



HEALTHCARE

VARIAN
medical systems

**ADVANCING
HEALTHCARE SERVICES**



YB DATUK SERI DR S. SUBRAMANIAM

Minister of Health

Since taking over the helm at the Ministry of Health (MOH), I am delighted to note that the year 2017 has shown remarkable growth in the Healthcare Industry. MOH's initiatives that have contributed profoundly to the NKEA are clearly exemplified by the positive results in the Industry Sponsored Research (ISR) conducted by Clinical Research Malaysia (CRM), to the increased revenues generated through healthcare travellers and tourists monitored by the Malaysian Healthcare Travel Council (MHTC). Alongside the initiatives conducted by the Medical Device Authority (MDA) that have led to the increased number of approvals of establishment licence applications, improved lab compliance to Organisation for Economic Co-operation and Development (OECD) Good Laboratory Practice (GLP) requirements for pre-clinical testing as well as increased Medical Devices registration are also to be trumpeted about and be proud of. To top off all these efforts, the upsurge in generic pharmaceutical products registered under the National Pharmaceutical Regulatory Authority (NPRA) has significantly contributed to the development of the Healthcare sector in Malaysia.

With these achievements and on-going commitments, our Healthcare Industry generated RM26 billion in GNI* in 2017 as compared to RM15 billion at the beginning of the NTP in 2010.

To further benefit the rakyat, Healthcare in Malaysia has embarked on two transformative processes. The first is the Enhanced Primary Healthcare, which

builds on the existing primary healthcare framework within the public and private sectors to target non-communicable diseases and emphasises early detection, intervention and treatment. The second is the development of the non-profit Voluntary Health Insurance Scheme (VHI), which will ensure the sustainability of our current public healthcare systems while bridging the gap between public and private healthcare.

Another highlight of the year was the tabling of the Private Aged Healthcare Facilities and Services Act to regulate all private aged care centres, thus ensuring adequate standards are maintained to care for our elderly. This Act is critical to meet mounting demands for aged care services, as Malaysia shall become an aged nation by 2030 with an estimated 15% of the population to be over the age of 60 years.

Additionally, the inception of e-Health such as MY Health Information Exchange (MyHIX) and MY Health Data Warehouse (MyHDW) will place Malaysia at the forefront of the Healthcare Industry. The total healthcare integration system as well as digitalisation efforts are aligned with our Industry 4.0 efforts, and focuses on modernising the health sector as Malaysia closes in on the completion of the NTP and moves towards the TN50 horizon.

*Includes public healthcare.

SHOWCASING THE QUALITY OF MALAYSIAN HEALTHCARE

Malaysia has established itself as one of the most preferred destinations for healthcare travel globally. This is evidenced by the recognition earned from the US-based International Living magazine which has ranked Malaysia as one of the world's top countries for healthcare in terms of service quality, accessibility, standard of post-procedure recuperation options and cost-competitiveness for three years since 2015. The International Medical Travel Journal (IMTJ) has also acknowledged Malaysia as "Health and Medical Tourism: Destination of the Year" for three consecutive years from 2015 to 2017.

Healthcare travel (Medical Tourism) is one of the fastest-growing sectors in the country, registering an average growth rate of 16% to 17% every year.



YB Datuk Seri Dr. S. Subramaniam, Minister of Health Malaysia, chaired a roundtable discussion with captains of the private healthcare industry on medical tourism and the way forward.

In 2017, the healthcare travel industry recorded a preliminary performance of RM1.3 billion*. The industry is expected to record a year-on-year growth of 16%*. Healthcare travel spending also creates sizeable multiplier effects. Malaysia has outpaced the regional industry growth with more than one million healthcare travellers, spending around RM5 billion* for medical treatment as well as non-medical expenditure such as hospitality services and tourism activities. The aim is to achieve 30% growth year-on-year by 2020.

Efforts in this area are led by the Malaysian Healthcare Travel Council (MHTC), which has introduced long-term sustainability initiatives to maintain the successful growth trajectory, in line with the three key tenets of industry facilitation, optimisation of digital marketing and sustainable growth. MHTC has set out the following strategies to drive the growth of this industry:

- Strengthening end-to-end experience from the arrival of the healthcare travellers through to their departure after treatment;
- Securing partnerships with industry players and to enhance network and relationships;
- Amplifying branding and recognition.

To effectively amplify promotion, MHTC has identified four focus countries as key target markets: Indonesia, China, Myanmar and Vietnam while continuing efforts to penetrate other important markets such as Singapore, Brunei, Bangladesh, the Middle East, India, Australia and New Zealand.



