MALAYSIAN INVESTMENT DEVELOPMENT AUTHORITY

MALAYSIA'S PHARMACEUTICAL INDUSTRY: A FAST-GROWING FORCE


COVID-19
Vaccine
COVID-19
Vaccine
COVID-19
Vaccine

CONTENTS

GEARED FOR MOVING UP THE VALUE CHAIN

Located in Southeast Asia, Malaysia is an upper-middle-income country with a diversified economy and world-class infrastructure supporting a pharmaceutical industry comprising manufacturers, importers and distributors.

Malaysia's strategic location in Southeast Asia, lying at the cross-roads of shipping lanes and air travel, makes the country a top choice for manufacturing and distribution activities, while its rainforests, among the world's oldest, is a rich source of pharmacological leads.

Business-friendly policies, intellectual property (IP) protection, supporting infrastructure such as industrial parks and transportation links as well as, an educated workforce with a wide use of the English language, make it an attractive location for the production and distribution of pharmaceuticals.

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 while 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 the assurance of regular policy reviews and the creation of adaptable roadmaps, to address the changing market dynamics 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 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 medicine supply and its distribution to all healthcare facilities.

Currently, about 6.6 per cent of the country's GDP is expected to be spent on healthcare. This is expected to increase with the growing population and longer life expectancy, as well as the Government's increasing expenditure for the provision of 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 Malaysian Government allocated RM32.4 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.

PUBLIC HEALTHCARE SECTOR
(As of December 2021)

135 PUBLIC HOSPITALS

39,263 Beds

11 SPECIAL MEDICAL INSTITUTIONS

5,586 Beds

MINISTRY OF HEALTH (MOH)
1,057 Health Clinics
1,749 Rural Clinics
255 Community Clinics

MINISTRY OF DEFENCE (MOD)
5 Military Hospitals

MINISTRY OF EDUCATION (MOE)
7 University Hospitals

4,932 Beds

PRIVATE HEALTHCARE SECTOR
209 HOSPITALS → **17,628** Beds

8,419 Medical Clinics

DOCTORS & NURSES
(As of December 2021)

40,803 DOCTORS
- Medical Officers
- Specialists
- House Officers

18,438 ASSISTANT MEDICAL OFFICERS

70,797 NURSES

20,308 COMMUNITY NURSES (under the MOH)

MOD, MOE AND OTHER GOVERNMENT AGENCIES

5,537 DOCTORS
- Medical Officers
- Specialists

704 ASSISTANT MEDICAL OFFICERS

7,629 NURSES

197 COMMUNITY NURSES

PRIVATE HEALTHCARE SECTOR

16,196 DOCTORS
- Medical Officers
- Specialists

4,187 ASSISTANT MEDICAL OFFICERS

36,804 NURSES

311 COMMUNITY NURSES

DEMOGRAPHICS - 2021*

Crude Birth Rate
(per 1000 population)
13.5

Crude Death Rate
(per 1000 population)
6.9

Infant Mortality Rate
(per 10,000 live births)
61

Life Expectancy-Male
(age in years)
72.6

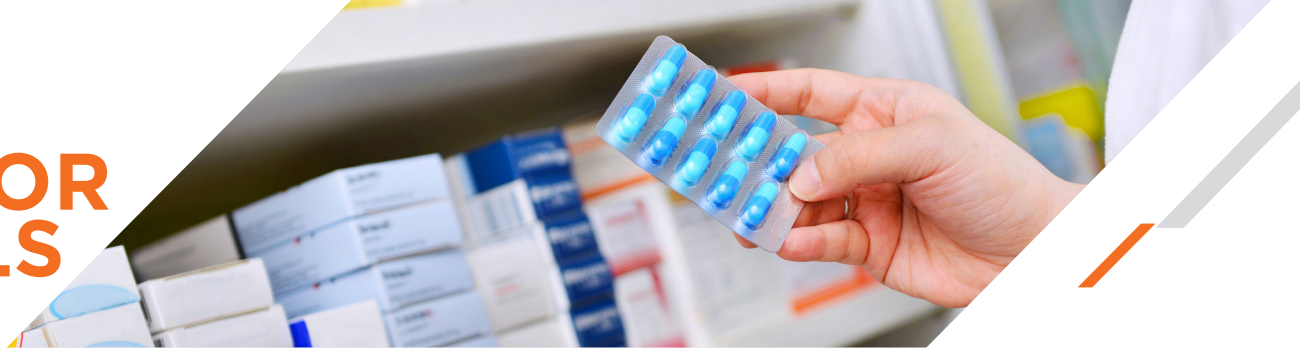
Life Expectancy-Female
(age in years)
77.3

