Guide on PHARMACEUTICAL Industry in MALAYSIA

MIDA
MALAYSIAN INVESTMENT DEVELOPMENT AUTHORITY
www.mida.gov.my

Preface

This guidebook for the pharmaceutical industry in Malaysia serves as an important source of information for investors intending to invest in this industry. It also spells out the procedures and requirements for the various applications for licences and permits for the setting up of a business in the pharmaceutical industry.

The Malaysian Investment Development Authority (MIDA) is the Government's principal agency under the Ministry of International Trade and Industry (MITI) responsible for the promotion and coordination of industrial development in Malaysia. MIDA assists companies which intend to invest in the manufacturing and services sectors in the country. MIDA has a global network of 20 overseas offices covering North America, Europe and Asia Pacific to assist investors. Within Malaysia, MIDA has 12 branch offices in the various states to facilitate investors in the implementation and operation of their projects.

For more information on investment opportunities in Malaysia and contact details of MIDA, visit www.mida.gov.my.

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Background of Malaysia

Malaysia covers an area of about 330,396 square kilometres, consisting of 13 states, namely Johor, Kedah, Kelantan, Melaka, Negeri Sembilan, Pahang, Perak, Perlis, Penang, Sabah, Sarawak, Selangor and Terengganu. Apart from the 13 states, there are three Federal Territories, which are Kuala Lumpur, Putrajaya and Labuan. Kuala Lumpur is the capital of Malaysia. Malaysia lies entirely in the equatorial zone and the average daily temperature throughout Malaysia varies from 21°C to 32°C.

Malaysia is a multi-ethnic country. The principal ethnic groups are Malays, followed by Chinese and Indians. Other significant groups are the indigenous people of Sarawak and Sabah, including the Dayaks, Kadazans, Bajaus, Melanaus and Muruts.

Major exports of Malaysia are manufactured goods such as electrical and electronics products, machinery and appliances, chemicals, plastic products, iron, steel and metal products, and petroleum-based products. In 2019, the share of exports of manufactured goods to total exports was 84.6%. Imports comprise mainly intermediate goods such as primary and processed industrial supplies, thermionic valves and tubes, parts and accessories of capital goods, primary and processed fuel lubricants, and parts and accessories for transport equipment.

Key Economic Indicators

	2018	2019
Population	32.4 million	33.6 million
Labour force	15.3 million	15.5 million
Unemployment rate	3.3%	3.3%
GDP	RM1,362.8 billion	RM1,421.5 bilion
GDP growth	4.8%	4.3%
Per capita income	RM42,937 (USD10,321)	RM44,686 (USD10,741)
Inflation rate (CPI)	1.5-2.5%	2.1% (2020 est.)
Total export (f.o.b.)	RM1,003.5 billion	RM986.4 billion
Total import (c.i.f.)	RM879.8 billion	RM849 billion

Exchange Rate : USD 1 = RM4.09 (December 2019)
Sources: 1. Department of Statistics Malaysia (DOSM)
2. MATRADE Press Release: Malaysia's Trade Performance for 2019 and December 2019

Healthcare in Malaysia

Malaysia's primary care model has been acknowledged by the World Health Organisation as a viable system to achieve "Health for All". The demand for quality healthcare continues to rise in Malaysia with increasing affluence and rising consumer awareness. Currently, about 7.25% of the country's GDP is expected to be spent on healthcare. This is expected to increase with the growing population and a longer life expectancy, as well as the Government's increasing expenditures on provision of better healthcare facilities and services.

Healthcare remains a priority of the Malaysian Government. For 2018, the Government had increased the budget allocation for healthcare to RM27 billion. A total RM21.4 billion for the budget will be spent on healthcare development to enhance health facilities and provide medical equipment, increase supply of medicines, develop human resources, intensify research and enforcement activities, as well as to build more hospitals, clinics and quarters.