Ms. Sherene Azli together with H.E Mr. Mohd Hassan Bal, Malaysian Ambassador to Zagreb and Keith Pollard, Chief Editor of the International Medical Travel Journal at the IMTJ Awards 2017.

*Projected data from MHTC as at 29 January 2018, for data ending 31 December 2017.



Elite Hospitals

The Malaysian Government has further supported the healthcare travel sector by facilitating investments in medical infrastructure for hospitals, putting Malaysia on par with well-developed countries through producing well-trained medical staff and providing excellent hospital facilities.

MHTC Elite Hospitals represent the best of these health services and are internationally accredited, providing international support services for foreign patients. The international accreditation of Elite Hospitals from reputable international agencies guarantees the highest standards of quality and safety to all patients. Its services are benchmarked against the best practices in the world and provide state-of-the-art facilities and served by highly qualified medical personnel.

In 2017, Malaysian Elite Hospitals geared towards serving the demand for high-value, niche quality healthcare. Many hospitals developed specialist treatment and diagnostic faculties, comprising high-end care centres as well.

Several of these hospitals have received global and regional awards as well as certifications along the year, namely Sunway Medical Centre for orthopaedics, Prince Court Medical Centre for paediatrics and healthcare travel, TMC Fertility Centre for fertility services, and KPJ Berhad as Malaysia's hospital of the year.

Strengthening end-to-end experience

MHTC strives to create a holistic ecosystem for healthcare travellers to enjoy a seamless healthcare experience through the following initiatives:

- The establishment of representative offices in focus markets to gain faster access to the markets and facilitate potential visitors with enquiries and any healthcare travel assistance needed;
- The introduction of a Meet-and-Greet service at the aerobridge by Malaysia Healthcare Concierge and Lounge;
- Fast-tracking passport and customs clearance at the Kuala Lumpur International Airport (KLIA).

2017 was focused on smoothing the airport greeting process. As the project goes on, more initiatives will be implemented to improve the services along the value chain. Moving forward, MHTC is looking to strengthen its partnerships with member hospitals and travel agents to ensure that patients' post-treatment experience is enhanced through their Affiliate programme.

Securing partnerships with industry players to enhance networks and relationships

Recognising the overall journey as an important facet of healthcare travel, the end-to-end experience will provide a seamless journey from the moment they begin searching for information from their home countries through to their successful treatments and return home. Accordingly, MHTC has worked to create more value-for-money and attractive packages for healthcare travellers by bundling hospital services with existing deals from tour agents and airline companies. Additionally, to increase awareness on its efforts, MHTC is selecting effective distribution channels through partnerships with local travel agents while maintaining its strategic integration between airlines, in-bound travel agencies and complementary services centred around the healthcare value chain.

Amplifying branding and recognition

Invigorating the Malaysia healthcare brand and gaining mindshare is important for expanding Malaysia's healthcare travel market size. As such, the "Malaysia Loves You" campaign was launched in 2016 to effectively advocate the essential attributes of Malaysian healthcare, namely quality, accessibility, affordability and ease of communication. In 2017, this marketing pursuit was continued with the "Share My Love" campaign which took on a more contemporary and artistic approach to convey what good health means to Malaysians. The "Share My Love" campaign has featured the works of 7 local artists to inspire others in spreading the value of care and healthy living.

Capitalising on the power of social media to increase publicity, the public was given an opportunity to win prizes through a social media contest by sending in their own version of fun heart doodles this year. MHTC had since received more than 1,400 submissions for the Instagram contest.

BOOSTING MALAYSIA'S PRODUCTION AND EXPORTS OF HEALTHCARE PRODUCTS

Malaysia's healthcare exports are focused on medical devices and pharmaceuticals, since the Government has identified and listed the medical devices sector as a high-growth sector under the 11th Malaysian Plan 2016-2020. Medical devices exports have increased consistently year-on-year at the average of 14.2%. In 2017, total exports of medical devices and products hit approximately RM11.3 billion and grew by 16.8% from 2016's export value of RM9.7 billion. The total market size of medical devices in Malaysia is now US\$1.4 billion, against global medical devices market worth an estimated US\$324 billion.

“Pharmaceutical exports grew at an average annual rate of 8%, from RM577.8 million in 2011 to RM938.5 million in 2017.”

Meanwhile, pharmaceutical exports grew at an average annual rate of 8%, from RM577.8 million in 2011 to RM737.3 million in 2016. Exports of pharmaceutical products for the year 2017 grew by 27.3% as compared to 2016 against the Ministry's target of 8%. Total export revenue hit RM938.5 million against the target of RM796.3 million.

