-TECH PARK (KHTP)**

The Kulim Hi-Tech Park (KHTP), officially opened in 1996, is the first Hi-Tech Park in Malaysia. The KHTP is situated in the district of Kulim, in the state of Kedah, in the north-west of Peninsular Malaysia. With more than 4,400 acres already developed, the KHTP is expanding further to encompass another 7,000 acres and more to cater to growing industry demands, well-supported by connectivity to an integrated world-class infrastructure.

Right from the onset, the development of the KHTP incorporated five elements or Zones, namely:

- Industrial;
- Amenities;
- Housing;
- Urban; and
- Institutional.

For further information on the Kulim Hi-Tech Park, visit [www.khtp.com.my](http://www.khtp.com.my).

**AVAILABILITY OF CLINICAL TRIALS AND BIOEQUIVALENCE CENTRES**

To date, there have been 220 study sites in Malaysia that have conducted sponsored research, with 66 per cent of them consisting of public hospitals and government clinics within the MOH. Many of these sites have performed and delivered research to the quality and standards as per Good Clinical Practice (GCP) guidelines. (Clinical Research Malaysia Annual Report 2021).

Companies manufacturing pharmaceutical products with shareholders’ funds of RM2.5 million and above or engaging 75 or more full-time paid employees must apply for a Manufacturing Licence from MITI as required by the Industrial Co-ordination Act 1975 (ICA).

In 2021, a total of seven projects were approved, with investments amounting up to RM419,451,013.00. Of this figure, four were new projects with investments totalling up to RM110,324,013.00 (26.3%) while three were expansion/diversification projects, with investments totalling up to RM309,127,000.00 (73.7%). Of the total investment amount, foreign investments accounted for 9.25 per cent (RM38,793,504.00) while domestic investments made up the remaining 90.75 per cent (RM380,657,509.00). The approved projects are expected to create 347 new jobs within the country.

Malaysia is committed to ensuring that foreign investors remain welcome and has rolled out a series of supporting policies, incentives and regulations with the supporting legal framework. Foreign investors can hold 100 per cent of the equity in all investments in new projects, as well as investments in expansion / diversification projects by existing companies.

**APPROVAL OF MANUFACTURING PROJECTS**
Manufacturing companies are allowed to bring in expatriate personnel to man “key posts” and term posts where there is a shortage of trained Malaysians as well as to safeguard their investments in the country. Key posts refer to posts that are permanently filled by expatriates, while term posts are posts approved for a stipulated period up to 5 years.

THE CURRENT GUIDELINES ON EXPATRIATE POSTS FOR MANUFACTURING COMPANIES ARE AS FOLLOWS:

Minimum paid-up capital requirement for applications based on equity ownership:

- Malaysian: RM250,000.00
- Joint Ventures: RM350,000.00
- Foreign: RM500,000.00

Minimum basic salary of RM5,000.00 per month per expatriate or as proposed (whichever is higher).

Minimum academic qualifications and working experience in related field requirements (only applicable for term posts):

- Degree Holders with 3 years of experience
- Diploma Holders with 5 years of experience
- High School Certification Holders with 10 years of experience

Companies are also required to train local understudies to take up the post after 6 months from the date the post is filled.

Additional guidelines on the employment of expatriate personnel in Key Posts for manufacturing companies state that the company’s foreign paid-up capital be at least RM1 million, which must be owned by the company as stated in their SSM e-Info Company Profile.

KEY INCENTIVES AVAILABLE TO THE PHARMACEUTICAL INDUSTRY COME UNDER THE FOLLOWING:

I. INCENTIVES FOR MANUFACTURING COMPANIES
II. INCENTIVES FOR HIGH TECHNOLOGY COMPANIES
III. INCENTIVES FOR STRATEGIC PROJECTS
IV. INCENTIVES FOR R&D
V. INCENTIVE FOR MANUFACTURERS OF PHARMACEUTICAL PRODUCTS INCLUDING VACCINES UNDER THE 2021 BUDGET
VI. REINVESTMENT ALLOWANCE
VII. AUTOMATION CAPITAL ALLOWANCE EXPENDITURE (ACA)
VIII. INCENTIVES FOR THE PRINCIPAL HUB
IX. OTHER INCENTIVES

PRE-REQUISITE REQUIREMENTS BEFORE THE SUBMISSION OF EXPATRIATE POST APPLICATIONS TO MIDA ARE AS FOLLOWS:

Registration of company account at ESD Online System via https://esd.imi.gov.my/

Advertise the expatriate position at https://www.myfuturejobs.gov.my/ and obtain approval. However, exemption on advertisement is granted subject to the following criteria:

- Important positions (C-Suite & Key Posts) AND expatriate/s with a monthly income of RM15,000 and above
- Representative Office / Regional Office (RERO)
- Investors / Shareholders / Owners
- Corporate Transfers / Placements / Trade Agreements

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INCENTIVES FOR MANUFACTURING COMPANIES
- Pioneer Status with income tax exemption of 70% of statutory income for 5 years, or
- Investment Tax Allowance (ITA) of 60% of qualifying capital expenditure incurred within a period of 5 years (to be offset against 70% of statutory income for each assessment year).

