# HEALTHCARE SIFESCIENCES REVIEW



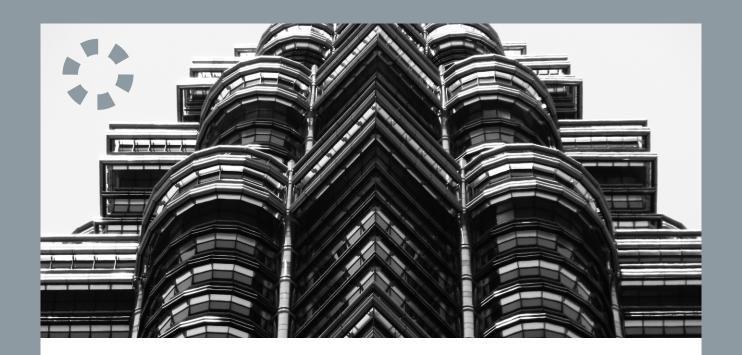
EXCLUSIVE INTERVIEW WITH MINISTER OF HEALTH PAGE 14 THE HALAL AND HERBAL MEDICINE NICHES PAGE 18 AN EMERGING CLINICAL RESEARCH HUB PAGE 33 AN AMBITIOUS HEALTHCARE REFORM PROGRAMME PAGE 41



A STEADY FORCE PAGE 24

# MALAYSIA

**DECEMBER 2018** 



## Acknowledgements

PharmaBoardroom is profoundly grateful to...

Datuk Seri Dr. Haji Dzulkefly bin Ahmad, Minister of Health

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Ewe Kheng Huat, executive director, PhAMA

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Azrul Mohd Khalib, founder and CEO, Galen Centre

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As well as all the companies and institutions we have met for their support, insights and enthusiasm.









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— December 2018





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Dear fellow members of the healthcare sector,

As Minister of Health of Malaysia, it is a pleasure to introduce this exclusive edition of the Malaysia Healthcare & Life Sciences Review that aims to present a deep insight on the current dynamics of our nation's healthcare system and industry.

Indeed, following the historical political change, the Ministry of Health has focused its energy on ensuring a better access to affordable and high-quality healthcare as well as on building the infrastructures to accommodate the needs of the Malaysian population, including the most fragile groups. Through our program, we are aiming to reconcile the private and public sectors and the pharmaceutical and life sciences industry will play a decisive role in shaping the future of Malaysia's economic development. In this regard, the country offers interesting investment perspectives in areas such as clinical trials, Halal and herbal medicines in which our governmental authorities have been leading the regulatory field in the region and globally.

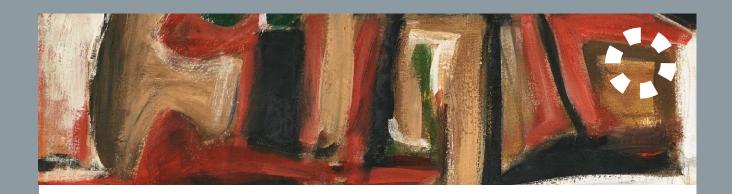
The Malaysia Healthcare & Life Sciences Review 2018 is a formidable platform to expose the healthcare advancements and business opportunities Malaysia can offer. I am welcoming all collaborators working in the pharmaceutical and healthcare fields around the world to read this exclusive report.

Sincerely,

Datuk Seri Dr. Haji Dzulkefly bin Ahmad, Minister of Health of Malaysia









Dear members of the international healthcare community,

On behalf of the National Pharmaceutical Regulatory Agency (NPRA), I am pleased to introduce this 2018 edition of the Malaysia Healthcare and Life Sciences Review, which is a strong platform showcasing the important changes our country is implementing to develop the healthcare ecosystem.

Indeed, Malaysia's recently elected government is intensifying its efforts to improve healthcare at the moment when the country strives to become a high-income nation. The country has showcased its commitment to improve universal coverage, especially for the poorer citizens, as well as the quality of healthcare and the viability and sustainability of Malaysia's health system. The industry is not left behind as the market has also been growing steadily over the last few years and opportunities for both innovative and generic players to bring more treatments to patients are present in the country. As the director of the regulatory agency of Malaysia, we have set a clear focus on quality for all healthcare products distributed in the country to participate in achieving the goals of our government.

The Malaysia Healthcare & Life Sciences Review will provide a unique insight to understand the potential and most recent developments across the local healthcare and life sciences industry in the country, including the key role of pharmaceutical companies to provide high-quality solutions to patients and further develop the Malaysian economy. It will also showcase how global and local enterprises are investing in the country due to attractive manufacturing capabilities, advantageous business environment and favorable geographic position.

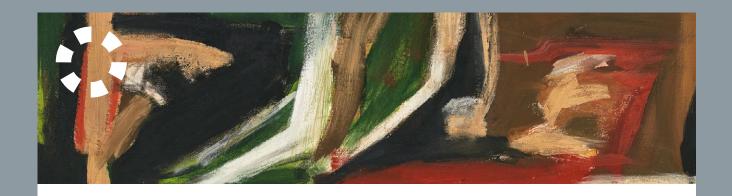
As Director of the NPRA, I invite you and the healthcare community at large to have a look at the exciting developments our country is making through this in-depth report.

Yours respectfully,

Dr. Ramli Zainal, Director, National Pharmaceutical Regulatory Agency (NPRA)









Dear members of the international pharmaceutical industry,

As CEO of PERKESO, I am proud to introduce the 2018 edition of the Malaysia Healthcare & Life Sciences Review. With a broad range of participants this report is looking deeply at the healthcare and life sciences industry of Malaysia, which I consider an excellent opportunity to showcase the strengths and opportunity Malaysia has to offer in this field.

Over the past decade, Malaysia has established itself as a local production base for the South Asian Pacific region. Furthermore, the market has been growing strongly and steadily and should not be overlooked by international stakeholders. As part of its commitment to support the growth of the sector, Malaysia's recently elected government is intensifying its efforts to improve healthcare. While Malaysia might not be the biggest market, it holds its weight in the region and the strength and growth potential of its domestic market should not be underestimated either. As a matter of fact, the latter is set to reach over 3.6 billion USD by 2020 and should benefit from the Minister's announcement to increase public health spending.

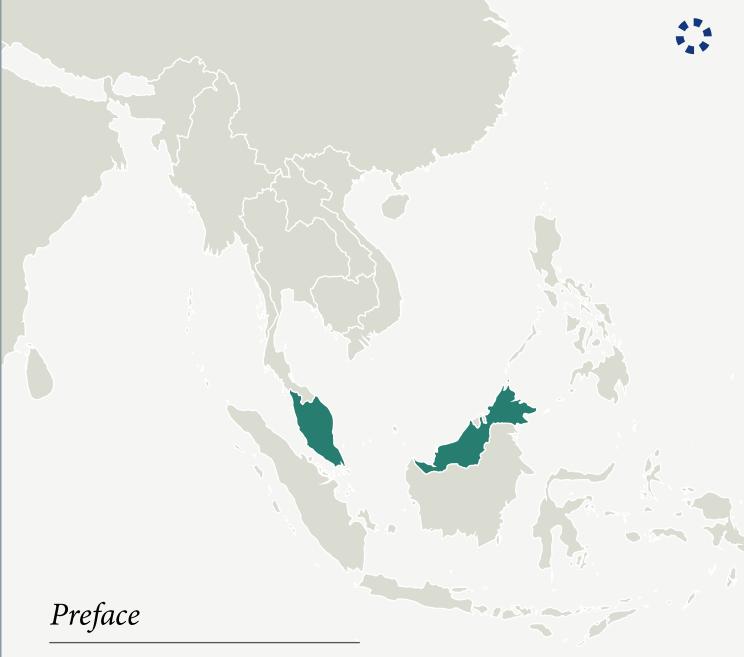
The Malaysia Healthcare & Life Sciences Review 2018 allows the international healthcare community to take a closer look at the promising opportunities Malaysia has to offer. This comprehensive study invites industry stakeholders to understand the challenges and opportunities the sector is facing right now and in years to come. I invite all members to learn more, discover and appreciate the full potential of Malaysia's life sciences and healthcare industry through this report.

With warm regards,

Dato' Sri Dr Mohammed Azman, CEO, PERKESO







A bastion of stability in Southeast Asia, with well-established institutions, a fully-functional IP framework and strong and open relationships between industry and government, Malaysia is a highly appealing investment destination.

This is especially true for the country's healthcare and life sciences sector. Despite a population size of only 32 million, Malaysian pharma is one of the best-performing sectors in the region, with an increasing number of multinational companies situating regional and global functions in the country and local firms capitalising on the nation's improving quality standards to export their medicines.

Through exclusive interviews with the Malaysian Minister of Health as well as the head of the country's regulatory body - the NPRA - this report examines

emerging trends in Malaysian healthcare, with Prime Minister Matahir Mohamad spearheading a bold health policy reform.

Also explored are the emergence of the halal medicine niche - where Malaysia has the potential to be a global leader given its geographic links to Southeast Asia and cultural ties to the Middle East - the first Malaysian biosimilars, the country's outstanding potential as a regional clinical research hub and the rise of medical tourism.

All is not perfect in Malaysia; the nation still spends a relatively low percentage of its GDP on health and non-communicable lifestyle-related diseases are on the rise, potentially straining the healthcare system to breaking point in years to come. However, for now at least, Malaysia remains a steady force and not to be discounted. \*\*



#### JOIN THE CONVERSATION

### Malaysia

Additional full-feature interviews from our Malaysia 2018 Report can be accessed on PharmaBoardroom, the premier website for C-Level executives, consultants and state actors in the pharmaceuticals and life sciences sector, alongside hundreds of exclusive interviews featuring the main movers and shakers of the industry, free country reports and sector insights supplemented by the latest news from global markets.

