Kim Ribbink

MALAYSIA Focuses on Growth with Healthcare a Top Priority

Malaysia presents an attractive market to pharmaceutical companies thanks to growing government support, good infrastructure, and a trusted manufacturing environment.

Malaysia is a federal constitutional monarchy with a population of about 29 million and an open and growing economy. According to the World Bank, Malaysia has successfully reduced poverty from more than 50% of households living below the poverty line in the 1960s to less than 2%. However, pockets of poverty persist and income inequality is high compared with developed nations, such as the Republic of Korea and Japan.

While its population is small compared with many other countries in the region, Malaysia is strategically located in the heart of Southeast Asia and is one of the gateways to a regional market of more than 600 million people — larger than the population of the United States and Japan combined, says Siew-Ping Goh, senior director and general manager, Quintiles Malaysia.

Malaysia is in the midst of an Economic Transformation Programme (ETP) designed to elevate the country to developed-nation status by 2020, says Ash Kuchel, global group president, Publicis Healthcare Communications Group.

Launched in 2010, the ETP focuses on 12 National Key Economic Areas (NKEAs) to drive growth and generate revenue. One such area is healthcare, Mr. Kuchel says.

"Under the healthcare NKEA are six core focus areas: private health insurance for foreign workers, creating a solid foundation to support 1,000 clinical trials by 2020, pursuing generic opportunities, promoting Malaysia as a destination for medical tourism, building and improving teleradiology services, and developing a medical metropolis, each presenting significant opportunity for healthcare companies and marketers," he says.

Ames Gross, president of Pacific Bridge Medical, says designating healthcare an NKEA has led to greater investment in developing an advanced clinical research hub, improving the healthcare infrastructure, building biotechnology parks, expanding the medical tourism industry, and promoting the manufacture of generic pharmaceuticals for export.

In December 2013, the government announced 10 new projects valued at $300 million under the healthcare NKEA program, Mr. Gross says. This brings the total to 37 NKEA healthcare projects.