The overall impact of focusing on Malaysia's production and exports of healthcare products is the gradual substitution of imported products, which will develop the capacity of local manufacturers, leading to an increase in export volume and value. The move is also cost-saving for the Ministry of Health (MOH).

Medical Devices

Malaysia's major export categories for medical devices are surgical and examination gloves, electromedical equipment, catheters, syringes,

needles and sutures, ophthalmic lenses, medical and surgical X-ray apparatus, orthopaedic appliances and medical furniture. These devices are exported mainly to the US (23%), Belgium (13%), Germany (12%) and Singapore (9%).

The sector recorded numerous achievements during the year, including a significant increase in medical devices registration. The increase in registration is reflective of the increasing number of medical devices which are of superior quality and are safe for patient use, as regulated by the Medical Devices Act 2012 (Act 737). As of December 2017, more than 195,000 medical devices have been registered and over 2,000 establishment licences, which are company licences given to facilities, have been issued by the Medical Device Authority (MDA).

To spur the sector, MDA has been working to increase the knowledge of industry players on the regulatory requirements governing the manufacturing of medical devices in Malaysia through training sessions, awareness programmes, consultation sessions and the International Medical Device Conference held on 8-10 August 2017.

Further supporting the medical device ecosystem, the Government provided grants for the establishment of two Good Laboratory Practice (GLP) labs in Malaysia in 2016, which are MyBioScience Lab Sdn Bhd, Melaka and Makmal Bioserasi, Universiti Kebangsaan Malaysia (UKM). The GLP labs will allow local medical devices manufacturers to incur lower costs and encourage foreign manufacturers to invest in Malaysia by



Mutation study lab with automated colony counter and biosafety cabinet in Makmal Bioserasi, UKM.



providing testing facilities for their products. The two labs have commenced the OECD GLP compliance process and expected to receive their OECD GLP status in 2018.

The new plant will manufacture surgical sutures such as Class II sutures, hernia meshes, antibacterial wound management solutions and antibiofilm orthopaedic implants which will then be exported worldwide.



The conference aims to obtain updates on global regulatory requirements for medical devices as well as spearheading growth of the medical device sector.

A key highlight recorded by the medical devices sector in 2017 was the conclusion of MOH's first off-take agreement (OTA) for medical devices with Vigilenz for Antibacterial Electro Activated Super Oxidized Water (Hydrocyn Aqua). The Hydrocyn product has received FDA 1510K approval.

Vigilenz Medical Devices Sdn Bhd

As one of the NTP's project champions, Vigilenz Medical Devices (Vigilenz) commenced the operations of its new plant in the Penang Science Park in 2017.

Moving forward, Vigilenz has started the development of nano fibre wound dressing and clinical trials of antibiofilm orthopaedic implants (Orthosyn). In ensuring that its products are up to standards, the company has provided training for its staff as per the new Medical Device Regulations and Risk Management requirements. In tandem, the company has kicked off its collaboration on development research with UKM, UTM, and USM. As for its progress in exports, 2017 has seen to the export market registration in the UK and additional product registration in Australia.



Vigilenz's ISO Class cleanroom manufacturing area compliant to ISO 13485:2016, equipped with in-house microbiology laboratory.



Fresenius Medical Care Sdn Bhd (FME) regional manufacturing facility in Bandar Enstek.

Fresenius Medical Care Sdn Bhd

Fresenius Medical Care Sdn Bhd (FME) created a new milestone in the Malaysian medical devices industry when it became the first Continuous Ambulatory Peritoneal Dialysis (CAPD) manufacturer in Malaysia in 2017.

The FME regional manufacturing facility in Bandar Enstek, Fresenius Medical Care Production Sdn Bhd (FMCP) was launched in September 2017. FMCP produces haemodialysis concentrates A & B, Citrosteril (a disinfectant for haemodialysis machines), as well as CAPD Stay.Safe Link for dialysis treatment.

FME products manufactured in Malaysia meet the FME's global quality standards, providing the local market with access to stable supply of the products and ensuring continuity of treatment for patients. FME has invested close to RM80 million in its facility to date, with additional investment for expansion in the next 5 years.



(From left to right) Mr. Carsten Fischer, Chargés d'Affaires of the German Embassy, Mr. Harry De Wit, President and CEO, Fresenius Medical Care Asia Pacific, Mr. Gerhard Breith, Senior Vice President, GMQ Asia Pacific, Mr. Mahesh Nair, Senior Vice President, Fresenius Medical Care South Asia Pacific, YBhg. Dato' Seri Dr. Chen Chaw Min, Secretary General, Ministry of Health Malaysia, and Mr. Michael Wong, Managing Director, Fresenius Medical Care Malaysia at the official opening of Fresenius Medical Care regional manufacturing plant at Bandar Enstek, Malaysia.