INCENTIVES FOR STRATEGIC PROJECTS
Incentives for Strategic Projects are dependent on:-
- Level of investment
- High technology / technology transfer
- Linkages with local ecosystem / vendor development
- High income employment / technical skills
- Level of R&D undertaken locally
- Pioneer Status with full income tax exemption of statutory income for 10 years, or
- ITA of 100% of qualifying capital expenditure incurred within a period of 5 years (to be offset against 100% of statutory income for each assessment year).

INCENTIVES FOR RESEARCH AND DEVELOPMENT
CONTRACT R&D COMPANY
- Pioneer Status with 100% income tax exemption of statutory income for 5 years, or
- ITA of 100% of qualifying capital expenditure incurred within 10 years (to be offset against 70% of the statutory income in each year of assessment).

R&D COMPANY
- ITA of 100% of qualifying capital expenditure incurred within 10 years and to be offset against 70% of the statutory income for each year of assessment.

IN-HOUSE RESEARCH
- ITA of 50% of qualifying capital expenditure incurred within 10 years and to be offset against 70% of statutory income for each year of assessment.

INCENTIVES FOR HIGH TECHNOLOGY COMPANIES
- Pioneer Status with full income tax exemption of statutory income for 5 years, or
- ITA of 60% on qualifying capital expenditure incurred within a period of 5 years (to be offset against 100% of statutory income for each assessment year).

INCENTIVES FOR STRATEGIC PROJECTS
- Pioneer Status with 100% income tax exemption of statutory income for 5 years, or
- Investment Tax Allowance (ITA) of 60% of qualifying capital expenditure incurred within a period of 5 years (to be offset against 70% of statutory income for each assessment year).

INCENTIVES FOR MANUFACTURERS OF PHARMACEUTICAL PRODUCTS INCLUDING VACCINES UNDER THE 2021 BUDGET
The incentive was announced by the government through Budget 2021 on 6 November 2020 with the objective of attracting investments in pharmaceutical products including vaccines.
This incentive is offered to both new and existing companies, offering the following:
- Income tax rate of 0% to 10% for a period of 10 years
- Income tax rate of 10% for the subsequent period of 10 years
Participating companies must undertake the manufacturing of pharmaceutical products (including the formulation of their products) in Malaysia and submit its drug formulation registration to the NPRA within 10 years of the incentive approval.
Applications for this incentive must be made latest by 31 December 2022.

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Applications for this incentive must be made latest by 31 December 2022.

REINVESTMENT ALLOWANCE
The Additional Reinvestment Allowance incentive was announced under the Pelan Jana Semula Ekonomi Negara (PENJANA). To further encourage the reinvestment activities of existing companies, the Additional Reinvestment Allowance will be given to the manufacturing projects and selected agricultural activities whose RA and Special RA incentives period have expired and continue reinvesting in year of assessment (YA) 2020 to year of assessment (YA) 2022.
The incentive is given at the rate of 60% on the qualifying capital expenditure incurred for reinvestment activities made within 3 years of assessment (YA 2020 – YA 2022).
AUTOMATION CAPITAL ALLOWANCE EXPENDITURE (ACA)

Manufacturers are also eligible to apply for Automation Capital Allowance Expenditure (ACA). The capital allowance to increase automation in labour intensive industries was announced in the 2015 Budget on 10 October 2014. This incentive is expected to be the key factor to encourage automation in the manufacturing sector. Investment incurred between the assessment years from 2015 to 2025 are eligible for ACA consideration.

CATEGORIES FOR AUTOMATION CAPITAL ALLOWANCE

CATEGORY 1: For high labour-intensive industries (rubber products, plastics, wood, furniture and textiles), an automation capital allowance of 200% will be provided on the first RM4 million expenditure incurred* within 8 years of assessment from 2015 to 2023; and

CATEGORY 2: For other industries, automation capital allowance of 200% will be provided on the first RM2 million expenditure incurred* within 8 years of assessment from 2015 to 2023.

*Note: “Incurred” refers to plant and machinery purchased and used for the purpose of the business in the approved Year of Assessment.

INCENTIVES FOR THE PRINCIPAL HUB

A Principal Hub refers to a locally incorporated company that uses Malaysia as a base for conducting its regional or global business and operations to manage, control, and support its key functions including the management of risks, decision making, strategic business activities, trading, finance, management and human resource.