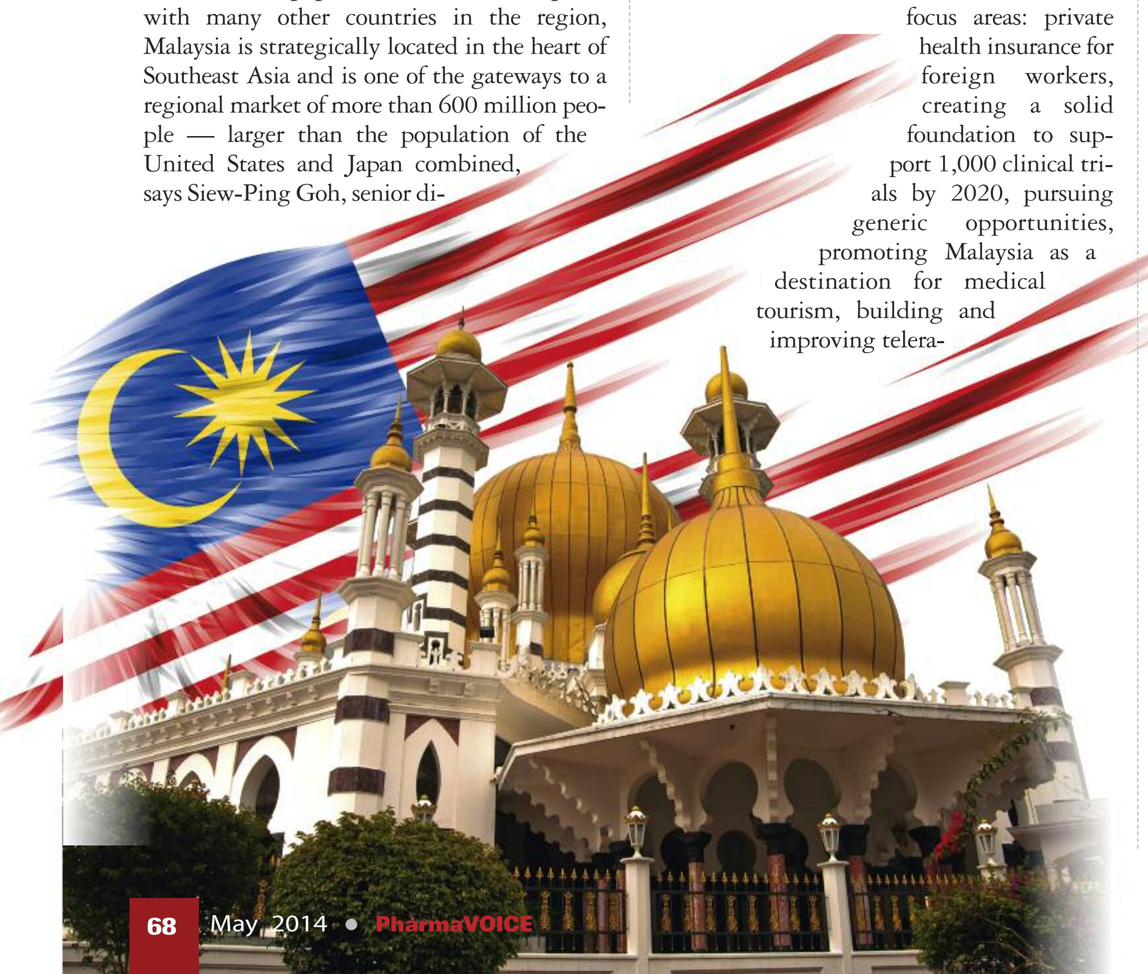
Pharma Climate

The healthcare sector is a leading driver of economic growth in Malaysia, growing at 11% per year, which is double Malaysia's overall 2012 growth rate of 5.5%, according to Pacific Bridge Medical. The consulting firm also estimates Malaysia's pharmaceutical market to be worth $3.2 billion in 2013, making it about three times larger than that of its neighbor Singapore.

Malaysia's healthcare sector has seen strong growth over the past decade. Ms. Goh says changing demographics, a more affluent society, and more health-conscious lifestyles have led to the creation of a robust domestic industry.

The government in Malaysia supports both the domestic pharmaceutical industry and in-country facilities of foreign drug companies, Mr. Gross says.

While the trend for multinational companies has been to import their pharmaceutical products into Malaysia and then market them



Malaysia at a glance

Total population: 29,240,000

Gross national income per capita (PPP international $): 16,270

Life expectancy at birth m/f (years): 72/76

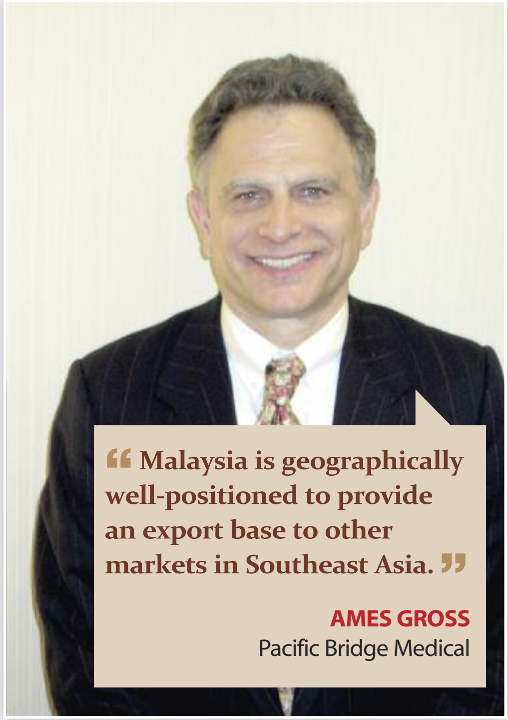
Probability of dying under five (per 1,000 live births): 9

Probability of dying between 15 and 60 years m/f (per 1,000 population, 2011): 174/90

