MALAYSIAN INVESTMENT DEVELOPMENT AUTHORITY

RESILIENT PHARMA, ACCESSIBLE MEDICINES: AN APPROACH FOR NATIONAL HEALTH SECURITY


COVID-19
Vaccine
COVID-19
Vaccine
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Vaccine

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CLOSING THE GAPS IN PHARMACEUTICAL INDUSTRY OUTLINED IN THE NIMP 2030

The Government has rolled out two blueprints namely the National Investment Aspiration (NIA) that provides the overview of the priority sector, while the New Industrial Master Plan 2030 (NIMP 2030) provides the strategy and expedites the transformation priority areas, aligning it with the country's mission.

Both blueprints will intensify the economic complexity through production of high value-added products to further boost export complexity and advancing knowledge-based economy. The blueprints also aimed at meeting the medicine security agenda.
Local manufacturers are encouraged to move up the value chain by collaborating with strategic technical partners through contract manufacturing or joint development of new pharmaceutical products that will generate higher global value chain, technology transfer and knowledge sharing. The immediate opportunities in pharmaceuticals will focus on positioning Malaysia as a regional generic hub and bolstering Malaysian capabilities in biopharmaceutical products, leveraging the nation's niche biodiversity as an API producer for nutraceuticals and traditional medicine.

Malaysia's diverse genetic pool offers potential to position Malaysia as the early stage clinical trial hub in ASEAN.
The Malaysian government is committed to driving economic growth and achieving national goals through two strategic blueprints, namely the National Investment Aspiration (NIA) and the New Industrial Master Plan 2030 (NIMP 2030).
The NIA provides a comprehensive overview of priority sectors, guiding investment and development efforts, while the NIMP 2030 outlines the strategy to accelerate the transformation of these priority areas.
These blueprints aim to increase economic complexity by promoting the production of high-value-added products resulting in boost export complexity and advancement of the knowledge-based economy, and ultimately ensuring medicine security goal.
In moving up the value chain, local manufacturers are encouraged to collaborate with strategic technical partners, either through contract manufacturing or joint development of new pharmaceutical products targeting global value chain integration and technology transfer. This will facilitate Malaysia's positioning as a regional generic manufacturing hub and bolstering Malaysian capabilities in biopharmaceutical segment.
The nation's unique biodiversity provides and opportunity for the nation to become an active pharmaceutical ingredient (API) producer for the neutraceuticals and traditional medicine.

THE NIMP 2030 IS FURTHER DIVIDED INTO 6 KEY GROWTH AREAS

- NEW DRUG PRODUCT / INNOVATOR DRUGS
- TRADITIONAL COMPLEMENTARY MEDICINE
- BIOLOGICS
- HEALTH SUPPLEMENT
- GENERICS
- VETERINARY PRODUCTS

BUSINESS OPPORTUNITIES

Malaysia is still a net importer of pharmaceutical products, resulting in a significant trade deficit exceeding RM5 billion annually between 2019 and 2023. To address this imbalance, Malaysian pharmaceutical companies should prioritise the production of essential medicines listed on the National Essential Medicine List (NEML), particularly those used to treat non-communicable diseases (NCDs). This import substitution strategy will improve the nation's trade balance.

In building up Malaysian companies' capability to manufacture high-tech products such as vaccines, biosimilars and precision medicine, strong technical partners with ready-to-go technology transfer is critical to provide exposure during the early stage of biologic production. In 2022, based on the NEML, a total of RM779 million of pharmaceutical products were imported, of which more than RM400 million were high-tech products (biologics and biosimilars).