A training on Malaysia's Pharmaceutical Regulatory System was held for 12 regulators from Tanzania, Uzbekistan, Nigeria, Thailand, Jordan, Sudan, Indonesia, Iran, Kazakhstan and Morocco which aim to promote Malaysia's Regulatory System and to build confidence towards pharmaceutical products manufactured locally.

Pharmaceuticals

Malaysia is ranked Asia's 14th largest pharmaceutical exporter, exporting to more than 50 countries including countries in Africa and South America. Its major export destinations are Singapore, Brunei, Hong Kong, Vietnam and Indonesia, with the main types of pharmaceuticals exported comprising medicaments in measured dosage forms containing antibiotics and health supplement such as vitamins and antibiotics. Despite the relatively small size of the industry and its concentration on generic medicines.

The investment climate for pharmaceuticals is promoted by the National Pharmaceuticals Regulatory Agency's (NPRA's) launch of QUEST 3+ in January 2017, an enhanced online registration system that will improve and raise efficiency of the pharmaceuticals registration process. On top of the automation of processes under QUEST 3+, NPRA has also implemented fast track registration of generic products, effectively reducing registration time to three months (90 working days) from the date of application as compared to seven months (210 working days) for other prescription drugs.

To build trust and receptiveness towards pharmaceutical products manufactured in

Malaysia, training on the Pharmaceutical Regulatory System was conducted by NPRA in September 2017, showcasing the alignment of Malaysia's pharmaceutical regulatory system to international requirements. This is expected to facilitate Malaysia's pharmaceutical exports further.

“Malaysia is Asia's 14th largest pharmaceutical exporter, exporting to more than 50 countries worldwide.”

The sector has also reached an important milestone with Thailand confirming its readiness to sign the ASEAN Mutual Recognition Agreement (MRA) for Bioequivalence (BE) Study Reports of Generic Medicinal Products. This leaves only one member state, Philippines, to confirm intention to sign the MRA.

The MRA eliminates the need to conduct another BE study as it would have been conducted in a listed BE Centre. Harmonising BE study requirements and eliminating technical barriers for registration of generic products within ASEAN will allow generic pharmaceuticals to gain earlier access in the region,

Strengthening the Country's Biotechnology Sector: Bringing It Home

Increasing local generic manufacturing for exports is a focus under the Healthcare NKEA of the National Transformation Programme (NTP). This ultimately spurred Malaysia's creation of a highly supportive legal, financial and institutional climate for the growth of biotechnology as well as its implementation of proactive policy measures.

"This enabling environment led to Biocon, India's largest and fully-integrated, innovation-led biopharmaceutical company to join hands with the Malaysian Government in 2010 to strengthen the country's biotechnology sector," says Srinivasan Raman, Vice President and Head of Biocon Malaysia's operations.

The company was chosen as an Entry Point Project (EPP) champion under the Healthcare NKEA after it proposed the largest investment in the Malaysian biotechnology sector to set up a high-end biopharmaceutical manufacturing and R&D facility at the BioXcell Biotech Park in Johor. Biocon Sdn

Bhd was incorporated as a wholly owned subsidiary of Biocon in Malaysia to set up this greenfield facility. To date, Biocon has invested nearly US\$275 million in the facility, which houses Asia's largest state-of-the-art integrated insulins manufacturing plant that is designed to manufacture insulin and insulin analogues to cater to the needs of people with diabetes in Malaysia and other global markets.

In November 2016, Biocon Sdn Bhd was awarded a contract to supply rh-Insulin cartridges and reusable insulin pens over a period of three years under the Malaysian Government's Off-Take Agreement (OTA) initiative.

Biocon's rh-Insulin, Insugen®, manufactured at the Johor facility, is Malaysia's first locally made biosimilar product to be approved by the National Pharmaceutical Regulatory Authority (NPRA) for commercial sales in the country. Insugen® is enabling access to a safe, affordable and quality treatment option for over 3.3 million people with diabetes in Malaysia.



Biocon's rh-Insulin, Insugen® is Malaysia's first locally made biosimilar product to be approved by NPRA for commercial sales in the country.



Biocon facility in Malaysia.

The benefits of purchasing insulin from a local vendor are manifold. There are currently 3.3 million individuals currently diagnosed with diabetes, and the Malaysian Government spends nearly US\$566 per year on every diabetic. These numbers are expected to multiply to a whopping 4.5 million diabetics by 2020, which will significantly impact the Government's healthcare expenditure. Locally manufactured affordable rh-Insulin has the potential to reduce the diabetes treatment cost burden and increase access to insulin therapy for diabetes patients in Malaysia.