Total expenditure on health per capita (Intl $, 2011): 616

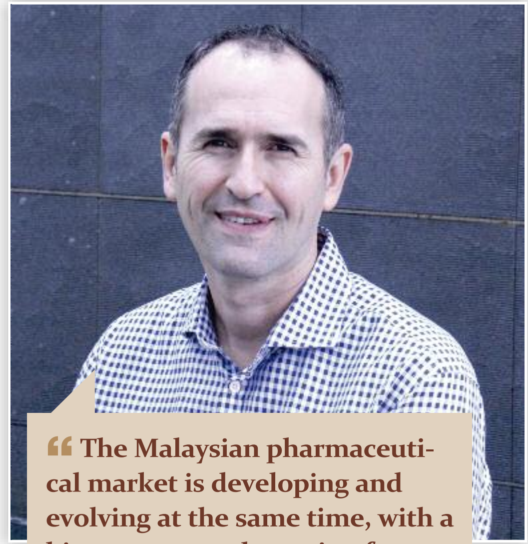
Total expenditure on health as % of GDP (2011): 3.8

Source: Global Health Observatory.



“Malaysia is geographically well-positioned to provide an export base to other markets in Southeast Asia.”

AMES GROSS
Pacific Bridge Medical



“The Malaysian pharmaceutical market is developing and evolving at the same time, with a big strategy push coming from the government.”

DR. VINCE GRILLO / Kantar Health

through either their own sales teams or local distributors, in recent years the government has become much more supportive of foreign companies building pharmaceutical facilities in Malaysia. This has led to a corresponding increase in the number of foreign firms building Malaysian manufacturing plants, Mr. Gross says.

“For foreign drug companies looking to establish facilities in Malaysia, the government offers a variety of incentives, including duty exemptions, a 10-year tax holiday, and the ability to easily access other ASEAN markets through free trade agreements,” Mr. Gross says.

Global pharmaceutical companies that have contract manufacturing facilities in Malaysia include Pfizer, Lilly, and AstraZeneca, Mr. Kuchel says.

Experts say Malaysia is one of the few countries in the region to be a member of the Pharmaceutical Inspection Cooperation/Scheme (PIC/S), and the government is considering permitting only audited PIC/S equivalent international generics into the Malaysian market, notes Vince Grillo, Ph.D., general manager, Kantar Health Singapore and Malaysia.

This, combined with the fact that Malaysia also has an export-oriented strategy targeted at the Organisation of The Islamic Conference (OIC) countries, will be an advantage as the country targets pharmaceutical manufacturing needing halal standards, Dr. Grillo says.

The country also has a strong infrastructure, which includes high-end hospitals, an established medical tourism industry, and a reputable healthcare system, divided into public and private sectors.

Additionally, Malaysia is geographically well-positioned to provide an export base to other markets in Southeast Asia, Mr. Gross says.

“Malaysia also offers a skilled and often English-proficient labor-force, good patent protection, a developed infrastructure, and comparatively low-cost overhead expenses for labor and land,” he adds.

The Malaysian government wants to foster growth in private healthcare services and is encouraging more private investments in areas such as the manufacturing of biopharmaceutical products and medical devices, and in clinical research, while supporting collaboration between public and private healthcare providers, Ms. Goh says.

On the Ground

Historically, Malaysia’s pharmaceutical market is comprised of small-to-medium-sized companies focused on generic, over-the-counter medications, and traditional medicines, including herbal or natural supplements.

According to the Malaysian Investment Development Authority, the government's principal agency for the promotion of the manufacturing and services sectors in Malaysia, there are 246 licensed manufacturers in Malaysia. Of these, 51 are licensed to produce “modern medicines,” including antibiotics or analgesics, while the remaining 172 are licensed to produce traditional and herbal medicines, Mr. Kuchel says.

Large local companies include Hovid Berhad, Pharmaniaga Manufacturing Berhad, and CCM Duopharma Biotech Sdn Bhd, according to Pacific Bridge Medical. Local manufacturers produce mostly generics, especially antibiotics, injectables, painkillers, and health supplements.

According to the Malaysia External Trade Development Corporation (MATRADE), the National Trade Promotion Agency of Malaysia, the country can produce almost 80% of the various categories of drugs in the Malaysian Essential Drugs List. But experts say the country still imports most high end drugs.

“The government is looking at developing its local generics manufacturing and considering permitting only audited PIC/S equivalent international generics into the Malaysian market,” Dr. Grillo says.