Demographics – 2017

Crude Birth Rate (per 1000 population)	16.1*
Crude Death Rate (per 1000 population)	5.2*
Infant Mortality Rate (per 1000 live births)	7.3*
Life Expectancy - Male (age in years)	72.7*
Life Expectancy - Female (age in years)	77.4*

* *Provisional/Preliminary data (as of December 2017)*

Health Facts – 2017

Number of registered doctors (Government & Private)	57,831
Population per doctor	1 : 554
Number of Hospitals	354*
Number of Clinics	16,409**
Number of Beds	66,814
Number of Dental Chairs	6,029***

* *Includes Government hospitals, MOH special medical institutions, non-MOH Government hospitals & private hospitals.*
** *Includes MOH dental clinics, MOH mobile dental clinics (including mobile and pre-school team); MOH Health Clinics, MOH Community Clinics, MOH maternal & child heart clinics, MOH mobile health clinics, private medical clinics & private dental clinics.*
*** *Includes MOH dental clinics and MOH mobile dental clinics.*

Source: Ministry of Health, Malaysia, (as at December 2017)

The Pharmaceutical Industry in Malaysia

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 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, as of December 2019, there were 263 licensed manufacturers with 69.2 per cent or 182 of these manufacturers categorised into producers of traditional medicine, 26.6 per cent or 70 being producers of pharmaceuticals and 4.2 per cent or 11 companies being producers of veterinary products.

Among the major local companies are Pharmaniaga Manufacturing Berhad, Hovid Berhad, Duopharma Biotech Berhad 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 Biocon Sdn. Bhd. (India), Oncogen Pharma (Malaysia) Sdn. Bhd., 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 the 26 th 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.

* *The PIC/S provides an active and constructive co-operation in the field of Good Manufacturing Practice(GMP) between countries and pharmaceutical inspection authorities. It leads the international development, implementation and maintenance of harmonised GMP Standards and Quality System of Inspectorates in the field of pharmaceutical products.*

Investment Opportunities

Biopharmaceuticals/Biogenerics (Biosimilars)

The potential expansion of biosimilars is expected to have a major implication on the biopharmaceutical industry. The impact of biosimilars on the biopharmaceutical industry is expected to be similar if not greater than the impact of generics on the pharmaceutical industry. Currently biopharmaceuticals are considerably more expensive than conventional medications. However, Malaysia offers a more competitive cost option to investors due to the available ecosystem.

A large number of first generation biopharmaceutical products are nearing maturity and major biopharmaceutical companies are likely to move these out to countries like Malaysia that offer a good value preposition.

Currently, in Malaysia, local and foreign players are already engaged in activities like biopharmaceutical APIs, FDA/EMEA cGMP compliant services, specialising in monoclonal antibodies and recombinant proteins. In addition, specialised research, development and commercialisation of biopharmaceutical products is on-going. The government is further encouraging potential investors to move up the value-chain.

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 generic and patented 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 Medicines

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

Manufacturing of Active Pharmaceutical Ingredients (API)

There is huge demand for API 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, biopharmaceuticals, inhalation products drug discovery activities or new chemical entity (NCE) and novel delivery systems.

"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

An 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

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 Multimedia Super Corridor (MSC)
- Advanced MSC Malaysia Cybercities and Cybercentres

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 practice 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

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

Starting a Business

In general, the overall cost of doing business in Malaysia is competitive. In Malaysia, the process is facilitated by experienced and reputable agencies that exist both within and outside the Federal and local governments. For starting a business in Malaysia, the main fees which need to be paid are fees to the Companies Commission of Malaysia (SSM) and fees for company secretarial services.