#### **AMPLIFIED CONTENT**



## IN BRIEF





CHUWN LEONG CH'NG CEO, Thunder Print, Malaysia

#### @pharmaboardroom

Halal Medicine in Malaysia: Here to Stay "The market for halal and Shariah-compliant products is growing rapidly because of greater awareness and greater acceptance of these products among the world's 1.6 billion Muslims." #Halal #Malaysia #medicine



TAN SRI DATO' ARIFFIN YUSUF Founder and Managing Director, Primabumi, Malaysia

#### Read the article

@pharmaboardroom

#Biosimilars in Malaysia: #Malaysia's location in SE Asia combined with its Muslim-majority population means the country is seen as a strategic partner for international companies looking to penetrate both ASEAN and Middle Eastern markets. #globalhealth

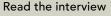


**HYZAN MOHD YUSOF** CEO, OSA Technology, Malaysia

#### Read the article

@pharmaboardroom

Datuk Seri Dr. Haji Dzulkefly bin Ahmad, Malaysia's Minister of talks to @pharmaboardroom about the sustainability of the countries healthcare system #Malaysia #globalhealth #Sustainability



#### @pharmaboardroom

#Malaysia's multi-ethnic population, disease burden, medical infrastructure and research speed, combined with its population's proficiency in English, makes the country a potentially excellent regional #clinicaltrials destination. #clinicalresearch





DHESI BAHA RAJA Special Officer to the Minister (Healthtech), Ministry of Health, Malaysia



We are present in more countries than anyone else.

We speak directly with healthcare leaders and pharmaceutical executives.

We are ready to share their insights and experiences with you.

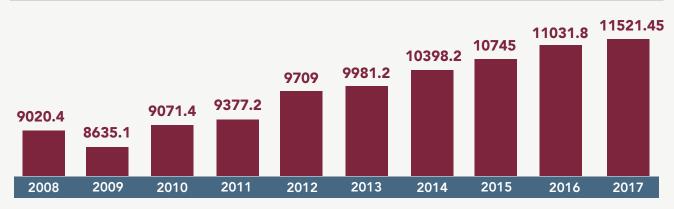




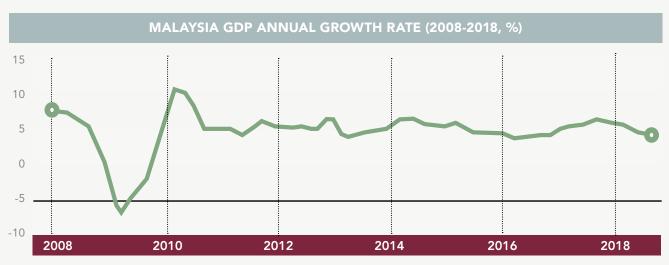
HEALTH PROFILE		
Total population (millions)	31 million	
Gross national income per capita (PPP international \$, 2013)	22	
Life expectancy at birth m/f (years, 2016)	73/78	
Probability of dying under five (per 1000 live births, 0)	not available	
Probability of dying between 15 and 60 years m/f (per 1000 population, 2016)	156/86	
Total expenditure on health per capita (Intl \$, 2014)	1040	
Total expenditure on health as % of GDP (2014)	4.2	

Source: WHO

#### MALAYSIA GDP PER CAPITA (2008-2018, USD)

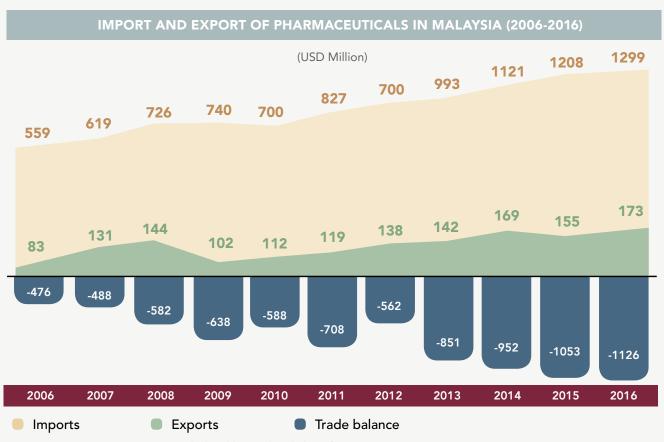


Source: Tradingeconomics.com; Department of Statistics of Malaysia

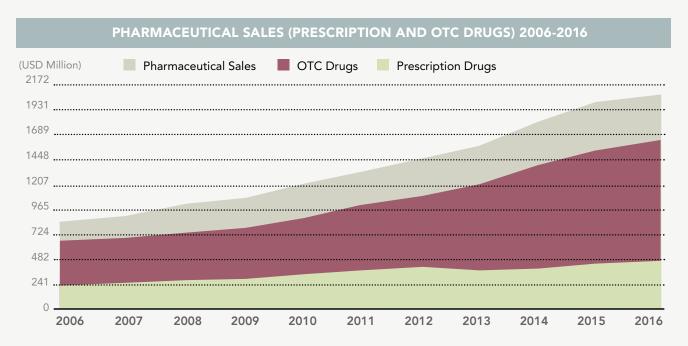


Source: Tradingeconomics.com; Department of Statistics of Malaysia



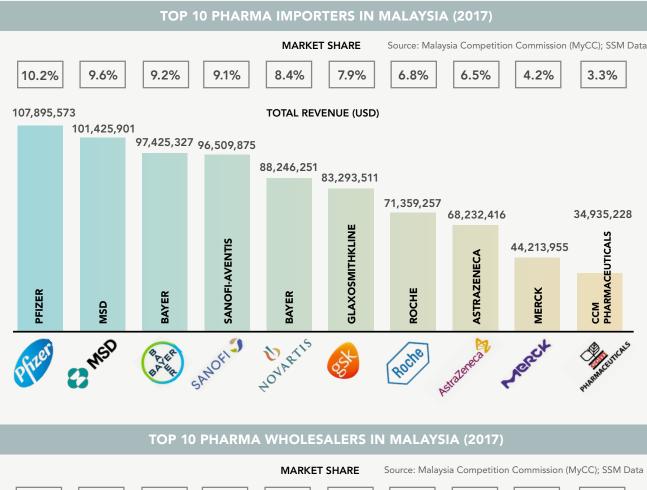


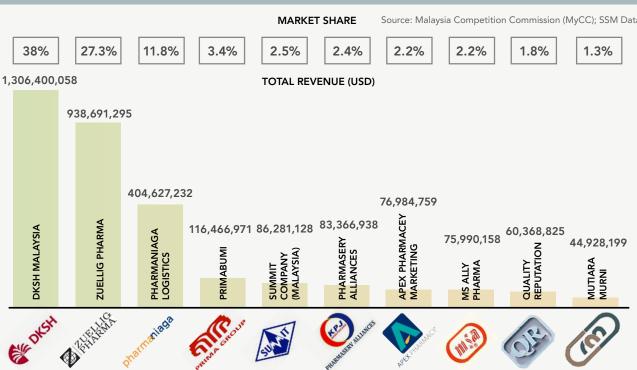
Source: MYCC; BMI Reports (2009-2017); Third World Network's calculation for 2006-2008



Source: Malaysia Competition Commission (MyCC); BMI (2011). Malaysia: Pharmaceuticals & Healthcare Report, Q1, 2011; BMI (2013). Malaysia: Pharmaceuticals & Healthcare Report, Q4, 2013; BMI (2017). Malaysia: Pharmaceuticals & Healthcare Report, Q3, 2017.

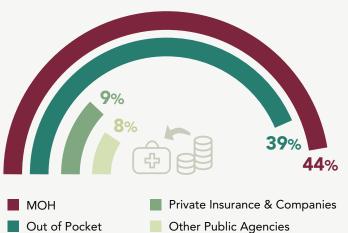






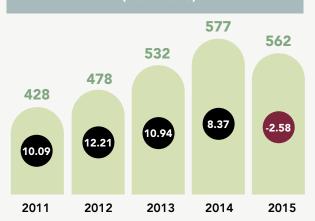


### SOURCES OF FUNDING FOR MALAYSIA'S **HEALTHCARE EXPENDITURE, 2014**



Source: MYCC; MOH-Malaysian National Health Accounts (MNHA)

#### **MOH MEDICINES EXPENDITURE** (2011-2015)

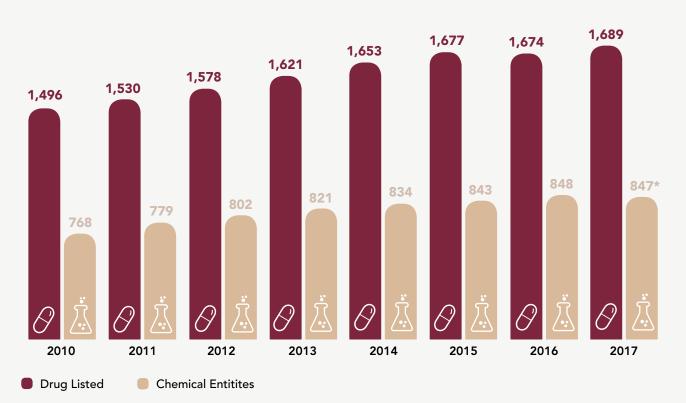


Total expenditure (USD million)

Percentage increment over the previous year (%)

Source: MYCC; Pharmacy Programme MOH Annual Report 2015

#### NUMBER OF ITEMS IN THE MOH MEDICINES FORMULARY (2010-2017)



Source: MYCC; Pharmacy Programme MOH Annual Report 2015 and MOH/PSD (\* data as of August 2017)

## KEY HEALTHCARE PRIORITIES

Datuk Seri Dr. Haji Dzulkefly bin Ahmad, Malaysia's Minister of Health, sets out his vision and key priorities for healthcare in the country over the course of the new parliamentary session.