Category	2019	2020	2021	2022	2023
Export (RM million)	1,943.5	1,948.7	2,417.4	2,761.7	2,920.4
Import (RM million)	7,756.0	8,156.6	12,145.1	10,563.0	11,300.4
Balance (RM million)	-5,812.5	-6,207.9	-9,727.7	-7,801.3	-8,380.0

Table Import & Export Figure

Companies venturing into manufacturing high-end products should synergise with academia and local research institutes (IMR, NIBM - MGVI, research universities) to boost R&D efforts in hastening product development and commercialisation. The Malaysian government has steadily increased healthcare spending over the past five years (2021-2025), with an average annual allocation exceeding RM25 billion. In Budget 2025, this commitment was further reinforced with a 10% increase, bringing the total healthcare expenditure to RM45 billion. This funding will be crucial for upgrading infrastructure and addressing the nation's healthcare needs, driven by:

- Ageing society and rising NCDs - The ageing population is projected to spend more due to poor health, while NCDs will cost the country RM9.65 billion annually.
- Strain on the public healthcare system
- Public clinics handle 64% of outpatient visits despite representing only 28% of total primary healthcare facilities in Malaysia.

Key Economic Indicators

2022	2023
32.7 million Population	**33.4 million** Population
16.0 million Labour force	**16.9 million** Labour force
15.4 million Employment	**16.3 million** Employment
3.9% Unemployment rate	**3.3%** Unemployment rate
RM52,968 Per capita income	**RM54,015** Per capita income

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.

DEMOGRAPHICS - 2023*

Crude Birth Rate
(per 1000 population)
13.6

Crude Death Rate
(per 1000 population)
5.9

Infant Mortality Rate
(per 10,000 live births)
6.7

Life Expectancy-Male
(age in years)
71.8

Life Expectancy-Female
(age in years)
76.6

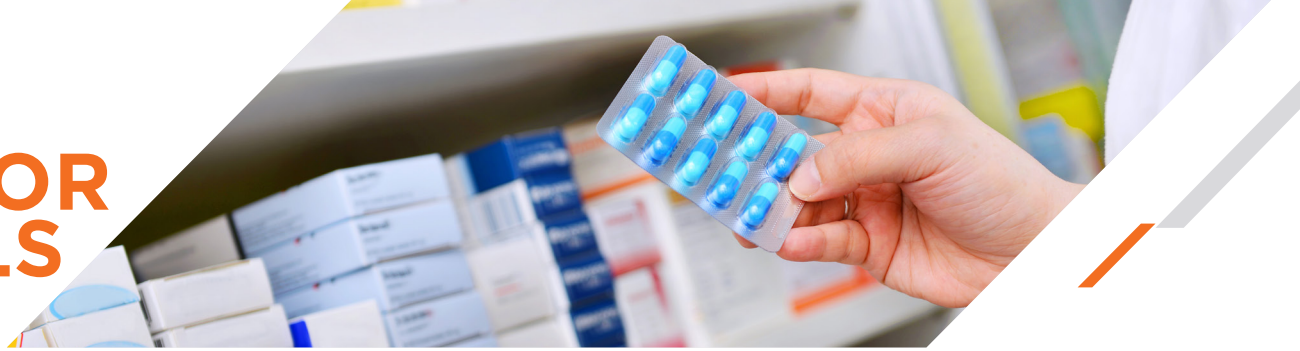
Provisional/Preliminary Data (as of December 2022)

HEALTH FACTS 2024*

NUMBER OF REGISTERED DOCTORS (Government and Private)	**82,227**
POPULATION PER DOCTOR	**1:406**
NUMBER OF HOSPITALS (Comprising Hospitals under MOH / MOD / MOE and the Private Sector)	**373**
NUMBER OF CLINICS (Government and Private)	**13,609**
NUMBER OF BEDS	**69,879**
NUMBER OF DENTAL CHAIRS (Comprising MOH-Operated Dental Clinics and Community Dental Clinics)	**3,279**

**Source: Malaysia's Vital Statistics on Births and Deaths: MOH 2024 Health Facts https://www.moh.gov.my/*

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 comes under the MOH. Under the NPRA is the Drug Control Authority (DCA), whose main task is to ensure the safety, quality and efficacy of pharmaceuticals, health and personal care products that are marketed in Malaysia.