**Provisional / Preliminary data (as of December 2021)*

HEALTH FACTS 2021

NUMBER OF REGISTERED DOCTORS (Government and Private)	**62,536**
POPULATION PER DOCTOR	**1:420**
NUMBER OF HOSPITALS (Comprising Hospitals under MOH / MOD / MOE and the Private Sector)	**356**
NUMBER OF CLINICS (Government and Private)	**11,480**
NUMBER OF BEDS	**67,409**
NUMBER OF DENTAL CHAIRS (Comprising MOH-Operated Dental Clinics and Community Dental Clinics)	**3,336**

RISING DEMAND FOR PHARMACEUTICALS



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 275 licenced pharmaceutical manufacturers, of which 176 or 64 per cent produce traditional medicine and health supplements; 88 or 32 per cent are producers of pharmaceuticals and; 11 or 4 per cent manufacture veterinary products.

Among the major domestic pharmaceutical companies are Pharmaniaga Manufacturing Berhad, Duopharma Biotech Berhad, Kotra 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.), Novugen Pharma (Malaysia) Sdn. Bhd. (part of UAE's Scitech International), Y.S.P. Industries (M) Sdn. Bhd. (Taiwan), Sterling Drug (M) Sdn. Bhd. (the manufacturing arm of the UK's Haleon) 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 licenced 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.

BIOPHARMACEUTICALS (BIOSIMILARS / BIOLOGICS)

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.

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.

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.

OTHER HIGHER VALUE-ADDED PRODUCTS AND SERVICES

The products include innovator drugs, vaccines, biopharmaceuticals, inhalation products, drug discovery activities or new chemical entities (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

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 RM2 trillion in 2022

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

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
- Premier global shopping hub for discerning shoppers worldwide

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

STARTING A BUSINESS

In general, the overall cost of doing business in Malaysia is competitive. The process is facilitated by experienced and reputable agencies that exist both within and outside the Federal and local governments. To start 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 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)

Other costs of doing business in Malaysia that investors need to be aware of are rental rates for prime office space, cost of industrial land, cost of ready-built factories 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 the 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)**
- Telecommunications - 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)**

ROBUST 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.

OTHER SPECIALISED PARKS DEVELOPED BY MALAYSIAN GOVERNMENT AGENCIES ARE AS FOLLOWS:

ENSTEK

Located within the township of Bandar Enstek, techpark@enstek is just 10 minutes 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 four (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 furnished with readily available infrastructure and amenities to support these specific sectors.

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 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 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;
- Amenity;
- Housing;
- Urban; and
- Institutional.

For further information on the Kulim Hi-Tech Park, visit **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).

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

- Info Kinetics Sdn. Bhd.
- Bioxis Sdn. Bhd.
- Borneo Kinetics Sdn. Bhd.

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

APPROVAL OF MANUFACTURING PROJECTS

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 2022, a total of five projects were approved, with investments amounting up to RM266,840,277.00. Of this figure, three were new projects with investments totaling up to RM80,246,031.00 (30.07%) while two were expansion/diversification projects, with investments totaling up to RM186,594,246.00 (69.92%). Foreign investments accounted for 67.8% (RM180,924,586.00) while domestic investments made up the remaining 32.2% (85,915,691.00).

Malaysia is committed to ensuring that foreign investors remain welcome and has rolled out an array of supportive policies, incentives and regulations within a robust legal framework to reinforce this commitment. 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.

CRITERIA AND GUIDELINES OF EXPATRIATE POST APPLICATIONS

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 five (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 three (3) years of experience
- **Diploma Holders** with five (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 six (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.

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

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. ADDITIONAL REINVESTMENT ALLOWANCE

VI. AUTOMATION CAPITAL ALLOWANCE EXPENDITURE (ACA)

VII. OTHER INCENTIVES

INCENTIVES FOR MANUFACTURING COMPANIES

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

INCENTIVES FOR HIGH TECHNOLOGY COMPANIES

- Pioneer Status with full income tax exemption of statutory income for five (5) years, or
- ITA of 60% on qualifying capital expenditure incurred within a period of five (5) years (to be offset against 100% 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 five (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

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.

ADDITIONAL REINVESTMENT ALLOWANCE

The Additional Reinvestment Allowance incentive was announced under the Pelan Jana Semula Ekonomi Negara (PENJANA) and subsequently, in Budget 2022. 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 periods have expired and continue reinvesting in year of assessment (YA) 2020 to year of assessment (YA) 2024.