Main fees to be paid to the Companies Commission of Malaysia (SSM):
(Refer to the Companies Regulations 2017)

Matter	Fee (RM)
Application for reservation of name of company under section 27 of the Act	50.00 for every thirty days or part thereof with a maximum of 180 days
Application for incorporation under section 14 of the Act:	
(a) Company limited by share	1,000
(b) Company limited by guarantee	3,000
(c) Unlimited Company	1,000
Application for registration of 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)

Other costs of doing business in Malaysia that investors need to know are rental rates for prime office space, cost of industrial land, cost of ready-built factory and average construction costs of factory building. The costs will depend on the business location selected by the investors.

For more details on these costs, visit **www.mida.gov.my**

Registration of Business/ Incorporation of Company

Companies Commission of Malaysia (SSM)
www.ssm.com.my

Application for Manufacturing and/or Tax Incentives

Malaysian Investment Development Authority (MIDA)
www.mida.gov.my

Application for Other Approvals and Permits

Approvals at the level of State Governments and Local Authorities

- Acquire land and premise (Industrial land /Premise / Factory Approval)
- No Objection Letter for location of projects
- Planning Permits
- Building Plans
- Certificate of Fitness (CF)
- Business Licence

Approvals at the level of Federal Ministries / Departments / Agencies

- Good Manufacturing Practice (GMP) & Registration of Products from National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health (www.npra.moh.gov.my)
- Department of Occupational Safety and Health (www.dosh.gov.my)
- Fire and Rescue Department (www.bomba.gov.my)
- Department of Environment (www.doe.gov.my)

Utilities

- **Electricity supply** - Tenaga Nasional Berhad (www.tnb.gov.my)
- **Water supply** - Local Water Authority (www.jba.gov.my)
- **Telecommunication** - Telekom Malaysia Berhad (www.tm.com.my)

Immigration

- **Expatriates** - MIDA (www.mida.gov.my) or Immigration Department (www.imi.gov.my)
- **Foreign Workers**
  - Ministry of Home Affairs (www.moha.gov.my)

Taxation

Generally, all income of companies and individuals accrued in or derived from sources outside Malaysia and received in Malaysia is liable to tax. However, effective from the year of assessment 2004 income remitted to Malaysia by resident companies (other than companies carrying on the business of banking, insurance, air and sea transportation), resident individuals, non-resident companies and non-resident individuals are exempted from tax.

Income tax in Malaysia is assessed on income earned in the current year. The self-assessment system was implemented for companies, sole proprietors, partnerships, cooperatives and salaried groups to streamline the tax administration system.

Corporate Tax	
Resident and non-resident companies	24%
Resident companies with paid-up capital of RM2.5 million and less at the beginning of the basis period for a year of assessment	
• on the first RM500,000 (USD162,337.67) chargeable income	17%
• on subsequent chargeable income	24%

Personal Income Tax	
Resident individuals with chargeable income (after deduction of personal reliefs) of more than RM5,000 and not more than RM1,000,000	1%-26%
Resident individuals with chargeable income (after deduction of personal reliefs) of more than RM1,000,000	28%
Non-resident individuals (not entitled to any personal reliefs)	26%

Withholding Tax (Non-resident persons)
Special classes of income which is derived from Malaysia: - Amounts paid for services rendered in connection with the use of property or rights or installation services or operation on the supply of plant, machinery or other apparatus - Amounts paid for technical advice, assistance or services rendered in connection with technical management or administration of scientific industrial or commercial projects - Rent or payment for the use of any moveable property.
Interest derived from Malaysia
Royalty derived from Malaysia
Remuneration or income from service performed or rendered in Malaysia by public entertainer

Contract payment:
- Payable by the non-resident contractor
- Payable by employees of the non-resident contractor

Gains or profits falling under paragraph 4(f) Income Tax Act 1967

Source : Inland Revenue Board – www.hasil.org.my

Sales and Service Tax

Effective from 1 September 2018, the Sales Tax Act 2018 and the Service Tax Act 2018 together with its respective subsidiary legislations are introduced to replace the Goods and Services Tax (GST) Act 2014.