This OTA provides assurance of public sector purchases of locally manufactured pharmaceutical products and incentivises exports. "When the Malaysian Government purchases and uses these products, it provides confidence to the export market about the safety and efficacy of these drugs. Winning the OTA thus endorses our credibility as a manufacturer of affordable yet high-quality insulin products."

To upskill the local community, Biocon employs a team of over 550, including 450 Malaysians at its insulin manufacturing plant in Johor. In addition

to creating local employment opportunities, the company has trained over 240 of its Malaysian employees at its headquarters in India. "We continue to provide training to our staff in Malaysia in various areas of biopharmaceutical manufacturing, quality control, supply chain and research and development. The company also utilises local vendors to source its input materials and services as well as in the construction and set-up of its manufacturing plant," says Srinivasan.

Biocon is also making a significant contribution to build the biotechnology industry ecosystem in Malaysia. Three senior leaders from Biocon Malaysia have joined the industry-academia panel of Universiti Teknologi Malaysia and Universiti Kebangsaan Malaysia. These industry-academia collaborations enable universities to tailor their curriculum to emerging industry trends and talent requirements.

Wrapping up the conversation, Srinivasan said "the Malaysian Government's support for the healthcare sector via the NTP has shown the world how progressive policies can make a transformational impact".

aside from reducing cost of registration in other ASEAN countries.

Further strengthening Malaysia's generic pharma production, these EPP champions have invested in high technology manufacturing. A significant contribution in this sector is that the total 11 projects have garnered RM852.95 million in committed investments, led by pharmaceutical project champions such as Kotra Pharma Sdn Bhd and Pharmaniaga LifeScience Sdn Bhd.

Kotra Pharma Sdn Bhd

Kotra Pharma is undertaking three projects under the Healthcare NKEA, namely:

- The Accessible Sterile IV Export Project / Prefilled Syringe Line (PFS) with 12 products to be manufactured;
- The Metered Dosage Inhaler (MDI) Project with eight products to be manufactured under this line;



Kotra Pharma's Vaxcel Omeprazole 40mg Injection for treatment of duodenal and gastric ulcer, reflux esophagitis and Zollinger-Ellison syndrome.

- The contract manufacturing partnership with Servier to manufacture its patented products.

The three projects involve an estimated investment of RM25 million for construction and development of manufacturing lines, staff training, product research and development.



Freeze dried product formulations are more stable than small volume liquid injectables and generally have longer shelf life.



The MDI and PFS lines are currently at the final stages of preparation and readiness for line inspection and audit by NPRA. Following NPRA's approval, the first product under PFS line is targeted to be commercialised in the second quarter of 2018 while the MDI products are expected for commercialisation in the fourth quarter of 2018. However, through Malaysia's contract manufacturing partnership with Servier, Kotra Pharma has already commenced exports of its products to Brunei.

A total of five OTAs have been awarded to Kotra Pharma. The drugs supplied under OTAs are for treating stomach and oesophagus problems, cardiovascular disorders, upper and lower respiratory tract infections and other intra-abdominal infections, and control of blood glucose for diabetes patients.

Pharmaniaga LifeScience Sdn Bhd

Pharmaniaga LifeScience (Pharmaniaga) is the first and only pharmaceutical Small Volume Injectable (SVI) manufacturer in Malaysia to install and utilise Lyophilisation (freeze-dry) technology following a RM21 million investment to expand its existing manufacturing facility.

The company currently has 15 products in its Lyophilisation product pipeline and manufactured pilot batches for its first four products in June 2016. Stability studies have been completed and the dossiers are undergoing final review by Pharmaniaga, after which the product will then be off for registration submission to the NPRA.

Commercialisation of the products are expected in 2018. This is expected to be followed by export to the ASEAN market in 2022, and Europe in 2024. The company expects to create an additional 21 highly skilled jobs from the expansion, with hiring expected to start in 2019.

The Government is expected to realise substantial savings by purchasing generic lyophilised products as the originator products are generally priced higher.

ADVANCING UP THE HEALTHCARE VALUE CHAIN THROUGH CLINICAL RESEARCH

Clinical research in Malaysia is led by Clinical Research Malaysia (CRM) as the centralised body managing the entire clinical research field, which also includes university hospitals. This centralisation of resources is vital in this niche space as it allows Malaysia to optimise and mobilise resources quickly and efficiently. The sector's positive trajectory has been acknowledged by international sponsors and research communities alike. This is again demonstrated by an investment value of over RM220 million since 2012 from companies conducting clinical trials in this country.