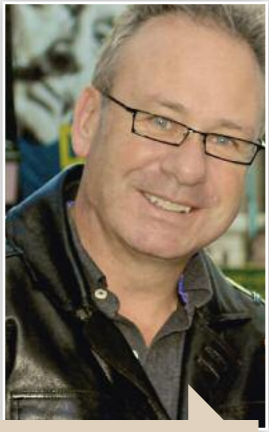
He adds that the government wants to push the industry toward what it calls “more profitable” medical technology such as medical devices, diagnostic equipment, and healthcare information technology.

“It also wants to pursue more exports of generics and enhanced generics through refocusing on higher value manufacturing,” he says.

The sector is expected to generate $11 billion (RM35.5 billion) of gross national income and create 181,000 new jobs by 2020. To achieve this target, the Malaysian health ministry announced 22 Entry Point Projects (EPP) from 2010 to 2013, including projects focusing on clinical trials, generics manufacturing, diagnostics services, and medical devices.

“The EPPs supporting Malaysia’s Healthcare NKEA clearly distinguish the country as a pharmaceutical market by identifying untapped opportunities and implementing initiatives that contribute to the overall development of Malaysia’s healthcare industry in an organized and progressive manner,” Ms. Goh says.

While the local industry has been domi-



“ It’s an exciting time to be watching Malaysia, as it’s currently in the midst of a large-scale Economic Transformation Program designed to elevate the country to developed-nation status by 2020. ”

ASH KUCHEL
Publicis Healthcare Communications Group

“ Malaysia has outlined plans to create a supportive ecosystem to grow clinical research in-country. ”

SIEW-PING GOH
Quintiles

nated by the public healthcare sector, over the past decade there has been tremendous growth of private healthcare services. Ms. Goh says the government is eager to encourage more private investments in areas such as manufacturing of pharmaceutical products, medical devices, clinical research, care services for the elderly, and supporting collaborative efforts between public and private healthcare providers.

One factor holding Malaysia back is the fact that the country has been slower than its neighbor Indonesia to develop its large-picture strategy, Mr. Kuchel says.

“For instance, at present, Malaysia remains a large importer of generic products, although one of the country’s key areas of growth centers on pursuing and attracting opportunities to manufacture and market generic medications,” he says.

“As a manufacturing country with established success in formulation, Malaysia could position itself to produce the generic version of medications that are set to lose patent in the coming years, or contract with larger companies to manufacture the new generics on their behalf,” Mr. Kuchel adds.

Malaysia is also competing with a number of other countries in the region for healthcare dollars, including Singapore, Thailand, and China, Dr. Grillo says.

“These countries either have a bigger population or have, to date, attracted more global investment,” he adds.

On the regulatory front, long waiting times for approval and stringent requirement on GMP and quality control procedures present a hurdle, Dr. Grillo says.

Clinical Research

The Malaysian Health Ministry has embarked on several initiatives to reach the goal of healthcare contributing $11 billion to the nation economy by 2020, including the establishment of Clinical Research Malaysia (CRM) in 2011.

The CRM is a not-for-profit organization wholly owned by the Malaysian government, Ms. Goh says. Established in 2012, the CRM’s vision of CRM is to establish Malaysia as a preferred destination for clinical contract research.

“The CRM leverages the strengths of the Malaysian health ministry’s integrated and extensive network of hospitals to collaborate with stakeholders to develop, expand, and strengthen the clinical research industry in Malaysia,” she says. “The CRM also supports investigators in managing and conducting clinical trials in the health ministry’s facilities, thereby accelerating growth of industrial-sponsored clinical trials and clinical trial sites.”

However, in terms of trial volume, Malaysia trails behind other countries in the region such as South Korea, China, and Hong Kong, and closer neighbors such as Thailand and Singapore, Ms. Goh says. However, the country has outlined plans to create a supportive ecosystem to grow clinical research in-country as one of the EPPs under the healthcare NKEA.

“The clinical research EPP calls for at least 1,000 clinical trials to be conducted in Malaysia and for the development of improvements in the clinical research ecosystem to support more efficient and higher quality trials by 2020,” she says. “One of the key initiatives under the clinical research EPP is the establishment of Clinical Research Malaysia, or CRM, to stimulate growth of clinical trials. Since the launch of CRM, seven new Malaysian Health Ministry hospital Clinical Research Centers — CRCs — were established, bringing the number of hospital CRCs in Malaysia to 27 in 2012.”