Sales Tax

Under the Sales Tax Act 2018, sales tax is charged and levied on imported and locally manufactured goods either at the time of importation or at the time the goods are sold or otherwise disposed of by the registered manufacturer.

Sales tax administered in Malaysia is a single stage tax imposed on the finished goods manufactured in Malaysia and goods imported into Malaysia.

Sales tax is imposed on taxable goods manufactured in Malaysia by any registered manufacturer at the time the goods are sold, disposed of other than by sales or used other than as a material in the manufacture of goods.

Sales tax on imported goods is charged when the goods are declared, duty paid and released from customs control.

Manufacturers who manufacture taxable goods with sales value which exceeds RM500,000 within the period of 12 months, are required to be registered pursuant to Section 12 Sales Tax Act 2018.

Manufacturers who manufacture taxable goods with sales value of RM500,000 and below, have the option to be registered on a voluntary basis under Section 14 of the Sales Tax Act 2018 to enable them to enjoy the facilities given under the Act.

Manufacturers who carry out its business as a subcontractor and the total labour charge of the subcontract works exceeds RM500,000 within 12 months, are required to be registered pursuant to Section 12 of the Sales Tax Act 2018.

Rates of Sales Tax

Sales tax is generally at 10%, certain non-essential foodstuffs, alcoholic beverages, tobacco/cigarettes and building materials are taxed at 5% while certain petroleum products and motor oil are taxed at individual specific rates.

Service Tax

Service tax in Malaysia is a form of indirect single stage tax imposed on specified services termed as “taxable services”. The Service tax cannot be levied on any service which is not included in the list of taxable services prescribed by the Minister under the First Schedule of Service Tax Regulations 2018.

The Service Tax Act 2018 (STA 2018) applies throughout Malaysia excluding designated areas, free zones, licensed warehouses, licensed manufacturing warehouses and Joint Development Area (JDA).

Taxable Service

Taxable services are any services which are listed in the various categories in the First Schedule of Service Tax Regulations 2018. Any taxable person providing taxable services and exceeding the respective thresholds is required to be registered. The categories are accommodation, food and beverage operator, night-clubs, dance halls, health and wellness centres, private club, golf club and golf driving range, betting and gaming services, professional services and other service providers such as insurance, telecommunication, parking operator, advertising and etc.

Charge to Tax

Service tax is charged on any provision of taxable services provided in Malaysia by a registered person in carrying on his business.

The service tax is due and payable when payment is received for any taxable service provided to a customer by the registered person. The service tax is not chargeable for imported and exported services under the STA 2018.

Rate of Service Tax

The rate of service tax is fixed under the Service Tax (Rate of Tax) Order 2018 and comes into force on 1 September 2018. The rate of service tax is 6% of the price or premium for insurance policy, value of betting and gaming, etc. of the taxable service as determined under section 9 of STA 2018.

Rate of Service Tax for Credit and Charge Cards

The rate of service tax on the provision of credit card or charge card services is RM25 per year on the principal and supplementary card. The service tax is chargeable on the date of the issuance of the card and every 12 months thereafter or part thereof after the issuance of the card or on the date of the renewal of the card and every 12 months thereafter or part thereof after the renewal of the card.

For more information, please visit
https://mysst.customs.gov.my

Rates of Capital Allowances

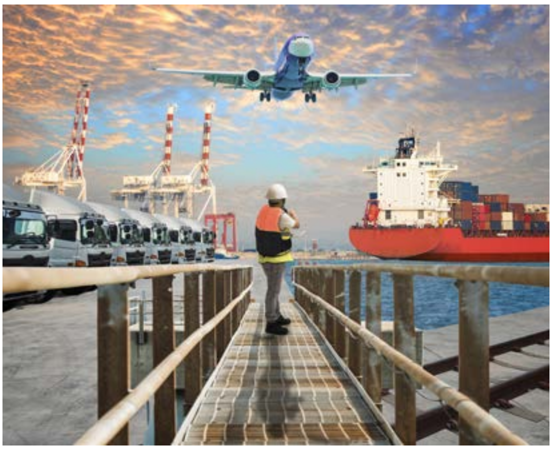
Capital allowances are given on qualifying capital expenditure. Initial allowances are given only once while annual allowances are given every year by the straightline method. Some of the items accorded allowances are shown below. For plant and machinery, companies are advised to verify with the Inland Revenue Board on the specific items which qualify.