Products manufactured by the industry include new drug products, generics (prescription and over-the-counter (OTC) products), nutraceuticals and traditional medicines, health and food supplements, and veterinary products. Domestic pharmaceutical companies produce generic drugs, traditional medicines and herbal supplements, as well as engage in contract manufacturing for foreign multinational corporations (MNCs). Whether producing for own brands or for MNCs, domestic 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 277 licensed 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.

Notable domestic pharmaceutical companies include Pharmaniaga Manufacturing Berhad, Duopharma Biotech Berhad, Kotra Pharma (M) Sdn. Bhd., Hovid Berhad, Goodscience Sdn. Bhd., Myvax Sdn. Bhd., Symbiotica Specialty Ingredients Sdn. Bhd., and Medica Natura Sdn. Bhd. These companies focus mainly on generic drugs, biosimilar, API, supplements, nutraceuticals and injectables.

MNCs with a manufacturing presence in the country include Biocon Sdn. Bhd., Novugen Pharma (M) Sdn. Bhd., Y.S.P. Industries (M) Sdn. Bhd. (Taiwan), Ranbaxy (M) Sdn. Bhd. (India), Xepa-Soul Pattinson (M) Sdn. Bhd. (Singapore) and SM Pharmaceutical Sdn. Bhd. (India). The prominent names in the global pharmaceutical industry who are mainly licensed importers distributing their branded drugs through locally incorporated 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 its members.

INVESTMENT OPPORTUNITIES

BIOPHARMACEUTICALS (BIOSIMILARS / BIOLOGICS)

The Malaysian government advocates the manufacture of NCDs medications, premium/ branded drugs and biopharmaceutical products as part of efforts to move up the value chain, achieve national health security, and generate economic growth.

To enhance national health security and drive economic growth, the Malaysian government is promoting the local production of high-value pharmaceuticals, including NCDs medications, premium brands, and biopharmaceuticals.

Malaysia already boasts a comprehensive, end-to-end pharmaceutical ecosystem, with domestic and foreign companies managing all aspects of the industry, from upstream to downstream. This includes the production of a full range of dosage forms, from sterile injections to soft gelatine capsules, as well as biopharmaceutical products such as monoclonal antibodies, recombinant proteins, biologicals and regenerative products.

In the area of generic drugs, Novugen Pharma Sdn. Bhd. operates the first integrated USFDA-approved facility in Malaysia, focusing on R&D and the production of oncology medications. Biocon Malaysia, also a USFDA-approved facility, manufactures insulin (a biosimilar), further demonstrating the country's advanced capabilities.

Venturing further into biopharmaceuticals promises significant economic benefits for Malaysia. It will boost the sector's contribution to GDP by creating high-value jobs and fostering innovation through R&D. This transition will also increase Malaysian exports, granting access to the global market while further diversifying the economy and improving its resilience. By adhering to international regulatory standards and alignment, Malaysia can ensure its biopharmaceuticals meet quality and safety benchmarks worldwide.

CONTRACT MANUFACTURING

Beyond manufacturing for domestic needs, the Malaysian pharmaceutical industry actively participates in contract manufacturing for global partners. It offers outsourcing services for patented, premium, and generic drugs, allowing MNCs to focus on drug discovery and R&D.

This collaborative approach benefits both companies, who gain valuable experience and revenue, and MNCs, who can leverage Malaysia's manufacturing expertise and cost-effective solutions.

GENERIC DRUGS

To date, more than 90 pharmaceutical companies in Malaysia are able to produce generics in almost all dosage forms, including sterile preparations, injectables, and soft gelatine capsules for antibiotics, injectables, painkillers and health supplements. These achievements are possible due to the presence of a significant number of available clinical trial and bioequivalence and bioanalytical (BE/BA) centres.

