

Malaysia's Pharmaceutical Future

MALAYSIA'S PHARMA BOOM

The nation has created a conducive ecosystem for the sector to expand and attract investments from all over the world

The pharmaceutical industry in Malaysia can be categorised into generic drug manufacturers, research-based pharmaceutical companies and over-the-counter (OTC) manufacturers. Local companies mostly focus on traditional medicine, supplements, OTC drugs and generic drugs. Meanwhile, the imports and distribution of pharma products in Malaysia are dominated by multinational companies like Pfizer, Novartis, Eli Lilly, and Astra Zeneca. However, MNCs like Oncogen Pharma, Ranbaxy, Biocon, and GlaxoSmithKline have manufacturing units here.

The industry is closely monitored and regulated by the National Pharmaceutical Regulatory Agency (NPRA), an executive arm of Drug Control Authority (DCA), a regulatory body created under the Ministry of Health (MOH). The pharmaceutical manufacturers here are set at a high standard in compliance with the Good Manufacturing Practice (GMP), and Good Clinical Practice (GCP). Malaysia is a member of various international organisations that set global standards related to the

pharmaceutical sector such as the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement administered by the World Trade Organization (WTO), the World Intellectual Property Organization (WIPO) and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation/Scheme (PIC/S). Malaysia is one of the few countries in the region that has been accepted into the PIC/S. This has opened the global market for local manufacturers to export vitamins, supplements, OTC and generic drugs.

Malaysia's strong intellectual property laws make it attractive for foreign pharma companies. As a member of WTO, it abides by the TRIPS - the most comprehensive international agreement on intellectual property.

Currently, pharmaceutical manufacturers are eligible to be considered for partial or full income tax exemption on statutory income for five years under the Pioneer Status scheme or Investment Tax Allowance of 60 per cent on the qualifying capital expenditure for five years to be offset against

70/100 per cent of the statutory income. The Malaysian government is also offering partial grant facilities for research and development and high-tech training of Malaysians to potential investors based on the merit of the project.

To further attract investment in the manufacturing of pharma products in Malaysia, the government recently announced enhanced incentives such as Off-Take Agreement and a preferential tax rate of 0 to 10 per cent for 10

rate for 15 years for new investments with capital investment over RM500 million (USD121.4 mill).

Malaysia has also developed several infrastructure projects to support the growing needs of the pharmaceutical industry. These include the Technology Park Malaysia in Kuala Lumpur, Kulim Hi-Tech Park and Penang Science Park in the northern part of Malaysia.

Malaysia is part of the Regional Comprehensive Economic

The government aims for Malaysia to be a clinical trial hub in Asia by increasing the number of trials conducted per year to 1,000. The Clinical Research Centre (CRC) has been formed to support the growth of this niche sector.

India's existing advantage of large-scale pharmaceutical production allows it to significantly leverage its expertise by investing in the outward growth of the pharmaceutical industry of other nations. Therefore, a much greater potential for India's pharmaceutical companies now to increase presence in Malaysia as a major manufacturing hub, especially for exports to ASEAN countries and other parts of the world.

Currently, Malaysian manufacturers import most of the raw materials and inputs, such as active pharmaceutical ingredients (APIs) and excipients (the inert substance). The pharmaceutical industry has not escaped the pandemic's impact. The increased demand for pharmaceutical products due to awareness towards having strong immune system has led the manufacturers to increase production capacity. Malaysia would need API

manufacturing companies to set up their facilities in Malaysia to enhance pharmaceutical ecosystem in the country.

Therefore, Indian companies should grab the opportunities to be part of the Malaysia pharmaceutical industry ecosystem. Malaysia is seen as a cost-competitive country for Indian companies to expand their operation with access to the larger markets through FTAs, no restrictions on equity, generous incentives and the world-class infrastructure.

India and Malaysia have a long history of business relations with the presence of over 160 Indian companies operating in Malaysia. The relationship has been dynamic, evolving in the rapidly changing international environment. To further strengthen business ties with India, the Malaysian Investment Development Authority (MIDA), the principal investment promotion agency for the country, set up its overseas office in Mumbai in 2008.

This office is responsible for the promotion of quality Indian investments into Malaysia, to provide potential investors with the latest information on policies and opportunities in the manufacturing and services sectors, as well as providing the necessary assistance to potential Indian investors interested in seeking joint venture partners or technology collaborations in Malaysia.