One distinct advantage Malaysia offers is its lower cost of conducting clinical trials relative to other developed countries with similar infrastructure. With a population of 29 million people, Malaysia also has a sizeable patient pool contributing to a wide spectrum of therapeutic areas for both infectious and non-communicable diseases, Ms Goh says.

The challenge, however, is the lack of skilled workers, although plans are in place to build a talent pool of clinical research associates for international CROs in Malaysia, as well as site coordinators to assist in the conduct of ISR and other research-related areas.

Ms. Goh says Quintiles is working with the government and CRM/CRC to create a strong, sustainable clinical research ecosystem needed to achieve the ambitious target of 1,000 industry-sponsored trials by 2020. Quintiles is working with sites and investigators on training and also to drive efficiencies at sites by improving patient recruitment, data quality, timelines for start-up, and overall clinical trial management.

“Quintiles is building strong relationships with key sites and investigators,” she says. “Some of these relationships are with what we call prime sites, which includes the University Malaya Medical Center (UMMC), that signed on to become the first Quintiles prime site in the Asia-Pacific.”

“We are also working with CRM/CRC and the Malaysian health ministry to identify and develop sites and investigators who have an interest in participating in clinical research — the other key element for clinical research infrastructure.”

The Malaysian Health Landscape

According to the World Health Organization, Malaysia’s total health expenditure per capita (public and private) in 2008 is $620, more than the Asia-Pacific countries of China, India, Philippines, and Indonesia.

Malaysia has a dual structure of public and private health sectors, like many healthcare systems worldwide, Dr. Grillo says.

Mr. Gross says about two-thirds of Malaysians are covered under the government’s healthcare system, while a growing private system provides coverage to those that can afford it. Out-of-pocket spending accounts for about 45% of total healthcare expenditures. PV

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Healthcare *NKEA* Fact Sheet

The healthcare sector is a leading driver of economic growth in Malaysia. Changing demographics, a more affluent society, and more health-conscious lifestyles have led to the creation of a robust domestic industry.

While the local industry has been dominated by the public healthcare sector, over the past decade, there has been tremendous growth of private healthcare services. As such, the government aims to further grow this sector by encouraging more private investments in areas such as manufacturing of pharmaceutical products, medical devices, clinical research, aged-care services, and supporting collaborative efforts between public and private healthcare providers.

By 2020, the Healthcare NKEA targets the sector to generate RM35.5 billion in GNI and create 181,000 new jobs.

Vince Grillo, Ph.D., general manager, Kantar Health Singapore and Malaysia, notes that by 2020, Malaysia will be an aging nation, with 10% of its population above the age of 60. Like all developing countries, it is seeing a shift of major health problems from acute infectious diseases to chronic, lifestyle-related disorders like cardiovascular diseases, diabetes mellitus, cancers, and age-related disorders.

In fact, non-communicable diseases (NCDs) have been reported by the Malaysian Ministry of Health (MOH) as the primary reason for mortality, premature death, and hospital admittance. About three-fourths of Malaysian adults already have a NCD, while NCD-related mortality is expected to increase more than 15% over the next 10 years, says Ames Gross, president of Pacific Bridge Medical.

"Cardiovascular diseases have been the fastest growing NCDs over the past decade in terms of both incidence and mortality — about 45% of Malaysians age 30 and older have hypertension," Mr. Gross says. "Obesity is also a problem, as about one-third of Malaysians over the age of 30 are obese. In Southeast Asia, Malaysia is the most overweight nation. One-fifth of Malaysians over 30 years of age have diabetes, although many have not been diagnosed. Malaysia will also soon be classified as an aging society."

The region is also seeing an increased focus on long-term projects for the aging population, says Ash Kuchel, global group president, Publicis Healthcare Communications Group. By 2020, 9.9% of the population will be over age 60, and by 2050, that number will be more than 20%, according to Global Health Watch. Investments are being made into longer-term initiatives, such as mobile health services, and even the development of retirement villages.

Dr. Grillo adds that as personal incomes have increased in tandem with the country's economic growth, people are spending more on healthcare. The result is growing pressure on the public healthcare system, such as a higher doctor-patient ratio compared with the private sector and the challenge of attracting more doctors to the public sector.