Despite Malaysian companies being able to produce various dosage forms of generic drugs, they are not producing 39% of the medicines listed on the National Essential Medicine List (NEML). In 2022 alone, Malaysia imports of NEML products stood at RM779 million, of which more than RM400 million was spent on high-tech biologics and biosimilars. This emphasises the need for domestic production to reduce reliance on imports and strengthen the industry to achieve the nation's medicine security.

NUTRACEUTICALS AND TRADITIONAL & COMPLEMENTARY MEDICINES

In addition to these strengths, the Malaysian nutraceutical and traditional & complementary medicine (TCM) market is experiencing rapid growth, both domestically and internationally, particularly in Asia. As consumers prioritise preventive healthcare to reduce costs, this segment is gaining significant traction. Leveraging the abundant supply of flora and fauna in Malaysia and the ASEAN region, Malaysian companies' welcome partnerships with technical and strategic experts to further develop and produce these products.

MANUFACTURING OF ACTIVE PHARMACEUTICAL INGREDIENTS (API)

Expanding API production presents another key opportunity. While there is already strong domestic demand for APIs, achieving economies of scale is crucial for the long-term sustainability of this sector. By positioning Malaysia as a regional manufacturing hub for APIs, the industry can cater to both local needs and serve the growing ASEAN market and beyond. This strategic approach will enhance Malaysia's position in the global pharmaceutical value chain.

WHY MALAYSIA

Malaysia is emerging as a prime location for pharmaceutical production due to a confluence of factors that create a compelling case for investment and growth in the sector.

ROBUST AND COMPREHENSIVE ECOSYSTEM

End to end capabilities

Malaysia boasts a complete pharmaceutical value chain, from API production and excipient manufacturing to formulation, packaging and distribution. This allows for streamlined operations and reduced reliance on external sources.

Established Infrastucture

The country has well-developed industrial parks, efficient logistic networks, and advanced manufacturing facilities, providing a solid foundation for pharmaceutical production.

SUPPORTIVE GOVERNMENT POLICIES

Pro-Investment Environment

The Malaysian government actively promotes the pharmaceutical industry through incentives, tax breaks, and streamlined regulations and ready infrastructure to support innovation, making it attractive for both local and foreign companies.

Focus on High-Value Production

The government is specifically encouraging the manufacture of complex generics, biosimilars, and other high-value pharmaceuticals, fostering innovation and technological advancement in the sector.

GROWING DOMESTIC MARKET

Rising Healthcare Needs

Malaysia's growing population and increasing prevalence of chronic diseases are driving demand for pharmaceutical products, creating a strong domestic market.

Focus on Preventative Health

The expanding nutraceutical and TCM market further strengthens the potential for local pharmaceutical production.

SKILLED AND AFFORDABLE WORKFORCE

Educated Talent Pool

Malaysia has a young and educated workforce with a strong command of English, ensuring a readily available pool of skilled labour for pharmaceutical industry.

Competitive Labour Costs

Compared to other developed nations, Malaysia offers competitive labour costs, making it a cost-effective location for pharmaceutical production.

COMMITMENT TO QUALITY AND COMPLIANCE

International Standards

Malaysian pharmaceutical manufacturers adhere to international regulatory standards and quality benchmarks, ensuring the production of safe and effective medicines.

USFDA-Approved Facilities

The presence of USFDA-approved facilities, like Novugen Pharma and Biocon Malaysia, demonstrates the country's commitment to meeting global quality standards

ABUNDANT NATURAL RESOURCES

Rich Biodiversity

Malaysia's diverse flora and fauna provide a valuable source of raw materials for pharmaceuticals, nutraceuticals, and traditional medicine.

Access to ASEAN Resources

The country's proximity to other ASEAN nations further expands access to a wide range of natural resources.

A THRIVING HUB FOR COLLABORATION

Contract Manufacturing Expertise

Malaysian companies actively participate in contract manufacturing, providing services to MNCs and fostering collaboration in drug development and production.