“Results of the study are expected to lower the cost of hepatitis C treatment from RM320,000 per patient to just RM1,200 per patient in Malaysia.”

Malaysia is successfully making its mark on the global map as a result of cutting-edge research conducted on hepatitis C in collaboration with the Drugs for Neglected Diseases Initiative (DNDi). The project is a one-of-a-kind model and will pave the way for more smart partnerships between the Government and NGOs. Results of the study are expected to lower the cost of hepatitis C treatment from RM320,000 per patient to just RM1,200 per patient in Malaysia, allowing more than 500,000 Malaysian patients suffering from hepatitis C to access affordable treatment.

On another note, the sector has also witnessed a reduction in Clinical Trial Agreement (CTA) reviews and approval timelines from three months to just five working days with the launch of the e-submission system.



Memorandum of Understanding (MoU) between C&R Research Inc and Clinical Research Malaysia signed to promote clinical trial activities in Malaysia and South Korea.

There are, however, challenges in terms of attracting more clinical research, including:

- Insufficient oncologists to take up oncology trials;
- Malaysia's involvement in mainly late-phase trials makes it less attractive to pharmaceutical and medical device companies;
- Lack of awareness and interest in the importance of clinical trials among medical professionals and the public.

The untapped field of clinical research brings numerous benefits in terms of improving patients' choices as well as raking in economic benefits to the country. Improvements in the field will provide patients with the opportunity to receive medication or treatment that is yet to be available in the market, especially expensive oncology drugs.

Besides difficulty in attracting more clinical research, the next challenge lies in ensuring Malaysia can move its activities upstream in the clinical research ecosystem. These will be mitigated by the Phase I Realisation Project (PIRP) which includes Project ACCELERATE. Both projects are spearheaded by CRM to enable Malaysia to

conduct early-phase trials and eventually move into drug development and discovery.

Early-phase studies play a crucial role in the development of medicines as it investigates the effect, efficacy and safety of pharmaceutical drugs in humans. Indeed, this phase overlaps between scientific research and clinical medicine. The conduct of early-phase studies may also contribute to the transfer of knowledge and recent technologies unto Malaysians, creating new jobs in clinical research, advancing local innovations and reducing the outflow of investments – hence moving the country higher in the clinical research value chain. In fact, Phase I of the Clinical Trial Guideline was completed in November 2017. This guideline gives sponsors, investigators and trial sites an overview of the conduct of Phase I in Malaysia.

Project ACCELERATE involves collaborations across agencies, clinical research industries and universities on pre-clinical projects. CRM will also collaborate with local universities and MOH in 'bench to bedside' projects. Additionally, a trained crisis management team has been prepared to tackle any issues in relation to early phase clinical trials.



Phase I trials have attracted interest from various companies in Malaysia, out of which one company has confirmed to conduct the Phase I trial at the beginning of 2018 while another three companies are already at the site evaluation stage to consider Malaysia as the Phase I centre of their drug development program. There are at least another five currently at the feasibility stage. Furthermore, CRM is assisting Aurigene in their pre-clinical work on novel anti-cancer compounds and associated biomarkers. This pre-clinical Phase I project is expected to sensitise the local industry towards discovery and eventually lead to the manufacturing of innovator drugs in Malaysia.

In view of the need to promote the importance of clinical trials, CRM has initiated the 'I AM AWARE' campaign and Clinical Trials Day, as well as other media-led awareness activities. To date, these campaigns have enabled CRM to register more than 2,000 patients and healthy volunteers who have shown interest in clinical trials.

CRM has been actively pursuing international collaborations, for instance:

- MoU with C&R Research Inc, Korea's largest contract research organisation (CRO). This collaboration will allow Malaysia to attract more Korean biopharmaceutical companies to conduct clinical trials in this country. With this cooperation, C&R and CRM have agreed to promote clinical trial activities in Malaysia and South Korea, while providing support and resources to complement the needs of each country in terms of business development, clinical trial operations and trainings. This has resulted in CRM receiving enquiries from Korean companies to conduct clinical trials in Malaysia. Moreover, C&R Research is also looking at establishing their office here in Malaysia;
- CRM has been assisting FIND, a global health non-profit organisation based in Geneva, Switzerland with identifying clinical trials sites for a hepatitis C diagnostic kit. The collaboration will greatly widen access to hepatitis C diagnosis in Malaysia and speed up the test result for patients.

ENSURING THE HEALTH OF SENIOR CITIZENS

Apart from providing affordable and quality health services for everyone in Malaysia, the healthcare industry has to pay specific attention to the needs of senior citizens. This is consistent with the shift in the country's demographics, whereby 15% of the population is projected to be aged 65 and above by 2030, from the current 9.3%. This shift is expected to exert considerable strain on the nation's healthcare system, especially with the rising rates of non-communicable diseases worldwide.