"The government is managing this dual structure by encouraging investment in the private sector while ensuring that a wide range of affordable and good quality care is available to the people," he says. "For example, one of MOH's goals is to promote and increase public satisfaction of at least 600 public health clinics in 2015 from 365 clinics in 2010. The government is also encouraging the use of tele-primary care to expand coverage and quality of healthcare, especially to people living in rural areas. In the MOH's Strategic Plan 2011-2015, the goal was to have at least 10% of public hospitals with the infrastructure to provide online teleconsultation services to target patients."

List of Entry Point Projects (EPPs)

EPP 1: MANDATING PRIVATE INSURANCE FOR FOREIGN WORKERS

Malaysia has about 3.1 million foreign workers in low-technology, labor-intensive jobs. Many were uninsured or under-insured, resulting in RM71 million in unpaid bills in government hospitals.

Beginning Jan. 1, 2011, through the Hospitalization and Surgical Scheme for Foreign Workers (SPIKPA), private health insurance is now accessible and made mandatory for foreign workers, which will provide better protection for them and relieve the strain on Malaysia's healthcare system. With an annual premium of RM120, foreign workers have access to hospitalization and medical coverage for all sickness and injuries requiring admission into Ministry of Health hospitals for up to a total coverage of RM10,000 annually.

SPIKPA has registered 25 insurance companies and two third party claims administrators as providers.

EPP 2: CREATING A SUPPORTIVE ECOSYSTEM TO GROW CLINICAL RESEARCH

The contract research industry for new drug development grew at an annual rate of 15% to exceed $20 billion in 2009, with Asia outgrowing the market at an annual 30% growth rate to reach $1.6 billion.

Although lagging behind its peers, Malaysia is taking steps to change this, with at least 1,000 clinical trials targeted by 2020. This EPP focuses on developing a supportive clinical research ecosystem that allows for more efficient and higher quality trials. This is done through setting up more clinical research centers, developing more clinical-practice certified investigators, and improvement of approval timeline by a medical research ethics committee.

EPP 3: MALAYSIAN PHARMACEUTICALS — INCREASING LOCAL GENERIC MANUFACTURING FOR EXPORTS

This EPP seeks to capitalize on the impending expiry of patents on major drugs to increase Malaysia's generic drug manufacturing capacity. In order for the country to reap the benefits from this market, estimated to be worth $132 billion, the Malaysian industry must take the following measures:

» Leverage the country's membership in The Organisation of the Islamic Cooperation and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme to create an export platform
» Drive efforts to localize and upgrade local manufacturing plants
» Develop strong ties between multinational corporations and local manufacturers
» Off-take Agreement with Ministry of Health
» Have a more comprehensive national pharmaceutical data

EPP 4: REINVIGORATING HEALTHCARE TRAVEL

With ASEAN member countries contributing $3 billion to the $75 billion revenue earned by the global health travel sector in 2010, Malaysia is positioning itself to become the region's healthcare destination of choice.

However, aggressive competition from neighboring countries such as Singapore and Thailand, coupled with the current nascent size of the Malaysian market, requires the country to broaden its patient base. This growth must occur in two phases, comprising:

• Phase 1: Growing patient volume through extensive marketing, cross-border alliances and enhanced customer experience

• Phase 2: Investing in better infrastructure and specialist capacity to shift toward more profitable in-patient care

In view of this, the Malaysia Healthcare Travel Council (MHTC) has been established to develop and promote this sector and to function as a one-stop centre for all matters related to healthcare travel.

EPP 5: CREATING A DIAGNOSTIC SERVICES NEXUS

The establishment of a Diagnostic Services Nexus (DSN) seeks to reduce waiting times for radiologist diagnostic services by coordinating and distributing the workload using a teleradiology system that connects public and private hospitals. This will allow domestic radiology to increase its scale and scope and create opportunities for international growth.

To this end, Diagnostic Services Nexus Sdn Bhd, a private consortium of strategic technology, telecommunications, and operations partners including General Electric Healthcare, was established to coordinate and implement the DSN project. In addition to providing DSN technology to hospitals, the consortium will also build capacity and link radiologists throughout the country to grow the talent pool while ensuring the system is sustainable.