**HCLS:** What are the key priorities you have set since receiving your mandate as Minister of Health in Malaysia?

DATUK SERI DR. HAJI DZULKEFLY BIN **AHMAD (DA):** I have two major priorities for health, an immediate priority and a longer-term priority. The former amounts to improving the shortcomings and quandaries in the delivery of health, such as waiting times, hospital and clinic congestion, and the high cost of medicines. Regarding the latter, on a longerterm basis, I would like to achieve enhanced collaboration between the public and the private sectors, in an effort to address both communicable and non-communicable diseases, in addition to an issue that can be easily overlooked - mental health, a pertinent area of wellness and wellbeing. Indeed, while cardiovascular diseases are the leading cause of mortality in developing countries, they are being overtaken by cancer and non-communicable diseases such as hypertension and diabetes in the developed world. Malaysia is following this pattern. There is also the re-emergence of communicable diseases such as Malaria, Tuberculosis, and in the Malaysian context, Dengue Fever.

We also need to improve diagnostics, accessing those who are suffering from conditions such as hypertension, but are unaware and inadvertently foregoing treatment, which will worsen the impact of non-communicable diseases on a sufferer.

#### **HCLS:** What propositions are you bringing to answer some of these challenges?

**DA:** My approach is to emphasise primary healthcare by allocating enough resources to empower the public health delivery system, and to enhance promotive and preventative medicine. This will more effectively manage the burden applied by non-communicable diseases.



If one can circumvent the occurrence of non-communicable diseases, other related ailments can be prevented too. For example, the incidence of heart attacks and strokes will decrease by tackling the incidence of obesity.

We must also address key issues like the hospital bed to population ratio, and the doctor to population ratio. As a consequence of underspending, we have insufficient places for out trainee doctors to enter the system. In Malaysia there are 5,000 new medical graduates annually from our 31 medical schools (11 in the public system, and the remaining in the private system), but only 3,000 places available for residencies. This figure also ignores Malaysian medical graduates who studied overseas. All of these bottlenecks in terms of delivery, policy, and spending are collectively the issues that I have to address.

#### **HCLS:** How is the new government endeavouring to safeguard the future sustainability of the Malaysian healthcare system?

**DA:** Our public service, which is financed through general taxation has been commendable over the years. However, we have reached a juncture where the system is no longer sustainable in its current form and cannot meet its financial burdens by increasing taxation. Consequently, we must implement the necessary reforms. This could result in Malaysia transitioning to a Statutory Health Insurance System (SHI), a Voluntary Health Insurance (VHI) system, or perhaps to another model with the foundations remaining as a tax base. Whatever the new system may be, we must launch it, in whatever form that may constitute, within the next three to five years.



#### WE HAVE REACHED A JUNCTURE WHERE THE SYSTEM IS NO LONGER SUSTAINABLE IN ITS CURRENT FORM AND CANNOT MEET ITS FINANCIAL **BURDENS BY INCREASING TAXATION**

I have also proposed the concept of a health advisory council. We have a plethora of talent in the public sector, namely in the Ministry of Health. The focus now is to leverage on the capacity of the private sector, involving them in consultations on policy matters and trouble shooting. Moreover, we could also agree to gain access to the private sector's facilities at a discount price. There is expensive equipment such as MRI scanners unutilised in the private sector. With a synergy of the systems, we could optimise resources and the private sector could alleviate some of the congestion and bottlenecks in the public sector hospitals. This is why we are creating a social agenda to guarantee access to the lowest groups. \*\*



#### LOW-DOWN ON PRIME MINISTER MAHATHIR MOHAMAD ADMINISTRATION'S HEALTH POLICY PROGRAM



- Introduction of New healthcare scheme the Skim Peduli Sihat which will allocate MYR 500 (USD 119) a year for the B40s (bottom 40 percent of households) to receive basic healthcare in registered private clinics.
- Pledge to double public spending on healthcare and increase the percentage of GDP spent on healthcare from 4.5 to six percent
- Removal of a six percent goods and service tax (GST) which will reduce the price of medicines not previously included on the zero-rating list, providing a short-term boost to drug spending in Malaysia.
- Suspension of the Patient Access scheme (PASc) that offered new medications not yet available in public hospitals for free to patients with cancer and rare diseases on the grounds that it may be a possible ethical violation.



## BECOMING A REGULATOR OF INTERNATIONAL **RENOWN**

Dr Ramli Zainal, the director at National Pharmaceutical Regulatory Agency (NPRA), explains the continuous work of NPRA to build a strong regulatory ecosystem in Malaysia and the important role that the Malaysian regulator has in the ASEAN region. He also takes time to explain the upcoming priorities to further establish the international recognition of NPRA.

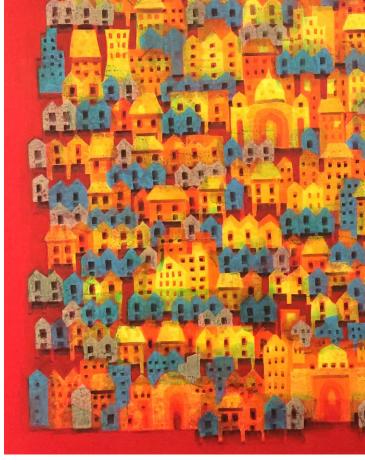


**Dr Ramli Zainal** NATIONAL **PHARMACEUTICAL REGULATORY AGENCY** 

#### **HCLS:** What were main priorities upon joining the NPRA as Director in 2017?

DR RAMLI ZAINAL (RZ): My main priority was to improve the organization to be on a par with other regulatory agencies and to strive towards regulatory excellence. We used the WHO Global Benchmarking Tool (GBT) as our reference and our early assessment showed that the Malaysian NPRA is at Performance Maturity Level three, which shows that we are performing well, considering that Maturity Level four agencies are WHO-listed authorities, more stringent regulatory agencies. To achieve Maturity Level four, National Regulatory Authorities (NRA) must fulfil additional requirements, some of which include the autonomy to recruit their own staff, enact mechanisms to promote transparency, accountability and communication, and promote Good Regulatory Practice. NPRA is already striving towards that goal. Only 50 countries are part of the Maturity Level three and four and we are among these countries.

We are a WHO Collaborative Center for Regulatory Control of Pharmaceuticals since 1996 and as such,





#### MY MAIN PRIORITY WAS TO IMPROVE THE ORGANIZATION TO BE ON A PAR WITH OTHER REGULATORY **AGENCIES AND TO STRIVE TOWARDS** REGULATORY EXCELLENCE.

we can assist member countries in terms of regulatory control of pharmaceuticals. We are also one of the very first ASEAN markets to gain the Pharmaceutical Inspection Co-operation Scheme or PIC/S accession which is the international reference standard for Good Manufacturing Practice (GMP) in the industry. Since obtaining PIC/S accession, we have also been assisting other countries to improve their GMP standards in order to be PIC/S participating authorities.

#### **HCLS:** How is NPRA performing in terms of registration approval times and price regulation?

**RZ:** In the context of registration timelines, we have collaborated with the Centre for Innovation and Regulatory services (CIRS) which conducted a survey at NPRA to analyze the timeline for approvals. Looking at their early findings, Malaysia is comparable to other countries' time frames and product registration times. One of the initiatives in this segment is the implementation of online registration





in 2002 to facilitate the registration process and also to improve transparency. Since the system was introduced in 2002, various enhancements, with input from stakeholders, were made with our latest version, QUEST3+, allowing online payments to be made. With the addition of these features, we are able to process applications more efficiently on top of ensuring greater transparency. Malaysia has also embraced the concept of reliance, which means that we are able to shorten the time of registration by relying on reports established by other recognised regulatory agencies around the world.

NPRA's focus is on determining the quality, safety and efficacy of a product before granting its marketing authorisation. With regards to pricing, it is not a determinant for product placement in the Malaysian market. This pricing issue falls under the hands of another division. Malaysia practices a dual healthcare system which comprises the public and the private sectors. As there is no pricing regulation in Malaysia as yet, the price is determined by pharmaceutical companies in the private sector. In the public sector, the national healthcare system is heavily subsidized by the government, and any product procured by the government needs to go through a process of tendering or contracts through bulk purchasing to procure at the lowest price. This entire process does not involve NPRA.

#### **HCLS:** What are the next improvements that you have set for NPRA in Malaysia?

**RZ:** We first want to work on our speed of approval, but there should be a good balance with ensuring safety. Indeed, the industry wants everything fast, but drug registration has to be well-assessed to avoid any issues with patients' safety in future. Good post-marketing surveillance and smart partnerships are vital in ensuring product safety on the market. Nowadays, regulatory agencies are communicating with each other about concerns and risks on certain aspects, which helps in hastening the process of approval. If a product is already registered in a reference country, we don't need to spend a lot of time reviewing it in Malaysia. Therefore, I believe that global networking is very important, and with WHO pushing in this direction, NPRA is looking forward to more collaboration with other regulatory authorities.

Secondly, we also want to improve the efficiency of our staff.



#### **GOOD POST-MARKETING SURVEILLANCE AND SMART PARTNERSHIPS** ARE VITAL IN ENSURING PRODUCT SAFETY ON THE MARKET

We already have a strong training programme as we send our people abroad for training and post graduate studies every year. With rapid advancement in regulatory science, we have to ensure that our staff keep abreast with current developments. Under the Asia Pacific Economic Cooperation (APEC) initiatives with regards to Good Regulatory Management, this comprises of Good Submission Practice by the industry and Good Review Practice by the regulators. In line with international agenda on regulatory system strengthening and capacity building as advocated by the World Health Assembly (WHA), we attended a lot of conferences and programmes as speakers to share our knowledge. As a WHO Collaborating Centre for Regulatory Control for Pharmaceuticals, we continue to impart our knowledge. The goal is to become a reference centre for other regulatory agencies.