	Initial Allowance	Annual Allowance
Industrial buildings	10%	3%
Plant and machinery	20%	14%
Heavy machinery and motor vehicles	20%	20%
Computer and IT equipment	20%	40%
Environmental control equipment	40%	20%
Others	20%	10%

Source: Inland Revenue Board - www.hasil.org.my

Infrastructure Support

Efficient Logistics and Well-Developed Infrastructure



The prime advantage to manufacturers in Malaysia has been and continues to be the nation's persistent drive to develop and upgrade its infrastructure. Integrated logistics have ensured that Malaysia's pharmaceutical products reach markets in Asia and worldwide on time, enabled by the extensive infrastructure that includes world-class airports, seaports and sophisticated telecommunications network.

Availability of Industrial Estates and Specialised Parks

Industries in Malaysia are mainly located in over 200 industrial estates or parks and 13 Free Industrial Zones (FIZs) developed throughout the country. FIZs are export processing zones which have been developed to cater to the needs of export-oriented industries such as pharmaceutical industry. Companies in FIZs are allowed duty free imports of raw materials, components, parts, machinery and equipment directly required in the manufacturing process. In areas where FIZs are not available, companies can set up Licensed Manufacturing Warehouses (LMWs).

Malaysia has also developed specialised parks to cater to the needs of specific industries which are technology-intensive and research-intensive. 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. These parks comprise state-of-the-art buildings with specific functions and fully-integrated high technology park.

Other specialised parks developed by the 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 59 km. Bio-XCell offers an environment conducive for the development and manufacturing of biologics, pharmaceuticals, 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, park maintenance and security as well as core facilities to nurture the ecosystem.

Key facilities of the park include:

- **Central Hub:** A multipurpose complex with a variety of office and lab space for rent. The focal point of the park providing amenities such auditorium, business centre, training facilities, Food & Beverage and retail outlets.
- **Central Utilities Facility:** Providing utilities for biomanufacturing such as industrial steam, chilled water and waste water treatment service to clients on a user pays basis.
- **Standard Shells:** These buildings providing 20,000 sq. ft. of space, can be fit-out to clients' needs and are available for rent or purchase.
- **Plots of freehold land:** Available for sale, enabling clients to build their own customised facilities.

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

Enstek

Located within the township of Bandar Enstek, techpark@enstek is just 10 minute away from Kuala Lumpur International Airport (KLIA) and only 38 minutes from downtown Kuala Lumpur via the Express Rail Link (ERL).

Bandar Enstek consists of 4 main components; residential area, technology land park, commercial hub and institutional zones.

techpark@enstek is envisaged to become a world-class technology hub catering for the need of high technology and eco-conscious industries such as biotechnology, green technology and information technology (ICT) industries. It is also endowed with ready infrastructure and amenities to support such sectors.

Penang Science Park

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

Facilities / Centres	Distance / Driving Time
Penang International Airport	42 km (40 minutes)
Penang Port (Butterworth)	23 km (20 minutes)
North-South Highway	5 km (5 minutes)
Urban Centres	19 km (20 minutes)
Butterworth	19 km (20 minutes)
Seberang Jaya	10 km (15 minutes)
Batu Kawan (new township)	5 km (5 minutes)
University Technology Mara	10 km (10 minutes)
University Science Malaysia	20 km (25 minutes)
Japan Malaysian Tech, Institute	within the park

For further information on Penang Science Park, visit **www.pdc.gov.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 developed, KHTP is continuing to develop another 7,000 acres and more to cater to growing industry demands and offers connectivity to an integrated world-class infrastructure.