The incentive is given at the rate of 60% on the qualifying capital expenditure incurred for reinvestment activities made within 3+2 years of assessment (YA 2020 – YA 2024).

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**

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 2023 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 eight (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.*

IP PROTECTION

Malaysia has strong IP protection in place and is committed to safeguarding IP on inventions.

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.

To ensure IP protection in Malaysia is aligned with international standards and provides protection for both local and foreign investors, Malaysia is 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; and
- Patent Cooperation Treaty (PCT) 1970

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

IP in Malaysia comprises:

- Patents
- Trademarks
- Industrial Designs
- Copyrights
- Geographical Indications
- IC Layout

REGISTRATION FOR PHARMACEUTICAL PRODUCTS

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.

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 legislation:

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

DEFINITION OF A PRODUCT

A “product” under the Control of the Drugs and Cosmetics Regulations 1984 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, a ‘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 purpose 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

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

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 containing 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 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 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 more details, please refer to the Drug Registration Guidance Document (DRGD) at **https://www.npra.gov.my/index.php/en/component/sppagebuilder/925-drug-registration-guidance-document.html**

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

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, orodispersible, 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.

KEDAH & PERLIS

Director
Malaysian Investment Development Authority
Level 4, East Wing, No. 88
Menara Bina Darulaman Berhad
Lebuhraya Darulaman, 05100 Alor Setar
Kedah Darul Aman, Malaysia
Tel: (604) 731 3978 | Fax: (604) 731 2439
E-mail: kedah@mida.gov.my

PULAU PINANG

Director
Malaysian Investment Development Authority
Unit 14.01, 14th Floor, Menara Boustead Penang
39, Jalan Sultan Ahmad Shah
10050 Pulau Pinang, Malaysia
Tel: (604) 228 0575 | Fax: (604) 228 0327
E-mail: penang@mida.gov.my

PERAK

Director
Malaysian Investment Development Authority
Level 4, Perak Techno Trade Centre (PTTC)
Bandar Meru Raya, Off Jalan Jelapang
P.O.Box 210, 30720 Ipoh, Perak Darul Ridzuan, Malaysia
Tel: (605) 5269 962 / 961 | Fax: (605) 5279 960
E-mail: perak@mida.gov.my

MELAKA

Director
Malaysian Investment Development Authority
Level 3, Menara MITC
Kompleks MITC, Jalan Konvensyen
75450 Ayer Keroh, Melaka, Malaysia
Tel: (606) 232 2877 | Fax: (606) 232 2875
E-mail: melaka@mida.gov.my

NEGERI SEMBILAN

Director
Malaysian Investment Development Authority
Suite 13.01 & 13.02, 13th Floor
Menara Zurich, 70200 Seremban
Negeri Sembilan, Malaysia
Tel: (606) 762 7921 | Fax: (606) 762 7879
E-mail: nsembilan@mida.gov.my

JOHOR

Director
Malaysian Investment Development Authority
No. 5, 13th Floor, Menara Tabung Haji
Jalan Ayer Molek, 80000 Johor Bahru
Johor Darul Ta'zim, Malaysia
Tel: (607) 224 5500 / 5057
Fax: (607) 224 2360
E-mail: johor@mida.gov.my

PAHANG

Director
Malaysian Investment Development Authority
Tingkat 10 KLM, Menara Zenith
P.O.Box 178, Jalan Putra Square 6, Putra Square
25200 Kuantan, Pahang Darul Makmur, Malaysia
Tel: (609) 513 7334 | Fax: (609) 513 7333
E-mail: pahang@mida.gov.my

KELANTAN

Director
Malaysian Investment Development Authority
Level 5-C, Menara Pejabat Kelantan Trade Centre
Jalan Bayam, 15000 Kota Bharu
Kelantan Darul Naim, Malaysia
Tel: (609) 748 3151 | Fax: (609) 744 7294
E-mail: kelantan@mida.gov.my

SELANGOR

Director
Malaysian Investment Development Authority
Level 22, Wisma MBSA, Persiaran Perbandaran
40000 Shah Alam, Selangor, Malaysia
Tel: (603) 5518 4260 | Fax: (603) 5513 5392
E-mail: selangor@mida.gov.my