Thirdly, we are re-organising our work processes in order to improve our efficiency and the needs of our industry. As a first step, we would like to put a lot more emphasis on post-marketing activities, as pre-marketing only offers limited data. In the future, we will have a lot more market surveillance activities to ensure the safety of products in the market. ::

## HERE TO STAY

The halal and herbal pharmaceutical segments both stand to grow significantly in Malaysia in the coming years as Malaysian consumers continue to exercise greater choice around their medicines.



## ALAL MEDICINE

Halal pharmaceuticals – medicines that do not contain any alcohol, parts of animals such as dogs, pigs, bees, or any other substances prohibited as 'haram' under Shariah law – are becoming increasingly widespread globally. This trend is especially prevalent in the Asia Pacific region, where the significant Muslim populations of Malaysia, Indonesia and Brunei are more frequently choosing medical products that have been officially certified as halal.

As Shahnas Oli Mohamed, the co-founder and managing director of Malaysian halal and natural product specialist Natural Wellness, explains, "The market for halal and Shariah-compliant products is growing rapidly because of greater awareness and greater acceptance of these products among the world's 1.6 billion Muslims."

66

THE MARKET FOR HALAL AND SHARIAH-COMPLIANT PRODUCTS IS GROWING RAPIDLY BECAUSE OF GREATER AWARENESS AND GREATER ACCEPTANCE OF THESE PRODUCTS AMONG THE WORLD'S 1.6 BILLION MUSLIMS.

— Shahnas Oli Mohamed NATURAL WELLNESS

Oli Mohamed continues, "In Malaysia, we are aided by the fact that it is easy to register halal products. We have a robust ecosystem in place, with the government promoting the halal agenda and Malaysia as a halal manufacturing hub. The conception of halal medicines in Malaysia is: if patients have the halal option available, they are free to take it. If they do not, they can choose among the remaining solutions. One is not obliged to forego a treatment if it is not halal."

Dr Ramli Zainal, director of the National Pharmaceutical Regulatory Agency (NPRA), is also keen to highlight the Malaysian state's receptiveness to the concept of halal medicine and its willingness to put forward the country as a leader in the field. He notes, "We see good opportunities for halal products. Indeed, in 2012 Malaysia set up the MS2424:2012 which was the first halal standard in the world. The NPRA is also involved in technical meetings to provide support to this industry."

Domestic players such as Chulia Group, a diversified Malaysian company with operations across the pharma value chain, are evermore paying attention to the



opportunities that the halal medicine field has to offer. Jamaludin Elis, country CEO for Malaysia of Chulia's Life Sciences subsidiary, proudly declares, "With one of our partners in Singapore, we are one of the only companies in the world that has registered a real, 100 percent halal vaccine. Indeed, our partners researched and released the first fully halal vaccine for Human Influenza Type B (HiB). It will be followed by another three vaccines currently in our pipeline."

Javed Ghulam Mohammad, CEO of AJ Research Pharma (AJRP), highlights the importance of the



segment for his organization. "Most of our products, other than our branded generic pharmaceuticals, are halal certified," he notes. "When it comes to herbal supplements and consumables, this is a very important segment as about 65 percent of the Malaysian consumer market are Muslim. Many consumers are reluctant to take medicine because of the non-halal factor. We can expand the market and make medicines available to this part of the community if we produce halal products. People who were reluctant to take the medicine will give us better compliance and AJRP can provide better service for this community."

The herbal medicine niche, including both Malaysia's traditional herbal remedies as well as prescription pharmaceutical derived from herbal materials, is also increasing in importance.

The NPRA's Dr Zainal outlines how Malaysia has been a first-mover in regulating this arena and now stands as a leader within ASEAN. "NPRA is involved at the ASEAN level to provide support to the traditional herbal medicine industry. Moreover, I am proud to say that we were among the first countries to regulate traditional herbal medicines." Dr Zainal continues, "For local plants, we have our own herbal monograph, which is a way to promote our local herbs. In terms of consumption, we have noticed that there seems to be an increased uptake of traditional and complementary medicines. It is currently a trend to consume these products to ensure well-being, leading to more than 50 percent out of the 24,000

products registered today being traditional and complimentary medicines."

Pharmaceutical companies are keen to jump on this particular bandwagon, with Chulia's Elis stating that, "We are also interested in herbal areas - creating prescription drugs using herbal materials. This is an area from which several successful prescription drugs have emerged. For example,



and Singapore

statins - the HMG-CoA reductase inhibitors cholesterol lowering agents - are from red yeast rice, and the drug that is used to treat Malaria is derived from molecules extracted from certain tree barks. Somewhere in the spectrum of pharmaceuticals, there is a need to look back into natural resources and convert them into drugs that heal rather than being segmented only as supplements."

Other firms have seen this trend as an opportunity to begin to supply herbal versions of established products, with promising results. Smit Soni, country manager of PT Kalbe Malaysia and Singapore notes how Kalbe in Malaysia provides "a cough syrup called Woods, a 90-year-old brand that we acquired from an Australian company. Woods has gained a revenue of USD five million per year and became the first-choice product for a recurring cough. Two years ago, we launched a herbal variant, as consumers are becoming more cautious about the chemicals within medicines. This brand is growing between five to ten percent every year despite the cough syrup market overall becoming fairly stagnant and seeing an influx of new competitors." ::



## THE BRIDGE BETWEEN THE MIDDLE EAST AND ASEAN

How Malaysia is setting itself up to provide biosimilars across the Islamic world as well as Asia.

nno Bio Ventures, a Malaysian state-owned company originally set up to create drug security by ensuring that the country was self-sufficient in terms of medicine supply, has been making its first moves into the burgeoning biosimilars market through two significant joint ventures with a Korean and an Iranian firm.

Malaysia's location in Southeast Asia combined with its Muslim-majority population means that the country is increasingly seen as a strategic partner for international companies looking to penetrate both ASEAN and Middle Eastern markets.

In this vein, Alteogen, a South Korean firm, this year signed a memorandum of understanding with Inno Bio Ventures to establish a joint venture for the development, clinical research, production and marketing of biosimilar drugs. "The idea is partly for us to utilize our connections to the Muslim world. The South Korean entity is seeking to deploy Malaysia as a hub to penetrate Middle Eastern markets," elaborates Tan Sri Rahman Mamat, chairman of Inno Bio Ventures.

Meanwhile the company has received international recognition from the D-8 Organization for Economic Cooperation – a grouping of heavily populated but geographically disparate Islamic countries (Bangladesh, Egypt, Nigeria, Indonesia, Iran, Malaysia, Pakistan, and Turkey) – for its biosimilar product invention efforts. This project has been undertaken in collaboration with the Iranian outfit Ayrogen Pharmed.

"This has been labelled the best joint venture effort to develop biosimilars as a solution for the D-8 countries," explains Rahman Mamat. "Our project, when realized, aims to bring benefit not just to the Malaysian market, but also to patients across the Islamic world."



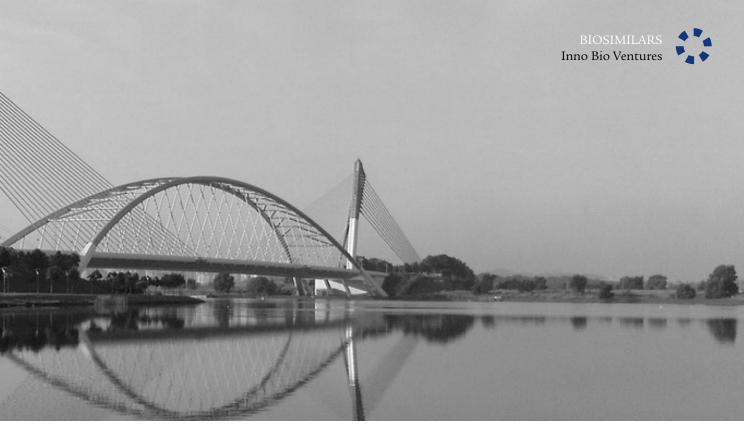
The potential combined market size of the D-8 countries is enormous, accounting for around one billion people, 60 percent of all Muslims, and close to 13 percent of the entire global population. Moreover, Intra-D8 trade stood at USD 122 billion in 2014 (see below graph).

However, the geopolitical uncertainties of the Middle East have already hindered Inno's



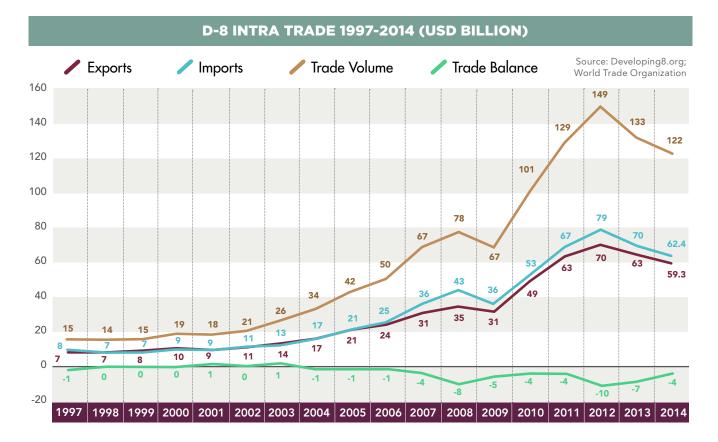
ambitions to bring their Iranian joint venture products to the domestic Malaysian market. Rahman Mamat notes that, "we encountered a setback when sanctions were re-imposed on Iran. As a result, Ayrogen Pharmed's products were only recognised in Iran, and not by the FDA or the EMEA. As this situation was unacceptable for the Malaysian authorities, it meant that we had us to delay our project in Malaysia."