Welcoming Partnerships

The industry actively welcomes partnerships with technical and strategic experts, particularly in areas like biopharmaceuticals and nutraceuticals, to further enhance its capabilities.

By combining these strengths, Malaysia offers a compelling proposition for pharmaceutical companies seeking a strategic location for production, R&D, and market access. The country's commitment to quality, innovation, and collaboration positions it as a rising star in the global pharmaceutical landscape.

GUIDE TO SETTING UP A BUSINESS

Malaysia offers a competitive business environment, supported by facilitative agencies at both federal and local levels. The process of establishing a business is straightforward, with clear regulatory guidelines.

The key fees involved in setting up a business include payments to the Companies Commission of Malaysia (SSM) and company secretarial service fees.

- For a detailed list of applicable fees under the Companies Regulations 2017, visit **www.ssm.gov.my**

Beyond registration costs, investors should also consider expenses such as office rental, industrial land prices, ready-built factory costs, and factory construction expenses. These costs vary depending on the chosen business location.

For further details, visit **www.mida.gov.my**

GUIDE TO SETTING UP A BUSINESS

Establishing a business is a transparent and straightforward process, as outlined below.

REGISTER BUSINESS AND COMPANY INCORPORATION (Sole Proprietorships / Partnerships / Company)
Companies Commission Of Malaysia (SSM) **www.ssm.com.my**

APPLY FOR MANUFACTURING LICENCES AND / OR TAX INCENTIVES
Malaysian Investment Development Authority (MIDA) **www.mida.gov.my**

APPLY FOR OTHER APPROVALS AND PERMITS

APPROVALS AT THE LEVEL OF STATE GOVERNMENT AND LOCAL AUTHORITIES

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

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 Malaysia ..... **www.npra.moh.gov.my**
- Department of Occupational Safety and Health ..... **dosh.mohr.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.com.my**
WATER SUPPLY	Local Water Authority	**www.jba.gov.my**
TELECOMMUNICATIONS	Telekom Malaysia Bhd	**www.tm.com.my**

WORKFORCE

EXPATRIATES	MIDA; or	**www.mida.gov.my**
	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-established and continuously evolving system ensures the seamless movement of goods, including pharmaceutical products, to markets worldwide. Additionally, the Malaysian government is actively driving the rollout of 5G across the nation's telecommunications network to support the smooth adoption of Fourth Industrial Revolution technologies.

AVAILABILITY OF INDUSTRIAL ESTATES AND SPECIALISED PARKS

The diversified manufacturing sector is spread across the country, with well-developed infrastructure ensuring smooth and efficient operations. Industrial estates and parks as well as the Free Industrial Zones (FIZs), 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. In areas where FIZs are not available, businesses can set up Licensed Manufacturing Warehouses (LMWs).

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 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 and communications technology (ICT) It is also equipped with readily available infrastructure and amenities to support these specific sectors.

PENANG SCIENCE PARK

The Penang Science Park is designed with robust infrastructure and amenities to cater for strategic industries such as high-technology, biotechnology, halal industries, and Small and Medium Industries (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. Located in the district of Kulim, Kedah, in the northwest of Peninsular Malaysia, KHTP has developed more than 4,400 acres and is expanding further to accommodate an additional 7,000 acres to meet growing industry demands. The park is 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

As of 2023, 259 study sites in Malaysia have conducted sponsored research, with 45% based in public hospitals and government clinics under the Ministry of Health (MOH). Sponsored research has also gained traction in university hospitals (41%) and private centres (14%), where institutions are actively strengthening their clinical research capabilities and expertise in conducting global sponsored clinical trials.

Many of these sites have successfully delivered research that meets the quality and standards outlined in the Good Clinical Practice (GCP) guidelines. (Clinical Research Malaysia Annual Report 2023).