THE PHARMACEUTICAL MARKET IN MALAYSIA IS AN EXCITING PLACE TO INVEST. WITH SEVERAL PROACTIVE POLICIES BY THE GOVERNMENT, THE INDUSTRY IS ALL SET FOR EXPONENTIAL GROWTH IN THE COMING YEARS

years. The nation is also offering a special relocation incentive until December 2022 for new investments in the manufacturing sector. This includes a zero per cent special tax rate for 10 years for new investments with capital investment between RM300 million (USD72.8 mill) to RM500 million (USD121.4 mill) or a zero per cent special tax

Partnership (RCEP), which is the largest FTA in the world that encompasses the 10 ASEAN countries, China, Japan and South Korea, as well as Australia and New Zealand. It will have a market of 2.2 billion people, accounting for nearly a third of the world's gross domestic product and trade flow of USD12 trillion.

INFRA PUSH FOR PHARMA: THE SUCCESS STORY

Malaysia has consistently improved its strategies to boost its pharmaceutical sector. The nation has accomplished many goals in this sector over time

AS OF 31 DECEMBER 2019; 263 PREMISES/ FACILITIES LICENSED BY DRUG CONTROL AUTHORITY (DCA):

- ✓ **Pharmaceutical Premises**
70
 - ✓ **Traditional Medicine Premises**
182
 - ✓ **Veterinary Premises**
11
- During same period; 23,254 products registered with DCA and segmented into:
- ✓ **Natural Products**
12,138
 - ✓ **Prescription Products**
4,232
 - ✓ **Non-Prescription Products**
1,581
 - ✓ **Traditional Products**
2,627
 - ✓ **Health Supplements**
2574
 - ✓ **Veterinary Products**
805

The pharmaceutical industry in Malaysia is currently experiencing rapid growth. Over the years, manufacturers here have demonstrated their capabilities to produce pharmaceutical products in various dosage forms. These products have the access to the global market, specifically in Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation/Scheme (PIC/S) member countries, as Malaysia is itself a member of PIC/S. The production of generic products in Malaysia is focused on domestic consumption and the nation relies heavily on the import of medicaments for lifestyle diseases such as high cholesterol, diabetes, cardiovascular and cancer.

RAPID EXPANSION

Malaysian pharmaceutical manufacturers produce generic medicines, as opposed to originator medicines. The local industry produces 70 per cent of the generic medicine consumed in the country. Majority of the importers of pharmaceutical products are MNCs with registered offices in Malaysia to register their products in the Malaysian market. Imported medicines are predominantly patented products. Nevertheless, the local manufacturers have the capabilities to produce almost all dosage forms including sterile preparations, injections and soft gelatin capsules. Therefore, there are opportunities for MNCs to collaborate with Malaysian manufacturers in contract manufacturing or setting up manufacturing facility in Malaysia

to cater for regional market.

MAJOR PLAYERS

Kotra Pharma is currently one of the major players. Founded in 1982, Kotra Pharma (M) Sdn. Bhd. (Kotra Pharma) is a wholly-owned subsidiary of Kotra Industries Berhad (KIB), a public listed company on the main board of Bursa Malaysia Securities Berhad. It is known for products in paediatric care, anti-infectious drugs and dermatological treatments that meet various prescription medication needs in the dosage form of tablets, capsules, creams and ointments. It has a strong presence in over 30 countries including the Middle East, African and ASEAN regions. Its manufacturing and research facility, Kotra Pharma Technology Centre, is a Good Manufacturing Practice (GMP) compliance facility, equipped with modern technology and was awarded Industry Excellence Award in 2012 by the NPRA.

HUB OF PHARMA

With its vast portfolio of oncology products, Oncogen Pharma is one of the fastest-growing companies in Malaysia. Its facility in Malaysia is its first Oncology API R&D Centre in the ASEAN region. In 2016, it completed the Formulation Research and Development Centre based in Glenmarie and later acquired industrial land in Bandar Enstek, Negeri Sembilan for its manufacturing facility. Malaysia's strategic importance, ease of operations, quality of infrastructure, and talent pool of upcoming scientists attracted Oncogen Pharma to set up its facility here.