Conversely, the Iran sanctions have meant that Ayrogen is looking to lean on Inno, and Malaysia, a lot more, potentially fast-tracking the country's transition into a biosimilars export hub. Rahman Mamat posits that, "There is a strong potential for exporting biosimilars from Malaysia, conditional on us transferring the technology. Given the political conflicts between Iran and the Arab world, Ayrogen's



intention is to use Malaysia as a hub as we are seen as the intermediary for its products to be accepted in the Arab states of the Middle East. We are fortunate as the Middle Eastern countries are connected to Asia

through Islam." Malaysia is also being seen as a gateway to the ASEAN region, with Inno already having been granted permission by Ayrogen to export products to China, for example. 🌣





## HOME IS WHERE THE HEART IS

American medtech giant Baxter and pan-Asian healthcare service provider Zuellig Pharma have been collaborating in Malaysia to increase the quality and quantity of care that can be given to patients in their own homes, generating significant cost-savings for the healthcare system and increasing patient-centricity.

hile home care has been an ongoing area of focus in many Western nations for over 15 years, the concept is only now gaining momentum across Asia, as governments and healthcare providers gain a greater awareness of its benefits. George Kazzi, general manager of Baxter's Malaysian affiliate, points out that "Home care is now being taken very seriously in Malaysia and has been recognized as one of the Ministry of Health's main priorities." Kazzi continues, "Home care requires experience and investment and goes beyond a simple treatment. However, it does reduce costs significantly, lightens the pressure on public hospitals and delivers an improved quality of life to patients.

[HOME CARE] REDUCES COSTS
SIGNIFICANTLY, LIGHTENS THE
PRESSURE ON PUBLIC HOSPITALS AND
DELIVERS AN IMPROVED QUALITY OF
LIFE TO PATIENTS — George Kazzi BAXTER

In the field of home care in Malaysia, Baxter is probably best-known for its home dialysis solutions, allowing patients suffering from kidney problems to receive treatment without having to enter a hospital. Kazzi acknowledges that "local healthcare professionals and the government are aware and supportive of our initiative" and underlines the company's contribution to creating a sustainable healthcare system: "In renal dialysis, the government priority is to control the rising cost of therapy. This can be done by implementing a policy that promotes a more balanced approach between home and hospital-based dialysis, creating a more sustainable model of care

whilst reducing cost and waiting times at the hospital."

However, Kazzi is keen to note that the state could go even further in promoting home care, stating that "we are firmly of the view that a 50-50 public/private model is more sustainable in the long-run. Currently, home dialysis penetration is only at 10 percent in Malaysia. Hospital dialysis is notably more expensive." Alongside savings to the healthcare system, home care also presents a potentially hugely profitable and largely untapped market. "The opportunity for companies like Baxter is clear," states Kazzi.

Baxter's main partner in Malaysia is the Singapore-

headquartered Zuellig Pharma, which provides logistics services and digital tools alongside Baxter products. Robert Kruit, the Malaysian affiliate's chief executive, explains that, for him, home care solutions are an essential element in achieving the company's mission of 'Making Healthcare More Accessible'. He adds, "We seek to reach as many Malaysian patients as possible and will not neglect some remote areas purely based on cost-effectiveness alone, even though the volumes delivered to these areas are almost negligible. This includes delivering home dialysis solutions regularly to the homes of patients in Malaysia, some of whom live in less-developed areas."



## GENERICS CHAMPION

Ch'ng Kien Peng, executive director of Xepa-Soul Pattinson, one of Malaysia's largest producer of off-patent drugs, offers insights on the dynamic healthcare industry in Malaysia and the new government's key role in supporting the local industry.



Ch'ng Kien Peng XEPA-SOUL PATTINSON

**HCLS:** Can you please introduce the company to our international readers?

CH'NG KIEN PENG (CKP): Xepa-Soul Pattinson was established 50 years ago by two Malaysian pharmacists and we are now one of the leading producers of off-patent drugs in the country and a subsidiary of the Apex Healthcare Group. We employ over 400 Malaysians who work together for our 10,000 customers which include doctors, hospitals and pharmacists. The company focuses on the development, manufacturing and marketing of products.

#### **HCLS:** What are you expecting from the recently elected Minister of Health?

**CKP:** Malaysia has solid foundations in regard to healthcare with high regulation standards and good manufacturing capability and ability. However, we need the government to take a stand and support the local industry even more. Xepa-Soul Pattinson has been very active in supplying materials and medicines to public healthcare facilities. In 2014, our government business segment represented only five percent of our revenues, while today, this segment has grown to ten percent. We are willing to make sure we can provide affordable medicines, participate in public tenders and be a good partner of choice for the Malaysian Ministry of Health.

I am confident that the new policy from the Ministry of Health will continue to support the local manufacturers' domestic and international expansion plans and will be beneficial for the country's economy. Indeed, the

Ministry has been focusing on this area as they realized that in terms of government budget spent, 75 percent goes to imported drugs which represent only 25 percent of quantity. However, Malaysia is still producing high quality and affordable medicine, and that the government needs to change the ratio spent on local products in the healthcare budget. We wish to see the Malaysian pharmaceutical market continue to grow and Malaysia become a strong manufacturing base in Asia.

#### **HCLS:** Looking forward, where can we expect Xepa-Soul's future investments?

**CKP:** Xepa-Soul Pattinson believes Malaysia is a very prospective market with high growth potential. That is why we decided to invest MYR 80 million (USD 19.5 million) in the construction of a new manufacturing plant in Malaysia instead of another location in other country. Malaysia will remain the priority market for Xepa-Soul Pattinson and the company will keep investing in the country through new infrastructures at the same time to fulfill our international expansion plan. In 2014, we reached MYR 100 million (USD 23.9 million) after seven years of effort. We are hoping the new investments will lead Xepa-Soul Pattinson to reach its 2022 financial target of MYR 200 million (USD 47.8 million) in revenue. Our corporate culture is continuously evolving to fit our new goal. 👯



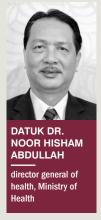
WE WISH TO SEE THE MALAYSIAN PHARMACEUTICAL MARKET CONTINUE TO GROW AND MALAYSIA BECOME A STRONG MANUFACTURING











Moreover, in the wake of the shock electoral victory of Pakatan Harapan (PH) in May after some 61 years of uninterrupted rule by a single party, the life sciences space has been receiving renewed political focus. Healthcare is now officially designated as one of the National Key Economic Areas under the Economic Transformation Programme (ETP) that strives to steer Malaysia to high-income status by 2020.

"Right now, Malaysia offers the best value for money among its neighbors to an investor looking to enter the region. Not only is it quick and easy to set up a limited liability company, but the infrastructure, tax breaks, talent pool and political backing are all in place for making R&D-related capital investments," ventures Roberto Benetello, CEO of the EU-Malaysia Chamber.

Certainly, an increasing number of international pharma firms appear to be eyeing Malaysia up as a decent destination to situate their regional hubs including for non-manufacturing activities such as R&D and business processing operations.

#### RIGHT NOW, MALAYSIA OFFERS THE **BEST VALUE FOR MONEY AMONG** ITS NEIGHBORS TO AN INVESTOR LOOKING TO ENTER THE REGION

Roberto Benetello EUMCCI

One example has been the establishment of the Roche APAC Shared Service Center (SSC). "Malaysia stands as one of only three such operations worldwide and provides finance, procurement, and IT services to 15 countries across the APAC region. Today, it employs some 350 personnel and we actually have ongoing plans to expand out its services to support additional countries," explains the company's general manager, Lance Duan.

Novartis, meanwhile, appears to have pursued a very similar logic. "We identified great potential to harness

the availability of diverse talent and strong market forces so set about establishing Kuala Lumpur as one of the five Novartis Global Service Centers," recounts Sandoz's country head Fabio Sperandei.

# general manager,

#### **CULTIVATING A MANUFACTURING BASE**

At the same time, Malaysia is starting to witness the maturity of a local manufacturing base and the simultaneous take-off of a fledgling pharmaceuticals export industry. Aside from a handful of notable exceptions - such as Ranbaxy, Biocon and SM Pharma - the bulk of pharma manufacturing in Malaysia has always been conducted by indigenous companies, with MNCs instead preferring to import



their products or harness the services of local contract manufacturers like Xepa-Soul Pattinson.

"We worked for more than ten years with Taisho Pharmaceuticals, the number one OTC company in Japan, and helped them enter Malaysia by developing and producing their cough syrup products. We have also acted as Sanofi's approved GMP site since 2016 and have been developing eye drop products for SNEC since 2014, all of which has furnished us with valuable expertise," explains the company's executive director, Ch'ng Kien Peng.

Nowadays, having learned from these partnerships, companies like Xepa-Soul Pattinson are beginning to ramp up their own export strategies. "Already we are managing to source some 25 percent of our revenues from export activity courtesy of a strong presence in Myanmar and are now in the process of entering Vietnam as well. We want to keep expanding and growing in South-East Asia but will simultaneously be seeking to deepen our presence in African countries," asserts Peng. "We aspire to place ourselves on the world map and to realize that goal we have to expand our solid base production capacity and secure the requisite accreditations," he adds.





Many industry insiders credit the National Pharmaceutical Regulatory Agency (NPRA) with raising the standards of Malaysian manufacturing and rendering locally produced pharmaceuticals fit-for-export. "The NPRA has been upgrading its regulatory and compliance standards in line with international norms with the unequivocal aim of rendering the Malaysian pharmaceutical industry as a lead-

er in the regulatory field within ASEAN. This has been useful to our members because it furnishes their exports with a competitive advantage," muses Billy Urudra, president of the Malaysian Organization of Pharmaceutical Industries (MOPI).

"Another big advantage has been that Malaysia is now a member of the Pharmaceutical Inspection Co-operation Scheme (PICS)," notes Javed Ghulam Mohammad, CEO of AJ Research & Pharma. "This is highly beneficial for companies looking to later distribute their products in any regulated market around the world, because the manufacturing processes will have already gone through very stringent guidelines."