“A ground-breaking Act under MOH was tabled in Parliament in October 2017 to regulate private nursing homes.”

Private Aged Healthcare Facility and Services Act

Private Healthcare Facilities and Services Act 1998 (Act 586), a legislation that regulates all professional medical centres. This is clearly insufficient to cater for the rising demand in aged care, and it has prompted the Government to propose a more specific regulation for private facilities and services for aged care. Thus, a ground-breaking Act under MOH was tabled in Parliament in October 2017 to regulate private nursing homes. The Private Aged Healthcare Facility and Services Act will set a minimum level of quality for care and services delivered at private aged care institutions, and encourages the licensing and regulation of unregistered care institutions as well as supports the elderly who choose to age in their own homes, reducing dependency among the elderly community as per World Health Organization (WHO) standards.

Sunway Shines As Malaysia's Medical Tourism Takes Off

Far sighted government policies to tap into the booming health tourism market are paying off as tourists flock to the country's shores to take advantage of the affordable yet world class medical care available in Malaysia. This is reflected in the medical tourist traffic streaming into the country with some 921,000 visitors traveling to Malaysia for medical purposes in 2016, up sharply from 643,000 in 2011.

One of the key players in the industry is Sunway Medical Centre, one of the most established and largest private hospitals in Malaysia as well as the ASEAN region. Sunway credited key NTP initiatives such as the Malaysia Healthcare Travel Council (MHTC) as having helped boost its profile in the regional healthcare tourism arena.

Dr. Michelle Mah, the Director of Business Development and Corporate Communications at Sunway Medical Centre said that the MHTC contributed greatly in promoting Malaysia as a medical travel destination of choice, and helped raise the profile of not just Malaysia but also Malaysian hospitals. This in turn helped draw in

increasing numbers of foreign medical patients.

"The launch of the NTP helped bring industry players together to more effectively brand the country as a medical travel destination," she said. "It also increased focus and urgency to implement necessary measures to facilitate the development of the sector and ease travel arrangements of foreign patients. It has certainly paved the way in putting Malaysia on the world map in terms of medical tourism."

Dr. Mah added that other non-healthcare related initiatives under the NTP such as improving public transportation also helped to enhance Sunway's appeal to medical tourists. This is because improved transportation infrastructure made the Sunway City's cluster of hospitals, malls, theme parks and hotels more attractive.

"The indirect knock-on effect from the NKEA with a special focus on the development of an integrated public transportation system has resulted in creating an excellent commuting hub for medical tourists especially in Sunway City where the BRT (Bus Rapid Transit) connects the hotels, shopping malls, theme park and residences to our hospital," noted Dr. Mah.



Sunway has also worked with Harvard University and the University of Cambridge to improve its standard of healthcare and education.



Sunway Medical Centre is an elite member of the MHTC.

Sunway is also an Elite member of the MHTC which also added to its appeal. Dr. Mah said that as elite member hospital, more pathways and opportunities opened up for it to tap into foreign markets. “The affiliation with MHTC has boosted our credibility in international markets and facilitated our outreach initiatives,” she said.

Dr. Mah also commended the commitment and dedication of MHTC representatives, noting that the MHTC CEO, Sherene Azli, was very supportive and helpful in supplying information and analysis on the market trends and competitors as well as promoting Sunway Medical Centre abroad.

Sunway Medical has also managed to attract medical talents residing abroad to return to Malaysia under the Returning Expert Programme (REP). This enabled it to increase its pool of specialists and deliver even more comprehensive medical services to patients. “Their return to Malaysia helped to augment the pool of medical talents for the country,” she said.

Looking ahead, Dr. Mah said that Malaysian hospitals are increasingly competing in terms of standard and comprehensiveness of care. “For example, Sunway Medical now has one of the most comprehensive cancer centres, not just in Malaysia but also the region,” she said. “We are also working with top institutions

like Cambridge University and the Royal Papworth Hospital, Europe’s top heart and lung hospital, to raise the bar in terms of the standard of care we deliver.”

Sunway also recently collaborated with some of the top global universities such as Harvard University and the University of Cambridge to enhance the standard of healthcare and education in Malaysia. As part of the collaboration, Sunway Medical Centre established the Sunway Clinical Research Centre which will be the Regional Site Partner of the University of Cambridge’s School of Medicine.