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

- industrial;
- amenity;
- housing;
- urban; and
- institutional.

For further information on Kulim Hi-Tech Park, visit **www.khtp.com.my**

Availability of Clinical Trials and Bioequivalence Centres

The Clinical Research Centre (CRC), comprising a network of 17 centres around the country, acts as a one-stop-centre by providing a single point of contact to access all Ministry of Health hospitals and clinics to conduct clinical trials in Malaysia. These clinical trial centres have linkages to more than 50 general and district hospitals, and more than 100 health clinics as potential sites for clinical trials with access to 550 clinical investigators and 17 million patients from diverse therapeutic areas in the public healthcare system in Malaysia.

The private entities which conduct clinical trials are as follows:-

- Infokinetics Research Centre Sdn. Bhd.
- International Medical University
- University Malaya Medical Centre
- NCI Hospital
- Universiti Kebangsaan Malaysia Medical Centre
- Hospital Universiti Sains Malaysia
- Sunway Medical Centre
- Universiti Teknologi Mara, Selayang and Sungai Buloh
- Mahkota Medical Centre
- Lam Wah Ee Hospital
- Mount Miriam Cancer Hospital
- Gleneagles Medical Centre
- Columbia Asia Medical Centre
- Island Hospital
- Penang Adventis Hospital
- Pantai Hospital Penang
- Loh Guan Lye Specialist Centre
- Monash University Sunway Campus & Johor Bahru Campus

Bioequivalence Centres

- School of Pharmaceutical Sciences, Hospital Universiti Sains Malaysia
- Info Kinetics Sdn Bhd
- Bioxis Sdn Bhd
- Borneo Kinetics Sdn Bhd

For further information on
CRC & BE centres in Malaysia, visit
www.crc.gov.my and www clinicalresearch.my

Approval of Manufacturing Projects

The Industrial Co-ordination Act 1975 (ICA) requires companies manufacturing pharmaceutical products with shareholders' funds of RM2.5 million and above or engaging 75 or more full-time paid employees to apply for a Manufacturing Licence for approval by the Ministry of International Trade and Industry (MITI).

Foreign investors can now hold 100% of the equity in all investments in new projects, as well as investments in expansion/diversification projects by existing companies.

Malaysia's commitment in creating a safe investment environment has convinced more than 5,000 international companies from over 80 countries to make Malaysia their regional and global operations.

Approval of Expatriate Posts

Manufacturing companies are allowed to bring in expatriate personnel i.e. ‘key post’ or ‘time post’. Key posts are posts that are permanently filled by foreigners whereby time posts are positions filled within a specified period.

Companies undertaking manufacturing activities are eligible to be considered for expatriate posts with the minimum paid-up capital as follows:

- 100% Malaysian-owned company: RM250,000.
- Jointly-owned by foreign and Malaysian: RM350,000.
- 100% foreign-owned company: RM500,000.

The approval of key posts will be subjected to the condition that the company must be incorporated in Malaysia and must deposit its foreign paid-up capital of at least RM1,000,000. However, the number of key posts cannot be linked directly with the foreign paid-up capital.

The approval for the term posts will be imposed the following conditions:

- Minimum basic salary of at least RM5,000;
- Minimum academic qualification and minimum experience;
  - For a manufacturing company :
    - Degree with at least 3 years’ experience in the relevant field; and/or
    - Diploma with at least 5 years’ experience in the relevant field; and/or
    - Technical Certification with at least 10 years’ experience in the relevant field; or Academic qualifications / experience proposed by companies, whichever is higher.

The number of expatriate posts will be considered based on the merits of each case.

All applications for expatriate posts from new and existing companies in the manufacturing and related service sectors should be submitted to MIDA.

For further information on the application for expatriate posts, please visit www.mida.gov.my.