"Moreover, the regulator is also more stringent in its testing of local as opposed to foreign companies," reflects Saravanan G., managing director of Biocare Group. "While MNCs get audited every five years, Malaysian companies are audited every year so there

is absolutely no compromise made on quality. This ultimately provides greater opportunities for local companies to export to the 54 PICS member countries," he reasons.

"Malaysia relies disproportionately on pharmaceutical imports with almost 60 of the therapies consumed coming through that channel. We are therefore doing all we can to support the local pharmaceutical industry and, in tandem, render Malaysia



more self-sustainable," affirms NPRA director, Dr. Ramli Zainal. "It is testament to these efforts that Malaysia can lay claim to being one of the very first ASEAN markets to gain the PICS qualification and we are therefore a benchmark and role model for others," he declares.

#### A SURGE IN GENERICS & BIOSIMILARS

One slice of the local market that has been registering particularly strong growth is generics. "Only a decade ago, innovator drug developers used to possess a strong foothold with originator products accounting for over 80 percent of market supply, but nowadays generic penetration is reaching 45 to 50 percent and this is only set to rise further as other top brands reach the patent cliff," reasons MOPI's Billy Urudra.





#### **Branching out into Bugtech**



**TUNKU NAQUIYUDDIN** 

executive chairman, Antah Healthcare Group



**TUNKU MOHAMED ALAUDDIN** 

managing director, Antah Healthcare Group

Antah Healthcare Group, one of Malaysia's leading domestic pharmaceutical distributors, has taken its first steps into the biotechnology arena through the establishment of Entogenex - a new company developing products that fight mosquito-borne diseases.

Tunku Naquiyuddin and Tunku Mohamed Alauddin, the Group's executive chairman & managing director respectively, explain the technology behind their innovative new products. "We received a grant from the Malaysian government to commercialize our science, which consists of modifying a molecule in the female mosquito cell to alter its digestive system so that larvae, upon consuming the peptide, die from metabolic starvation, thus controlling the spread of mosquito-borne diseases such as dengue fever," they note.

This technology has proved highly effective thus far. "Entogenex has further developed a product containing that molecule to be sprayed onto surfaces like roofs, gutters and trees to minimize

the mosquito population without polluting the environment," claim Tunku Naguiyuddin and Tunku Mohamed Alauddin. "As it became more effective, we received another grant from the government to use our product across the country. It has proved to be a great success and the Ministry of Health has seen the incidence of dengue decrease by 54.7 percent."

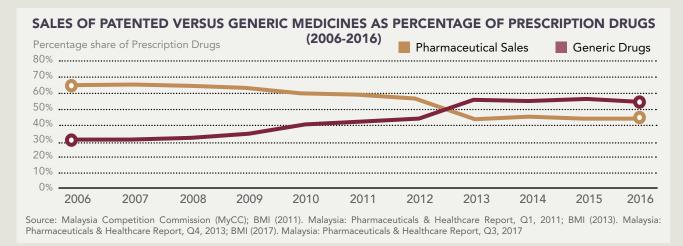
Entogenex could yet prove to be a global success story for Malaysian innovation. Tunku Naquiyuddin and Tunku Mohamed Alauddin proffer that "The next step is to enter the EU, thanks to another grant. We are currently preparing a launch in Portugal and planning to expand this science towards the control of caterpillars which destroy plantation crops."

The segment remains, nonetheless, a crowded field where competition is notoriously stiff. "Many more companies now understand the merits of the Malaysian market and are angling for a piece of the action and therefore it pays off to be able to deliver up a differentiated offering," counsels Sandoz's Sperandei. "The main risk for a generics player is to enter a large number of therapeutic areas without any real focus. We have therefore made it our strategy to prioritize three to four therapeutic areas where we know we can be dominant," he adds.

Local actors, meanwhile, have had to come up with their own distinctive pathways. "We are not able to







compete head to head with large generics players from India or China that possess a heavyweight domestic market to fall back on," frankly acknowledges David Ho, managing director of Hovid. "Our strategy has thus been to bring innovations in niche segments. We focused on developing different controlled

release delivery systems and combination products," he elaborates.

Interestingly, discernable momentum can equally be witnessed in the biosimilars field. "The Malaysian authorities are particularly keen to encourage and incentivize investment into biosimilars and any firm





entering this market is being welcomed with open arms... already we have introduced two such items into the local market: namely the oncology product Filgrastim, and Epoetin Alfa, used by nephrologists and dialysis centers," recounts Sperandei. Similarly, last year, the Indian outfit, Biocon, was awarded a three-year contract by the Ministry of Health to supply recombinant human insulin (rh-Insulin) formulations manufactured at its biopharmaceutical facility in Johor.

#### BUDDING HEALTHCARE TOURISM DESTINATION...

When it comes to the healthcare sphere, Malaysia certainly seems to have scored some memorable wins. "Notwithstanding the ongoing challenges that we face, the performance and quality of healthcare in Malaysia remains robust: we have recently become the first western pacific state to eliminate what is known as mother-child transmission of HIV and syphilis, the culmination of work that is a decade in the making," enthuses Minister of Health, Dr. Haji Dzulkefly bin Ahmad.



#### NOTWITHSTANDING THE ONGOING CHALLENGES THAT WE FACE, THE PERFORMANCE AND QUALITY OF **HEALTHCARE IN MALAYSIA REMAINS ROBUST**

— Dr. Haji Dzulkefly bin Ahmad

What's more the country has managed to assert itself as a prominent leader in health tourism. Malaysia began developing the healthcare travel scene in the early 2000s. Seeing its potential to contribute to the nation's GDP, the government set up the Malaysia Healthcare Travel Council (MHTC) in 2009 to facilitate and promote the country's healthcare travel service offerings. The results have been a resounding success: Malaysia today ranks eighth worldwide for medical tourism, possessing a market that is currently worth USD 290 million and is predicted to grow at around 30 percent annually for the next six years, reaching USD 3.5 billion by 2024.

Sherene Azli, CEO of the MHTC explains, "We offer world-class quality healthcare facilities and services. Malaysia houses almost 200 private hospitals with exemplary quality and safety standards benchmarked against the best in the world. Moreover, the country's

healthcare system is internationally recognized for its excellence and the cost of treatment is affordable compared to both countries within the region and further afield. Additionally, it is easy to communicate with healthcare professionals in the country as English,

#### **Southeast Asia's First Medial Device Refurbishment Park**



**JAMALUDIN ELIS** 

CEO, Chulia Life Sciences

One hidden cost of the healthcare value chain is the refurbishment and repair of medical devices which can no longer be used effectively. With some 60,000 pieces of medical equipment currently in disrepair in Malaysia, a plan to invest MYR 400 million (USD 95 million) in a medical device refurbishment and innovation park - the ASEAN Medtech Innovation Park (AMTOP) - was put forward in 2016, with construction slated to be completed within 2018.

With funding from the investment arm of Yayasan Bina Upaya Darul Ridzuan (YBUDR) – a non-profit foundation set up to assist the Malaysian government to address poverty issues - the project will be jointly developed by YBUDR and the privately-held healthcare group, Chulia Life Sciences.

Assessing the potentially wide-ranging impact of the park - the first in the region - on the Malaysian healthcare industry, Chulia's Jamaludin Elis asserts that "AM-TOP will be the first medical device refurbishment and innovation park in the region covering four main areas: medical equipment upgrading and repair, education and skills training, research and development, conformance testing, prototyping and manufacturing. The park will address the gaps in the medical device industry and help save costs to reduce rising healthcare expenses in Malaysia."

Elis feels that AMTOP also has the ability to bolster the economy of Malaysia as well as those of its regional neighbours. He elaborates, "This park will be a complete ecosystem of medical technology and innovation in ASEAN which can be replicated across the region. In the future, we want to expand into other markets, creating specializations unique to each location. For example, Thailand could be the center for X-ray machines and Vietnam for ultrasound technology with the Malaysian park acting as central hub. This can be a platform to exchange knowledge and experiences which will create a strong base of collaboration across ASEAN."





Malay, standard Chinese dialects and Indian languages are widely spoken. Malaysia is also incredibly well connected to all major travel hubs around the world," she details.

Günther Beissel, CEO of the Malaysia International Trade and Exhibition Center (MITEC), adds, "Malaysia was recognized as the 'Health & Medical Tourism: Destination of the Year'

for three consecutive years from 2015 to 2017 by the International Medical Travel Journal and in 2017 also ranked first in International Living's 'Four Countries with the Best Healthcare in the World' and sixth for 'Best Retiree Healthcare on the Planet.'"

#### .... BUT STRUCTURAL DEFICIENCIES

However, some systemic problems lie bubbling beneath the surface. Firstly, there is recognition that the country has been skimping on health expenditure and that there is a lot of catching up to do for the public health apparatus to become properly capitalized. "As an upper middle-income economy, we have simply underspent on healthcare. While the average spending on healthcare for an economy of our size is around six to seven percent of GDP, we are only spending 4.5 percent on healthcare" candidly admits Minister Dzulkefly bin Ahmad. "Consequently, I am determined to oversee an incremental increase of budgetary allocation towards healthcare over the next five years in this parliamentary session so that we can address pressing infrastructure issues, such as aging facilities and equipment," he pledges, noting that of Malaysia's 145 public hospitals, 45 are over 100 years old!