The Principal Hub initiative is a driver for innovation as it encourages the transfer of high-value technology to the country, including R&D and high-end technical support. It also creates job opportunities for Malaysians in a knowledge rich environment.

Malaysia has seen a steady increase in companies setting up their regional headquarters in the country whereby a total of 35 PH projects have been approved. Not only do they bring in business for the long term, which stands at RM35.1 billion, but also spill-over effects of spending on ancillary services amounting to RM5.5 billion and the creation of 2,686 high value jobs for Malaysians over the next 10 years.

It is evident that the PH incentive has been successful in encouraging many MNCs to make Malaysia their regional operations hub. The attractiveness of the PH Incentive was further enhanced under Budget 2019 which is PH 2.0, whereby companies with existing operations in Malaysia can now enjoy 10% corporate tax rate on their statutory income, compared to the earlier treatment of tax exemption on only value-added income. The enhancement of the PH Incentive reflects the commitment of the Malaysian Government to support the continued business growth of MNCs and local companies which have long made Malaysia their base for regional expansion.

The PH2.0 guidelines are already available in MIDA’s website at www.mida.gov.my

OTHER INCENTIVES

1. Exemption from Import Duty on Raw Materials / Components
2. Exemption from Import Duty and Sales Tax on Machinery / Equipment, Spare Parts and Consumables

For further information on incentives for investment, please visit www.mida.gov.my
NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA)
The NPRA, an institution under the Pharmaceutical Services Division (PSD) of the MOH, gained accession as the 26th member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) on 1 January 2002. The NPRA carries out regulatory control 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. Since 2002, it has been actively involved in the International Good Manufacturing Practice (GMP) and Quality Assurance programmes.

DRUG CONTROL AUTHORITY (DCA)
The DCA, as the executive body established under the Control of Drugs and Cosmetics Regulations 1984, has the main task of ensuring the safety, quality and efficacy of pharmaceuticals, traditional medicines, health supplements, veterinary products and personal care products that are marketed in Malaysia.

REGISTRATION FOR PHARMACEUTICAL PRODUCTS

PRODUCT REGISTRATION INTRODUCTION
The Drug Registration Guidance Document (DRGD) guidelines have been drawn up in accordance with the legal requirements of the Sale of Drugs Act 1952 and the Control of Drugs and Cosmetics Regulations 1984. The guidelines include other related legislation but applicants for the DRGD are reminded that they also have to ensure that their products comply with the requirements of the following legislations:

- Dangerous Drugs Act 1952;
- Poisons Act 1952;
- Medicines (Advertisement & Sale) Act 1956;
- Patent Act 1983; and
- any other relevant Acts.

DEFINITION OF A PRODUCT
A "product" under the Control of Drugs and Cosmetics Regulations 1984, has the main task of ensuring the safety, quality and efficacy of pharmaceuticals, traditional medicines, health supplements, veterinary products and personal care products that are marketed in Malaysia.

To encourage R&D activities, there are generous R&D and IP-specific tax incentives in place while the Intellectual Property Corporation of Malaysia (MyIPO), an agency under the Ministry of Domestic Trade and Consumer Affairs, has patent prosecution highway agreements with the European Patent Office and the Japan Patent Office.
BIOAVAILABILITY (BA)

BA 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 (BE)

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.

BE studies are required for all generic medicines in the form of:
- immediate release, oral solid dosage [effective 1 January 2012]
- modified release (extended, prolonged, sustained release, etc.) [effective 12 June 2013]
- effervescent, dispersible, sublingual, buccal and chewable [effective 1 January 2018]

The BE studies shall be conducted at BE centres accredited by NPRA in order to support the registration of generic medicine in Malaysia. In line with this requirement, NPRA has been inspecting BE centres since January 2012.

USE OF THE HALAL LOGO

The HALAL logo cannot be used for pharmaceutical products except for OTC products (products containing substances not scheduled in the Poisons List), 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).

PRODUCT LABELLING, BIOEQUIVALENCE, NEW/ADDITIONAL INDICATION


For details, please visit the Halal Industry Development Corporation website at www.halal.gov.my

BIOAVAILABILITY AND BIOEQUIVALENCE STUDY FOR PHARMACEUTICAL PRODUCTS

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

BIOAVAILABILITY (BA)

BA 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.

PRODUCT LABELLING, BIOEQUIVALENCE, NEW/ADDITIONAL INDICATION


For details, please visit the Halal Industry Development Corporation website at www.halal.gov.my

NEW APPLICATION PROCESSING PROCEDURES

Product license holders can conduct secure online transactions on registrations, request changes, market samplings and renewals through the NPRA’s QUEST online submission system.