By May 2013, four hospitals had participated as pilot sites for the DSN comprising Hospital Kuala Lumpur, Hospital Selayang, Hospital Tengku Ampuan Rahimah, and Hospital Sultanah Aminah.

EPP 6: DEVELOPING A HEALTH METROPOLIS: A WORLD-CLASS CAMPUS FOR HEALTHCARE AND BIOSCIENCE

Under this EPP, UM Holdings Sdn Bhd will develop and position the University of Malaya Health Metropolis (UMHM) as Malaysia's premier medical hub. Together with urban renewal efforts, the metropolis, which will combine the capabilities of the UMMC Faculty of Medicine and the UM Specialist Center, will offer medical education, research and clinical care.

When operational in 2017, the metropolis will house a 320-bed hospital, a 338-healthcare hotel, a medical research centre, convention and exhibition facilities and other supporting facilities.

EPP 7-EPP 13: MEDICAL DEVICES ENTRY POINT PROJECTS

The medical devices EPPs were formulated to drive the growth of Malaysia's medical devices industry, which has reached a critical juncture due to its burgeoning size. These EPPs will leverage the country's cost advantage, capabilities in the large electronics and electrical industry, strong intellectual property (IP) protection framework, and accessibility throughout Asia to develop the medical devices industry further.

The Medical Device Authority (MDA) was established in August 2012 as the statutory body responsible for enforcing and implementing the Medical Device Act 2012. The MDA has drafted the Medical Device Regulation 2012 to support the implementation of Act 737. Compulsory registration of Class A, B, C, and D medical devices started Oct. 1, 2013.

EPP 7: UPSCALE IN-VITRO DIAGNOSTICS

Medical Innovation Ventures Sdn Bhd (Mediven), a medical diagnostics firm, will spearhead this EPP through its IVD project. The project will provide the foundation for the upscaling of Malaysia's IVD industry and help to raise the country's IVD profile globally, starting with developing countries.

EPP 8: BUILD MALAYSIAN SHOWCASE ON NEXT GENERATION OF CORE SINGLE USE DEVICE (SUD) PRODUCTS

Vigilenz Medical Devices Sdn Bhd has been identified to lead local medical device manufacturers in positioning Malaysia as the preferred supplier of high-quality contract manufacturing for SUDs.

EPP 9: BECOME THE HUB FOR HIGH-VALUE MEDICAL DEVICES CONTRACT MANUFACTURING

Two local firms, Medical Devices Corporation Sdn Bhd (MDC) and Straits Orthopaedics (Mfg) Sdn Bhd, are leading developments in this field by expanding their manufacturing activities to spur greater participation from Malaysian entrepreneurs.

EPP 10: MALAYSIAN CLINICAL DEVICE CHAMPIONS

In its initial stage, this EPP is focused on preparing three potential project owners to launch projects related to the orthopaedic implant manufacturing industry.

EPP 11: MEDICAL EQUIPMENT SUPPLY

Medical Equipment Supply Chain Orchestration Manufacturer UWC Holdings, which caters to the medical and healthcare industry among others, leads this EPP through its investment in the construction of a medical equipment manufacturing facility in Bukit Minyak, Penang. The 80,000 square foot facility will manufacture equipment including hospital beds, trolleys, stretchers, immobilizers and pre-filled humidifiers

EPP 12: MEDICAL REFURBISHMENT HUB

This EPP seeks to lower purchasing and maintenance costs for quality medical equipment, with the Medical Device Authority (MDA) taking the lead in the establishment of a local medical equipment refurbishment hub.

The MDA will also launch an awareness program on refurbished systems and introduce regulations for this sector in a bid to spur investor interest.

EPP 13: MEDICAL HARDWARE

This EPP is spearheaded by LKL Advance Metaltech Sdn Bhd, a medical furniture manufacturer specializing equipment including hospital beds, patient transport trolleys, birthcare tables, medical treatment carts, peripheral support equipment, and the fabrication of steel and wooden products.

Source: The Economic Transformation Programme, http://etp.pemandu.gov.my/upload/NKEA_Factsheet_Healthcare.pdf PV

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