TERENGGANU

Director
Malaysian Investment Development Authority
Level 5, Menara Yayasan Islam Terengganu
Jalan Sultan Omar, 20300 Kuala Terengganu
Terengganu, Malaysia
Tel: (609) 622 7200 | Fax: (609) 623 2260
E-mail: terengganu@mida.gov.my

SABAH

Director
Malaysian Investment Development Authority
Lot D9.4 & D9.5, Tingkat 9, Block D
Bangunan KWSP Karamunsing
P.O Box 11915, 88100 Kota Kinabalu, Sabah, Malaysia
Tel: (6088) 211 411 / 230 411 | Fax: (6088) 211 412
E-mail: sabah@mida.gov.my

SARAWAK

Director
Malaysian Investment Development Authority
4th Floor, Bangunan Bank Negara Malaysia Kuching
Jalan Satok, P.O. Box 716
93714 Kuching, Sarawak, Malaysia
Tel: (6082) 254 251 / 237 484 | Fax: (6082) 252 375
E-mail: sarawak@mida.gov.my

ASIA PACIFIC

SINGAPORE
Consul (Investment) / Director
Malaysian Investment Development Authority
No. 7, Temasek Boulevard, 26 – 01
Suntec Tower One, Singapore 038987
Tel: (65) 6835 9326 / 9580 / 7069
Fax: (65) 6835 7926
E-mail: singapore@mida.gov.my

JAPAN
TOKYO
Director
Malaysian Investment Development Authority
32F, Shiroyama Trust Tower, 4-3-1, Toranomon
Minato-ku, Tokyo 105-6032, Japan
Tel: (813) 5777 8808 | Fax: (813) 5777 8809
E-mail: tokyo@mida.gov.my

OSAKA
Director
Malaysian Investment Development Authority
Mainichi Intecio 18F, 3-4-5 Umeda
Kita-ku, Osaka 530-0001, Japan
Tel: (816) 6451 6661 | Fax: (816) 6451 6626
E-mail: osaka@mida.gov.my

REPUBLIC OF KOREA
Counsellor (Investment) / Director
Embassy of Malaysia
(Malaysian Trade and Investment Centre)
Malaysian Investment Development Authority
17th Floor, Standard Chartered Bank Korea
Limited Building, 47, Jongro, Jongno-Gu
Seoul 03160, Republic of Korea
Tel: (822) 733 6130 / 6131 | Fax: (822) 733 6132
E-mail: seoul@mida.gov.my

AUSTRALIA
Consul (Investment) / Director
Consulate of Malaysia (Investment Section)
Malaysian Investment Development Authority
Level 6, 16 Spring Street, Sydney N.S.W. 2000, Australia
Tel: (6102) 9251 1933
E-mail: sydney@mida.gov.my

TAIWAN
Director (Investment)
Malaysian Friendship & Trade Centre
Malaysian Investment Development Authority
12F, Suite A, Hung Kuo Building
No. 167, Tun Hua North Road
Song Shan District 10549, Taipei, Taiwan
Tel: 886 (2) 2718 6094 | Fax: (8862) 2514 7581
E-mail: taipiei@mida.gov.my

INDIA
Consul (Investment) / Director
Consulate General of Malaysia (Investment Section)
Malaysian Investment Development Authority
81 & 87, 8th Floor, 3rd North Avenue Maker Maxity
Bandra Kurla Complex, Bandra (E), Mumbai 400051, India
Tel: (9122) 2659 1155/ 1156 | Fax: (9122) 2659 1154
E-mail: mumbai@mida.gov.my

UNITED ARAB EMIRATES
Consul (Investment) / Director
Consulate General of Malaysia (Investment Section)
Malaysian Investment Development Authority
Unit 2205, 22nd Floor, Tower A
Business Central Tower, Dubai Media City
(P.O Box 502876) Dubai, United Arab Emirates
Tel: (9714) 4343 696 / 4343 697 | Fax: (9714) 4343 698
E-mail: dubai@mida.gov.my

PEOPLE'S REPUBLIC OF CHINA
SHANGHAI
Consulate General of Malaysia
(Investment Section)
Malaysian Investment Development Authority
Units 807-809, Level 8, Tower 1
Shanghai Kerry Centre
No. 1515, Nanjing Road (West)
Shanghai, 200040
People's Republic of China
Tel: (8621) 6289 4547
Fax: (8621) 6279 4009
E-mail: shanghai@mida.gov.my

GUANGZHOU
Director
Malaysian Investment Development Authority
Unit 1804B-05, CITIC Plaza Office Tower
233 Tianhe Bei Road Guangzhou
510610, People's Republic Of China
Tel: (8620) 8752 0739
Fax: (8620) 8752 0753
E-mail: guangzhou@mida.gov.my