In terms of suggestions on how to improve the healthcare tourism landscape in the country, Dr. Mah said that the government could look into assistance in the form of grants and sponsorships for the private sector in the area of training and research to intensify research efforts and position Malaysia to be a regional leader in various medical fields.

“Shift the focus of Malaysian healthcare to quality and not just as a more value for money destination compared to our competitors,” said Dr. Mah. “This will require not just investing in talent and technology, but also more active clinical research and active benchmarking on the clinical outcomes. We believe MHTC is already working on some of these initiatives.”

Delivering healthcare to your doorstep

In an era when digitalisation and mechanisation of services are at the forefront, one of the NKEA's project champions, Love on Wheels is providing mobile nursing and physiotherapy services straight to the patients' doorstep or easy-to-understand medical advices remotely through a mobile app.

The company has recently developed a structured programme that is approved by the Department of Skills Malaysia to train caregivers on the knowledge, skills and attitude needed for delivering quality care to the elderly. The programme emphasises practical training and is supplemented by centre-based (theory) learning to ensure that caregivers are sensitive towards the needs of the elderly and able to detect critical health conditions. The capacity building initiative is expected to reduce dependency on foreign workers as well as lowering the cost of elderly care over the long-term.

Another initiative undertaken by Love on Wheels is the mSIHAT mobile app. Through the application, caregivers will be aware of when their services are required by the patient in real time, wherever they are in Malaysia. This application provides a platform for patients and healthcare practitioners to connect for mobile physiotherapy, nursing and caregiving. mSIHAT also assures that the practitioner is qualified and certified and that the

patient has continuity in care even if attended to by multiple practitioners while maintaining the privacy and security of users' information. This service is currently available in the Klang Valley and will roll out nationwide over time. Looking ahead, given that Malaysia is expected to be an aged nation by 2030, mSIHAT can help address some of the challenges such as limited beds, overcrowded hospitals and high cost of care.

The future of aged care

The Eden-on-the-Park project, an integrated retirement and care residence resort in Kuching was completed in 2015. It comprises a 71-suite (142-bedded) state-of-the-art care complex, a 104-apartment condominium block and 14 single-storey villas.

Since its inception, the Care Centre has opened the eyes of Malaysians to what dignified senior living and aged care can be, changing the negative perception of care centres to one which is positive and supportive of a healthy lifestyle.

Eden-on-the-Park Sdn Bhd, the promoter and creator of the Malaysian Integrated Seniors Lifestyle and Care residence, is planning to replicate the concept in its first off-site venture in Kota Kinabalu, which will commence construction once development plans are approved.



Eden's Active Senior Lifestyle Apartment with its 50 metre salt water pool.



MOVING FORWARD ▶▶

Healthcare travel in Malaysia is booming rapidly as the country had witnessed a positive growth trend in healthcare travel revenue over the past six years to stay on track to achieve the 2020 goal of RM2.8 billion. MHTC is raising the profile of Malaysia as the leading global healthcare destination and the industry will be strengthened as one of the country's sources of income. Plans are in place for the establishment of flagship hospitals, the positioning of Malaysia as Asia's leading hub for fertility and cardiology, and the introduction of high-end medical packages for healthcare travellers.

In terms of healthcare exports, the Government should consistently engage with the industry to understand its challenges and needs. This will also help the balance between supply from local manufacturers and demand from MOH. Alliance between the two will ensure that production is aligned with the relevant national goals and health policy. Moreover, greater synergy between the Industry Pharmaceutical Master Plan, National Medicine Policy and National Healthcare Plan is required to achieve a strong multiplier effect for the pharmaceutical industry.

The private sector should also focus on market expansion for large players and developing niche strategies for small players. Local manufacturers must be able to differentiate their products and services in some unique way and create a stronger and competitive ecosystem by systematically enforcing their brand presence.

CRM will continue working on increasing public-private partnership (PPP) in oncology to optimise the uptake of oncology clinical trials in Malaysia. This will enable oncologists from private hospitals to conduct trials in MOH hospitals. CRM will also continue working with the Institute of Medical Research (IMR) and other companies in pre-clinical collaborations to drive a turnover to early phase clinical trials. Additionally, the organisation will promote Malaysia as a clinical trial hub in Asia through participation in international congresses, meetings and social media.

To bolster the elderly healthcare initiative, the industry should consider an integrated financial system and a stronger financial support, such as long-term care insurance and reverse mortgage, to ensure sustainability for the ageing population in utilising aged care facilities.

The future of the Malaysian healthcare industry will increasingly hinge on the adoption of e-Health, in line with the Industrial Revolution 4.0 concept to further modernise healthcare services and unlock more growth opportunities. This will also require appropriate regulations to maximise the benefits of using technology in healthcare.