Malaysia is an enticing investment destination. It has developed infrastructure, stable political climate, and a large pool of skilled workforce. Moreover, the pro-active support of various government agencies, such as MIDA has efficiently facilitated investments into the country

MALAYSIA: A VIBRANT HUB

Malaysia is fostering a conducive environment for the growth of Biotech

Biocon Biologics Integrated Insulins Manufacturing Facility in Malaysia is playing a very important role in enabling Biocon Biologics mission of impacting millions of patients' lives across the globe. It furthers Biocon's aspiration of ensuring '1 in 5' insulin dependent people across the globe have access to its high quality yet affordable insulins.

growth of the industry.

Biocon's plant in Malaysia is the largest integrated insulin manufacturing and R&D facility in Asia with an investment of over USD350 million. This facility manufactures insulin drug substance and drug products in vials, cartridges and devices. This is the largest foreign investment in biotechnology in Malaysia.



The company started commercial operations in Malaysia in 2016 with recombinant human insulin becoming the first locally manufactured biosimilar product approved for sale in Malaysia. Since then, Biocon has been supplying to the Ministry of Health, Malaysia with the range of insulin products that have benefitted over 350,000 people with diabetes in Malaysia.

The first overseas biologics manufacturing and R&D facility in Malaysia and the Malaysian government providing an enabling ecosystem. When Biocon were looking at expanding the capacities to meet the growing global needs of high quality, affordable insulin and analogs, Malaysia was chosen due to attractive government policies and a conducive environment for the biotech industry. The government put in place a highly supportive legal, financial and institutional ecosystem to enable the

Today, Biocon Sdn Bhd is the only healthcare company in Malaysia to have approvals from both the U.S. Food and Drug Administration and European Medicines Agency for sterile injectables. 'Made in Malaysia' insulins are today making a difference to people with diabetes in developed markets of U.S., Australia and Europe as well as selected emerging market countries. The company has employed the best of talent from Malaysia's top universities and have built a pool of over 750 trained science personnel- at our facility.

In creating this incredible journey, the support from various authorities has been commendable. The initial experience of obtaining business approvals for setting up a large manufacturing facility set the course for the long haul. Biocon is excited to be part of the growth of Malaysia as a vibrant hub in the ASEAN region.

Pioneer in certified halal pharma products

Malaysia's pharmaceutical industry's work on halal certified products is garnering praise from across the globe

Halal pharmaceutical products are steadily gaining popularity throughout the world. The increasing number of Halal certifications worldwide is likely to boost its market growth. Halal pharmaceuticals are drug products that are derived from a permissible source i.e., animals, plants, organic or inorganic substance that follows a method of preparation, manufacturing and extraction that

follows the recommendations of Islam.

According to Adroit Market Research, the Halal pharmaceuticals market is projected to reach USD174 billion by 2025 growing with a CAGR of 9.4 per cent. The Asia Pacific is likely to remain the largest market comprising high Muslim population followed by the Middle East, Africa and Europe. Halal pharmaceutical products are well supported by the increasing demand

among both the Muslim and non-Muslim consumers worldwide.

Malaysia is the pioneer in the certified Halal pharmaceutical industry for its global Halal pharmaceutical standards. The world's first Halal pharmaceutical standard the Malaysian MS 2424:2012 Halal Pharmaceutical Guidelines was launched in 2012. MS2424:2012 was developed by the country's Department of Standards Malaysia in cooperation

with the Department of Islamic Development Malaysia (JAKIM).

Currently, Malaysia has over 150 companies that have obtained Halal certification by JAKIM for various types of pharmaceutical products such as over-the-counter (OTC), health and food supplements and traditional medicines segments. Malaysia has produced many prominent Halal pharmaceutical companies and one of them is

Duopharma Biotech Berhad.

Malaysia is recognised to have the potential in championing the Halal pharmaceutical manufacturing due to membership to the Organization of Islamic Committee (OIC) and being a member of Pharmaceutical Inspection Cooperation/Scheme (PIC/S). As a member of PIC/S, Malaysia has already owned its standing in the pharmaceutical industry globally.

Malaysia is an ideal location for Indian pharmaceutical companies to invest in Halal pharmaceuticals as the country provides incentives, infrastructure and market for the companies. Malaysia had also established a separate Halal certification scheme for pharmaceutical products due to the specialised requirements.

Malaysian Halal standards have been recognised in many other countries, including the Organization of Islamic Cooperation (OIC) and most Muslim countries. Therefore, Indian companies could position Malaysia as their hub for the manufacturing of Halal pharmaceuticals to penetrate the regional and global halal industry.