BEIJING
Counsellor (Investment) / Director
Embassy of Malaysia
(Investment Section)
Malaysian Investment Development Authority
Unit C, 12th Floor, Tower A, Gateway Plaza
No.18 Xiaguangli, East Third Ring North Road
Chaoyang District, 100600 Beijing
People's Republic Of China
Tel: (8610) 8440 0071 / 0072
Fax: (8610) 8440 0076
E-mail: beijing@mida.gov.my

EUROPE

FRANCE
Director
Malaysian Investment Development Authority
42 Avenue Kleber, 75116 Paris, France
Tel: (331) 4727 3689 / 6696
E-mail: paris@mida.gov.my

GERMANY
FRANKFURT
Consul (Investment) / Director
Consulate General of Malaysia (Investment Section)
Malaysian Investment Development Authority
Level 9, HAT 64, Bleichstrasse 64-66
60313 Frankfurt Am Main, Germany
Tel: (4969) 8700 679-0
Email: frankfurt@mida.gov.my

MUNICH
Director
Malaysian Investment Development Authority
Level 6, Bürkleinhaus, Bürkleinstrasse 10
80538 Munich, Germany
Tel: (4989) 2030 0430 | Fax: (4989) 2030 0431-5
E-mail: munich@mida.gov.my

ITALY
Consul (Investment) / Director
Consulate of Malaysia (Investment Section)
Malaysian Investment Development Authority
2nd Floor, Via Alberico Albricci, 9
20122 Milan (MI), Italy
Tel: (3902) 8909 3824 | Fax: (3902) 8909 5418
E-mail: milan@mida.gov.my

SWEDEN
Malaysian Investment Development Authority
c/o Embassy of Malaysia
Karlavaegen 37, P.O. Box 26053
S-10041 Stockholm, Sweden
Tel: (468) 440 8400 / (468) 440 8416
Fax: (468) 791 8761
E-mail: stockholm@mida.gov.my

UNITED KINGDOM
Counsellor for Investment / Director
High Commission of Malaysia
Malaysian Investment Development Authority
c/o Embassy of Malaysia
17, Curzon Street, London W1J 5HR
United Kingdom
Tel: (4420) 7493 0616
Fax: (4420) 7493 8804
E-mail: london@mida.gov.my

TÜRKİYE
Director
Malaysian Investment Development Authority
APA-GIZ Plaza, Büyükdere Caddesi
No: 191 Level: 12, No: 24
34330 LeventİstanbuI / TÜRKİYE
Tel: +90212 905 11 00
E-mail: istanbul@mida.gov.my

UNITED STATES OF AMERICA

SAN JOSE
Director
Malaysian Investment Development Authority
226 Airport Parkway
Suite 480, San Jose, California 95110
United States of America
Tel: (1408) 392 0617
E-mail: sanjose@mida.gov.my

CHICAGO
Director
Malaysian Investment Development Authoriy
John Hancock Center, Suite 1810
875, North Michigan Avenue, Chicago, iL 60611
United States of America
Tel: (1312) 787 4532
Fax: (1312) 787 4769
E-mail: chicago@mida.gov.my

NEW YORK
Consul (Investment) / Director
Consulate General of Malaysia
(Investment Section)
Malaysian Investment Development Authority
313 East, 43rd Street, New York, NY 10017
United States of America
Tel: (1212) 687 2491
Fax: (1212) 490 8450
E-mail: newyork@mida.gov.my

MALAYSIAN INVESTMENT DEVELOPMENT AUTHORITY

HEADQUARTERS

MALAYSIAN INVESTMENT DEVELOPMENT AUTHORITY

MIDA Sentral, No.5, Jalan Stesen Sentral 5, Kuala Lumpur Sentral, 50470 Kuala Lumpur, MALAYSIA
Tel: (603) 2267 3633 | Fax: (603) 2274 7970 | E-mail: investment@mida.gov.my
Website: **www.mida.gov.my**

For more information, please contact:

LIFE SCIENCES & MEDICAL TECHNOLOGY DIVISION
Malaysian Investment Development Authority

Level 24, MIDA Sentral, No. 5, Jalan Stesen Sentral 5, 50470 Kuala Lumpur, MALAYSIA
Tel: (603) 2267 3495 | Fax: (603) 2274 5611 | E-mail: investment@mida.gov.my
Website: **www.mida.gov.my**

EDITION 2022/2023