Secondly, the country's transition towards a high-income status is adversely impacting Malaysia's epidemiological profile. In recent decades, Malaysia's population has witnessed a dramatic surge of non-communicable diseases (NCDs) due to the prevalence of unhealthy diets and lifestyles. NCDs currently account for 70 percent of all deaths in the country and, in 2017, the country had the ignominy of having the highest rate of diabetes in the Asia-Pacific, with almost one-fifth of its population living



TOP 10 PHARMA IMPORTERS IN MALAYSIA (2017)					
Company	Total Revenue (USD)	Market Share (%)			
1 PFIZER	107,895,573	10.2			
2 MSD	101,425,901	9.6			
3 BAYER	97,425,327	9.2			
4 SANOFI-AVENTIS	96,509,875	9.1			
5 NOVARTIS	88,246,251	8.4			
6 GSK	83,293,511	7.9			
7 ROCHE	71,359,257	6.8			
8 ASTRAZENECA	68,232,416	6.5			
9 MERCK	44,213,955	4.2			
10 CCM PHARMACEUTIC	ALS 34,935,228	3.3			
Source: Malaysia Competition Commission (MyCC); SSM Data					

with the disease. "The incidence of diabetes has increased from 6.6 to 17.5 percent of the population. Hypertension is now at around 30 percent, and 45 percent of the population is now overweight. Half of those with diabetes are undiagnosed and, amongst those diagnosed, 50 percent are poorly controlling the condition," laments Dr Noor Hisham bin Abdullah, director general at the Ministry of Health.

Naturally this is, in turn, placing great strain on the finances of the social security apparatus known as PERKESO. "NCDs are jeopardizing our financial viability: we receive around 14,000 new claims for invalidity pension or survivors' pension due to NCDs each year



and this now accounts for some 50 percent of all invalidity claims," reveals the social security system's CEO, Mohammed Azman.

Unfortunately the existing toolbox for competently dealing with these problems is inadequate. "The snag at the moment is that the treatment of NCDs is based on a comparatively expensive curative and therapeutic approach with no guarantee of success. Healthcare professionals are treating diseases without necessarily looking at preventive measures. Therefore, the government has to focus on investing more resources into prevention - the only way to change stakeholders' mindsets and ultimately reverse the situation," analyses Dr. Azrul Mohd Khalib, chief executive of the Galen Center for Health and Social Policy.

Saunthari Somasundaram, president of the National Cancer Society Malaysia (NCSM) very much agrees. "Unfortunately, in Malaysia the mindset is still set on care means therapy, meaning that all resources are allocated to therapies and treatments while care (physical

therapists, nutritional therapists, cancer nursing care) is left apart. There is nothing done at the moment to accompany patients through the transition in their cancer journey from the hospital to home," she argues.

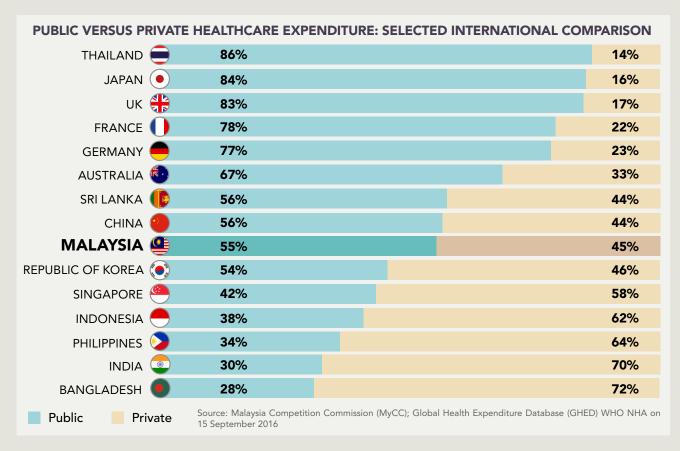
Nor does Malaysia yet possess the requisite digital infrastructure to track patient groups and apportion resources in an optimum manner. "Currently, there are a lot of inef-



ficiencies in the system due to poor planning. There is no real-time inventory showing which hospitals have an excess of a particular drug that could be needed in another hospital. A mechanism that allows for the efficient allocation of resources could easily save the government up to two-three percent of the public health budget," regrets Cliford Patrick, regional vice president of listings at the Master Index of Medical Specialty (MIMS).







Dr. Dhesi Baha Raja a consultant at the Ministry of Health who has been recruited specifically to address these issues, very much concurs. "One of the main issues in the country is the lack of Big Data. Malaysian hospitals are not interconnected, and some are still using paper medical records. However, having an electronic platform that is shared by all hospitals and gathers all patients' medical records would help the Ministry of Health understand the evolution of specific health burdens in different region and adapt their policies to the Malaysian needs," he concludes.

Nor are all potential options being explored. "The time is ripe to start looking externally for inspiration and begin coopting the private sector through proper PPPs. The government needs to recognize private enterprise as a solution which can drive healthcare forward and alleviate the burden, rather than merely viewing it as a commercial entity," opines Chulia's Jamaludin Elis.

#### **GREAT EXPECTATIONS**

Many will, no doubt, be vesting their hopes in the surprise return to power of Mahathir Mohamad, a nonagenarian former 5-term prime minister credited with liberalizing healthcare in the 1980s, who now spearheads a populist coalition whose unorthodox policies include, among others, monopoly busting in life sciences procurement, free medical insurance

for the poor, and lavish spending on public healthcare.

"The newly elected government has seemingly embarked upon a decent reform trajectory by announcing their intention to double the budget allocation for healthcare, but we are still in the dark about how they actually intend to reach this unprecedented target," frets Kheng Huat Ewe, executive director of PhAMA, the Malaysian association for innovative companies.

"The new regime has been voted in for their progressive thinking and it's the very first time that such a laudable program dedicated to supporting the health needs of the poor has been mooted, but, to date, no concrete financial plan has been established to buttress this initiative," agrees Antah's Tunku Naquiyuddin.

## A CLINICAL TRIALS HUB FOR SOUTHEAST ASIA?

Malaysia's multi-ethnic population, disease burden, medical infrastructure and research speed, combined with its population's proficiency in English, make the Southeast Asian nation a potentially excellent regional clinical trials destination.

Akhmal Yusof, CEO of Clinical Research Malaysia (CRM) - the organization tasked by the Malaysian Ministry of Health with increasing the level of clinical research in the country - notes, "We have a population of 32 million which represents a third of the world's genomics." Dr. Goh Pik Pin, director of Malaysia's Clinical Research Centre (CRC) adds, "We have a wide demographic and genetic pool, which is important for the testing of new drugs which may have different effects on different genetic makeups. In this regard, clinical trials conducted with the multi-ethnic Malaysian population can root out different responses to different drugs."

Furthermore, as the below chart shows, Malaysia is highly competitive in terms of the costs of conducting clinical research at USD 350 per patient per doctor's visit, compared to USD 640 in Thailand, USD 820 in Taiwan and USD 1,210 in Singapore.

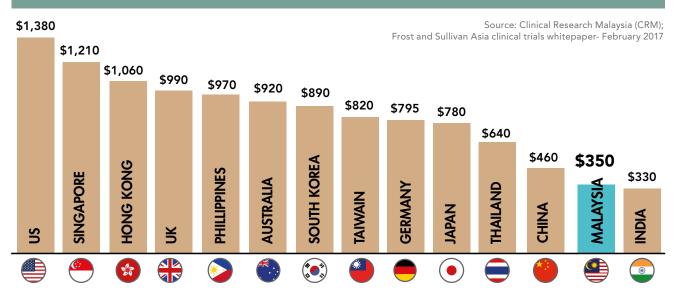
Dr Yusof also highlights the fact that "Kuala Lumpur is home to the biggest hospital in Southeast Asia - Hospital Kuala Lumpur - which has more than 2,000 beds and over 6,000 health care personnel working there. Moreover, there are several hospitals of a similar size in Malaysia and therefore there is a



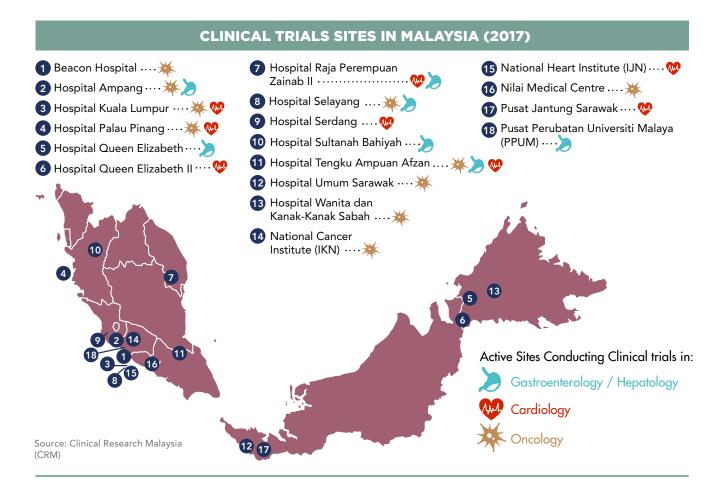
huge pool of patients within a diverse range of therapeutic areas here."

Dr Yusof continues, "We Malaysians also have a good command of English so there is no need for documents to be translated. This cuts bureaucracy and

#### **COMPETITIVE COSTS OF CONDUCTING CLINICAL RESEARCH**







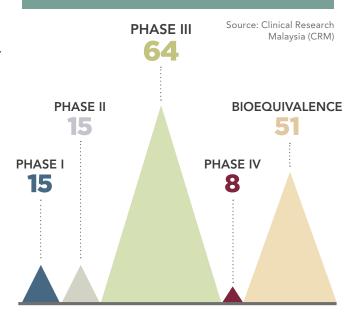
increases the accuracy of administration. Furthermore, the common diseases in Malaysia are similar to those seen in western countries. Finally, we work very hard in maintaining timelines. The timeline to review clinical research in the country has been reduced tremendously. The ethics review committee under the Ministry of Health now sits twice a month, helping us to complete

GOH PIK
PIN
director,
Malaysia Clinical
Research
Centre (CRC)

the review of these study proposals at Ministry of Health sites within six to eight weeks. Moreover, reports have shown that the timeline could be cut further down to 31 days in the case of no issues. Considering reduced timelines in ethics and regulatory reviews, Malaysia is now one of the most efficient places in the region to conduct research."