Private entities that have also carried out clinical trial includes:

- Infokinetics Research Centre Sdn. Bhd.
- International Medical University
- National Cancer Institute 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

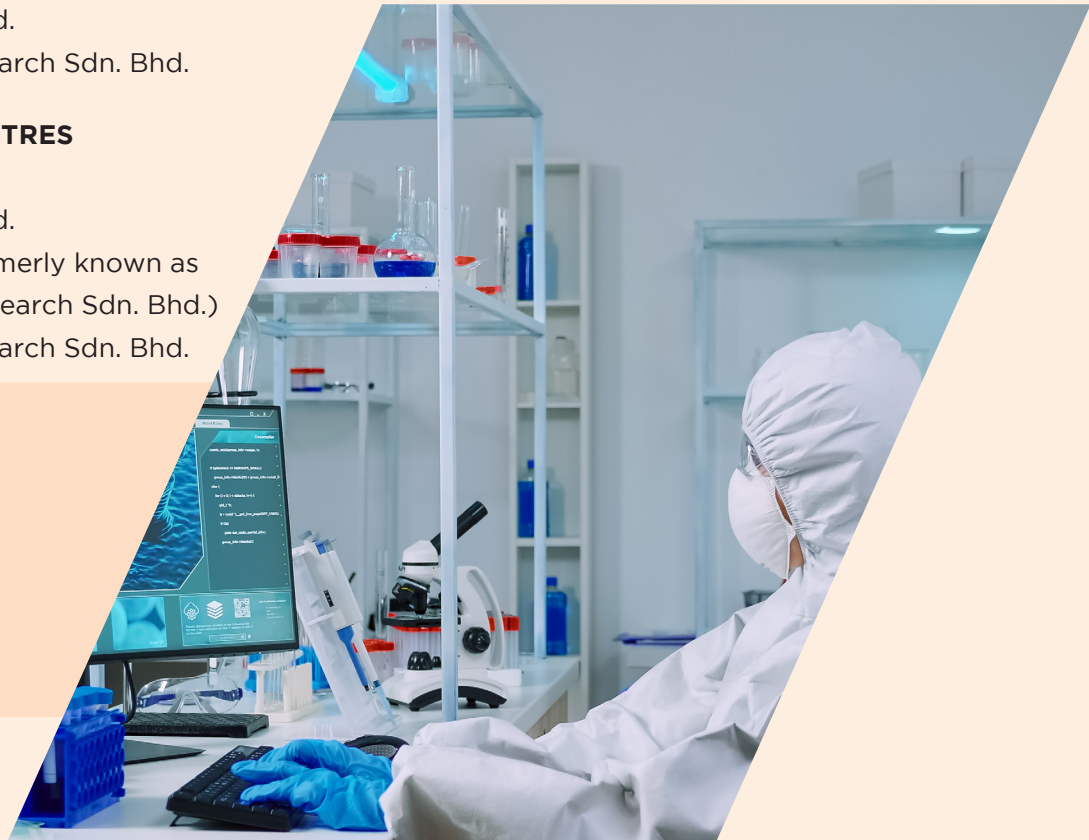
BIOEQUIVALENCE CENTRES

- Clinical Research Ward, Center for Clinical Trial
- Info Kinetics Sdn. Bhd.
- Questra Clinical Research Sdn. Bhd.

BIOANALYTICAL CENTRES

- Bioxis Sdn. Bhd.
- Info Kinetics Sdn. Bhd.
- Attest Sdn. Bhd. (formerly known as Pharmacy-Attest Research Sdn. Bhd.)
- Questra Clinical Research 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 undertake manufacturing of 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).

Foreign investors can hold up to 100 per cent of the equity in all investments in new projects, as well as investments in expansion / diversification projects by existing companies.