For further information on immigration procedures, please visit www.imi.gov.my.

Intellectual Property (IP) Protection

Malaysia has strong IP protection in place and is committed to safeguarding IP on inventions. To ensure IP protection in Malaysia is in line with international standards and provides protection for both local and foreign investors, Malaysia is a party to the following treaties:

- World Intellectual Property Organisation (WIPO), 1967;
- Paris Convention for the Protection of Industrial Property 1883;
- Berne Convention for the Protection of Literary and Artistic Works (1886);
- Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement;
- Patent Cooperation Treaty (PCT) 1970

For further information on IP protection in Malaysia, visit **www.myipo.gov.my**

IP in Malaysia comprises:

- Patents
- Trade Marks
- Industrial Designs
- Copyrights
- Geographical Indications
- IC Layout Designs

Incentives for Investment

Pharmaceuticals and related product is categorised as "promoted activities" or "promoted products". Please refer to the List of Promoted Activities and Products in MIDA website at www.mida.gov.my

Some of major tax incentives available for the pharmaceutical industry are as follows:-

i. Incentives for Manufacturing Companies
ii. Incentives for High Technology Companies
iii. Incentives for Strategic Projects
iv. Incentives for Research & Development (R&D)
v. Reinvestment Allowance
vi. Automation Capital Allowance Expenditure (ACA)
vii. Incentives for the Principal Hub
viii. Other incentives

i. 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.)

ii. 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.)

iii. Incentives for Strategic Projects

Incentives for Strategic Projects are dependent on:-

a) Level of investment
b) High technology/technology transfer
c) Linkages with local ecosystem/vendor development
d) High income employment/technical skills
e) 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.)

iv. Incentives for Research & Development (R&D)

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 within 10 years and to be offset against 70% of the statutory income for each year of assessment

In-house Research

- Investment Tax Allowance of 50% of qualifying capital expenditure incurred within 10 years and to be offset against 70% of statutory income for each year of assessment

v. 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).

vi. 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 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 year of assessment from 2015 to 2023 are eligible to be considered for ACA.

- 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.*

vii. 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 businesses and operations to manage, control, and support its key functions including 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 is already available in MIDA's website at www.mida.gov.my

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viii. Other Incentives

- Exemption from Import Duty on Raw Materials/Components
- 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**

Registration for Pharmaceutical Products

National Pharmaceutical Regulatory Agency (NPRA)

The regulatory control of pharmaceutical products and traditional medicines in Malaysia is carried out by the National Pharmaceutical Regulatory Agency (NPRA), 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 NPRA also successfully gained accession as the 26th member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) on 1st January 2002. Since then, NPCB has been actively involved in International Good Manufacturing Practice (GMP) and Quality Assurance programmes.

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.

Product Registration

Introduction

The guidelines outlined in the Drug Registration Guidance Document (DRGD) are 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

- Regulation 7 (1) (a) of the Control of Drugs and Cosmetics Regulation 1984 (Amendment 2006) requires all products to be registered with the DCA prior to being manufactured, sold, supplied, imported or processed or administered, unless the product is exempted under specific provisions of the Regulation.
- Any drug in a pharmaceutical dosage form intended to be used, or capable or purported or claimed to be capable of being used on humans or any animals, whether internally or externally for a medical purposes is required to be registered with the DCA.

For more information, please refer to the ‘Drug Registration Guidance Document’ in the NPRA’s website at
http://npra.moh.gov.my

New Application Processing Procedures

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

Other Information

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 needs 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.

Use of HALAL logo

The use of HALAL logo on the labels of pharmaceutical products will not be allowed 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

Please refer to the Drug Registration Guidance Document in NPRA's website for details.

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

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.

Effective 1 January 2012, the DCA has imposed Bioequivalence (BE) studies requirement for all immediate releases oral, solid dosage form generic products containing scheduled poison as active ingredients as well as accreditation of BE research centres.

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