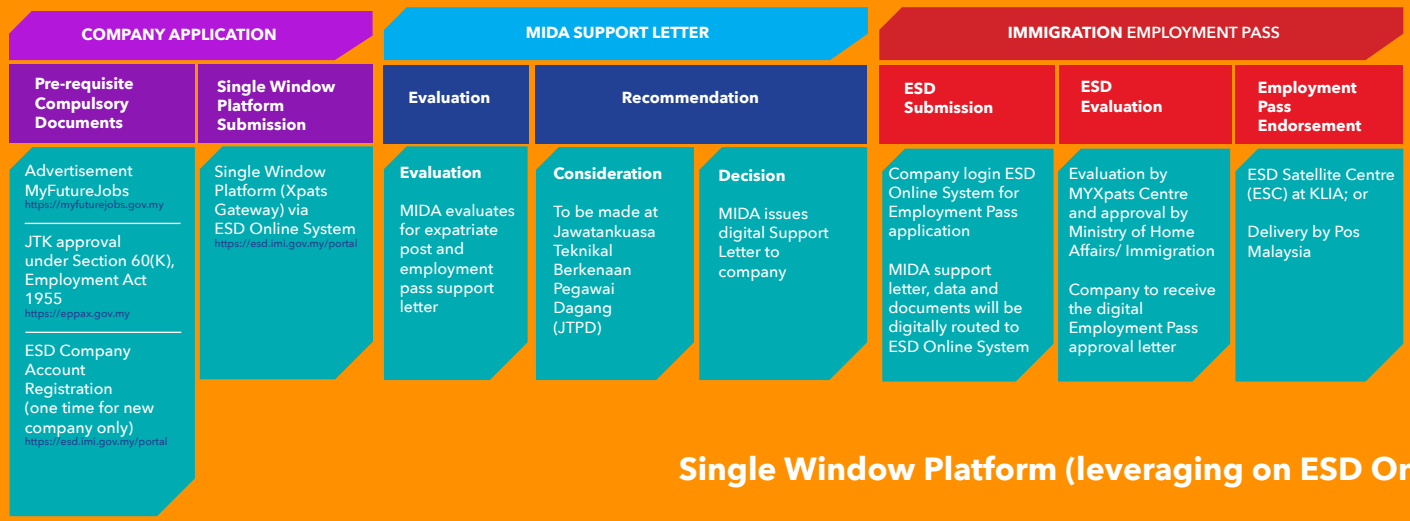
CRITERIA AND GUIDELINES OF EXPATRIATE POST APPLICATIONS

Manufacturing companies are allowed to bring in expatriate personnel to fill “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 positions that are permanently filled by expatriates, while term posts are positions approved for a stipulated period up to five (5) years.

Starting from 15th June 2023, applications for the expatriate Employment Pass (EP) has been centralised and fully implemented through Single Window Platform (SWP) known as Xpats Gateway System. Companies can now apply for expatriate posts and employment passes (EP) through the Xpats Gateway System accessible via the ESD online system at esd.imi.gov.my. For further details on the guidelines, please refer to SWP guideline

SINGLE WINDOW PLATFORM IN MIDA

Process Flow



KEY INCENTIVES AVAILABLE FOR PHARMACEUTICAL INDUSTRY

I. INCENTIVES FOR MANUFACTURING COMPANIES

II. INCENTIVES FOR HIGH TECHNOLOGY COMPANIES

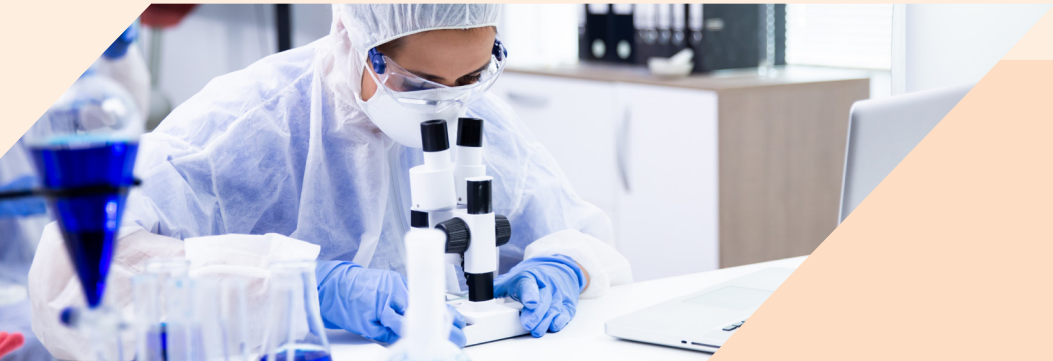
III. INCENTIVES FOR STRATEGIC PROJECTS

IV. INCENTIVES FOR R&D

V. DUTY EXEMPTION

VI. AUTOMATION CAPITAL ALLOWANCE EXPENDITURE (ACA)

VII. REINVESTMENT INCENTIVES UNDER THE NEW INDUSTRIAL MASTER PLAN 2030 (NIMP 2030)



INCENTIVES FOR MANUFACTURING COMPANIES

- Pioneer Status (PS) 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

- PS with full income tax exemption of statutory income for five (5) years; or
- ITA of 60% of 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

- PS 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).
- The following considerations apply to either incentive:
  - Level of investment
  - High Technology / technology transfer
  - Linkages with local ecosystem / vendor development
  - High income employment / technical skills
  - Level of R&D undertaken locally

INCENTIVES FOR RESEARCH AND DEVELOPMENT

CONTRACT R&D COMPANY

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

DUTY EXEMPTION

- 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 duty exemption please visit **https://www.mida.gov.my/forms-and-guidelines/**

AUTOMATION CAPITAL ALLOWANCE (AUTOMATION CA) INCENTIVE

Manufacturers are also eligible to apply for Automation Capital Allowance. This incentive is a key factor in encouraging automation in labour-intensive industries within manufacturing and services sector.

CATEGORIES FOR AUTOMATION CAPITAL ALLOWANCE

CATEGORY 1:
Labour-intensive industries industries (rubber products, plastics, wood, furniture and textiles), an automation capital allowance of 200% will be considered on the first RM10 million expenditure incurred within the year of assessment 2023 to 2027

CATEGORY 2:
For other industries, including the services sector, an automation capital allowance of 200% will be considered on the first RM10 million expenditure incurred within the year of assessment 2023 to 2027.

Scope of automation includes the adaptation of Industry 4.0 elements; and

The capital expenditure threshold for Categories 1 and 2 will be aligned and increased up to RM10 million.

REINVESTMENT INCENTIVES UNDER THE NEW INDUSTRIAL MASTER PLAN 2030 (NIMP 2030)

The Government, through Budget 2024, has introduced an incentive for reinvestment under the New Industrial Master Plan (NIMP) 2030 with a tiered and outcome-based approach. This provides opportunity for existing companies that have exhausted their RA under the Schedule 7A of Income Tax Act,1967 to continue to increase their capacity and investment in the country.

The Type of Incentives

TIER 1:
Investment Tax Allowance of 100% on the qualifying capital expenditure (excluding land cost) incurred for a period of 5 years to be offset against up to 100% of statutory income.

TIER 2:
Investment Tax Allowance of 100% on the qualifying capital expenditure (excluding land cost) incurred for a period of 5 years, to be offset against up to 70% of statutory income.

Application received by MIDA from 1 January 2024 until 31 December 2028 are eligible to be considered for this incentive.

INTELECTUAL PROPERTY (IP) PROTECTION

Malaysia has a 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 available, 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. The NPRA will provide facilitation for investors on GMP, dossier, and process validation assistance.

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;
- Medicines (Advertisement & Sale Act 1956.

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, or 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 the following categories:

- Over-the-counter (OTC) products (containing substances not listed in the Poison List)
- Traditional products
- Dietary supplements
- Cosmetics

These products must be certified and approved as Halal by the 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**

To learn more about Halal certification, visit the Halal Industry Development Corporation (HDC) 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.

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EDITION 2024