Despite these appealing factors, Dr Yusof feels that Malaysia does not have the reputation it deserves

## TYPES OF CLINICAL TRIALS CONDUCTED IN MALAYSIA (2017)



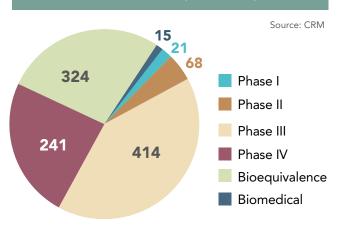
as a clinical trials destination. "Malaysia lacks exposure on the world stage for its involvement in early stage research, as the number of trials we conduct is still small. Therefore, we are working with centres in Malaysia to develop their capacity for phase I and pre-clinical research ... In conjunction with this, we are ensuring that our researchers have the appropriate training to conduct early stage research. We are sending medical professionals on scholarships to train in centres that have conducted a significant amount of early phase research such as King's College London and The Christie in Manchester, UK."

#### CONSIDERING REDUCED TIMELINES IN ETHICS AND REGULATORY REVIEWS. MALAYSIA IS NOW ONE OF THE MOST **EFFICIENT PLACES IN THE REGION TO CONDUCT RESEARCH**

Dr Akhmal Yusof CRM

In terms of clinical trial density, Malaysia does stand slightly above neighbours Thailand and the Philippines but lags far behind more established research destinations like Taiwan, Hong Kong and Singapore (see above

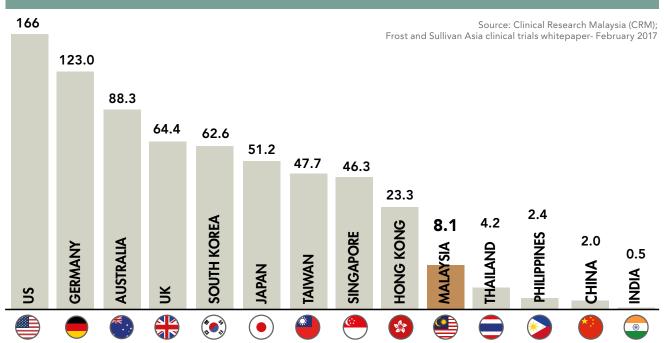
#### TYPES OF CLINICAL TRIALS CONDUCTED **IN MALAYSIA (2012-2017)**



Following are the breakdown of clinical trial phases between 2012 and 2017. In terms of the phases and types of clinical trials conducted, 69% consisted of phases I to IV trials, with bioequivalence and resgistry studies as well as biomedical research making up the other 31%.

chart). As Dr Yusof exclaims, "Taiwan and Hong Kong are currently conducting three to four times more sponsored clinical research per capita than Malaysia. Therefore, we have significant scope for growth!"

#### COMPETITIVE COSTS OF CONDUCTING CLINICAL RESEARCH



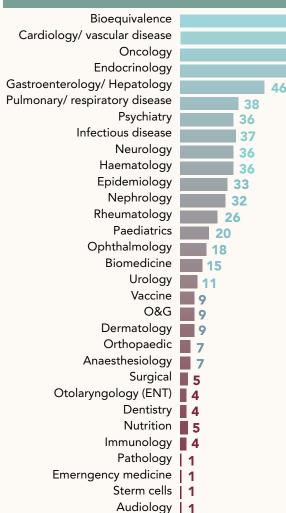




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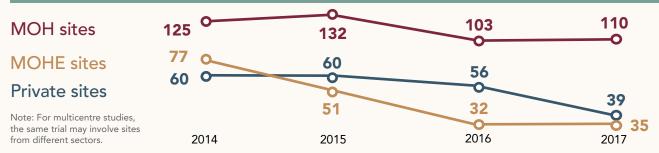


Disease patterns in Malaysia are almost similar to those in developed countries. Malaysian patients have similar unmet needs that these countries have. Cardiovascular disease and cancer are the major cause of mortality and morbidity in Malaysia. The high incidence of these non-communicable diseases provide a large patient pool for clinical trials in these therapeutic areas. Over the years, the therapeutic areas of ISR in the country has expanded to 30 different areas, ranging from drug-related trials to medical devices and biomedicine.

Source: CRM

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## ISR CONDUCTED ACROSS PRIVATE HOSPITALS, MINISTRY OF HIGHER EDUCATION-AFFILIATED AND MINISTRY OF HEALTH-AFFILIATED SITES (2014-2017)



Premises for clinical trials are available both in the private & public sector and each sector offers numerous sites across the country. Due to the variable in population groups and expertise available at the different sectors and sities, the same clinical trial may be conducted at different sectros and involving more than one site each. This is referred to as multicentre studies. Multicentre studies offer better data comparison on effectiveness of a product over large populations with varying genetics, environment, ethnic and cultural background.

Following is the breakdown on ISR conducted across different sectors and sites from 2014 to 2017.

Source: CRM

## END TO END SOLUTIONS

Jamaludin Elis, country CEO of Chulia Life Sciences Sdn Bhd, discusses the Chulia Group's diverse business activities across the healthcare spectrum.

#### **HCLS:** Can you present the different healthcare businesses under the Chulia Group, including Chulia Pharmaceuticals?

JAMALUDIN ELIS (JE): Chulia Life Sciences Sdn Bhd (CLSSB) is the main holding company focusing on the healthcare industry, including Chulia Pharma Sdn Bhd (CPSB), Chulia Medical Solutions (CMSSB) and Chulia Biomedical Engineering Sdn Bhd (CBESB). CPSB is principally engaged in the manufacturing, distribution, import, and export of generic pharmaceuticals, nutraceuticals, cosmeceuticals, and consumer products. CMSSB handles non-pharma related support services for the company's clients such as logistics, supply chain, and medical device sourcing and maintenance. Lastly, CBESB is aiming to establish and operate the first medical device refurbishment and innovation park in Southern Asia.

Chulia Facilities Management (CFMSB), our parent company, operates in healthcare facility maintenance. CFMSB offers air quality, facility cleaning, waste management, and biomedical engineering maintenance solutions. Chulia Group is the partner of choice for healthcare institutions as a single company providing end to end support services. We manage equipment, facilities, and the delivery of consumables to our clients all within one organization.

#### **HCLS:** Could you explain Chulia's move into logistics and supply chain management?

**JE:** To meet the need for supply chain improvement, we have introduced within CMSSB's activity, an innovative, cost-saving and environmentally friendly cold chain logistics system. The box lasts for about 24 months and is equipped with a temperature control device called the Phase Change Module (PCM). The module is conditioned to have the desired temperature and will stay consistent for 96 hours. It has a data logger that will track and record the temperature consistently

Jamaludin Elis CHULIA LIFE SCIENCES SDN BHD



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#### CHULIA GROUP IS THE PARTNER OF CHOICE FOR HEALTHCARE INSTITUTIONS AS A SINGLE COMPANY PROVIDING END TO END SUPPORT SERVICES.

and monitor and locate the package. This data is sent back to our cloud database and the recipients of the product will receive a digital certificate to show that the product has been consistently monitored and according to the required standard.

#### **HCLS:** What about hemodialysis supply?

**JE:** We provide hemodialysis machines, dialyzers, consumables, bloodlines, and other solutions. Again, by dissecting the overall cost of supply chain, we noticed there are hidden costs such as maintenance, consumables as well as transportation costs. Partnering with suppliers, we secured on block volume purchases which allows us to negotiate prices. This way the patient treatment costs in healthcare institutions are maintained for a long period of time, increasing patient accessibility.

#### **HCLS:** To what extent is Chulia embracing digital healthcare solutions?

**JE:** We have also developed a software system which allows patients to visit any healthcare institution for treatment. The system connects the patients to the doctors, the dialysis centers and the payment gateway. When patients visit a new dialysis centers, they are required to provide full medical background, otherwise receiving treatment can be a challenge. Using our system, patients log in to provide quick access to their medical history report to doctors in each healthcare center. Immediately, visiting a new hospital or clinic is streamlined and all the data of treatment during the visit is sent back to the system for processing. Patients have the freedom to travel without having to be concerned about how they will receive treatment. 🛟

## PREVENTATIVE HEALTHCARE AND PERSONALIZED MEDICINE

Lance Duan of Roche and Kshitij Panse of Servier discuss how their affiliates are advocating for preventative healthcare and personalized medicine in Malaysia.

#### ON PREVENTATIVE HEALTHCARE...

"We believe prevention should be a highly prioritized area, not only in Malaysia but in all healthcare systems. Prevention begins with awareness. Looking at the reason patients in Malaysia receive a very late diagnosis, we know that patients are unfamiliar with the disease and often do not perform regular screenings. Therefore, Roche is working to develop public awareness of cancer, especially lung, colorectal and breast cancers. We have over 20 collaborative partnerships with associations and NGOs to bring knowledge and better educate the public."

— Lance Duan ROCHE



"Recently our head office has worked on a strategy called "Patient-In". This not only attempts to do things for the patient, but also with the patient. To provide a concrete example, first we improve the awareness for certain diseases. In the case of hypertension, we launched a project called "because I say so". We took the campaign to the streets and to the universities handing out t-shirts with "because I say so" written on them after they agree to check their blood pressure. Through this, we help to increase awareness and improve diagnoses. We have plans for a similar programme with angina. At a global level, there is a new Patient-In officer who has been recruited. As a result, it is imperative that we work with the Patient-In strategy in Malaysia too."

— Kshitij Panse SERVIER

#### ON PERSONALIZED MEDICINE...

"In the future, we anticipate the prevalence of personalized healthcare discussions. Before this development can be realized, we have two major questions to address with the government: is the country ready for the radical change in the healthcare system and equipped with the knowledge to handle personalized healthcare, and what is their intent to distribute that knowledge across to all stakeholders. For example, all policymakers, regulators, payers, healthcare professionals, and patients should be on the same page. Once these issues are addressed, the health system will be ready to include personalized healthcare into the conversation."

— Lance Duan ROCHE

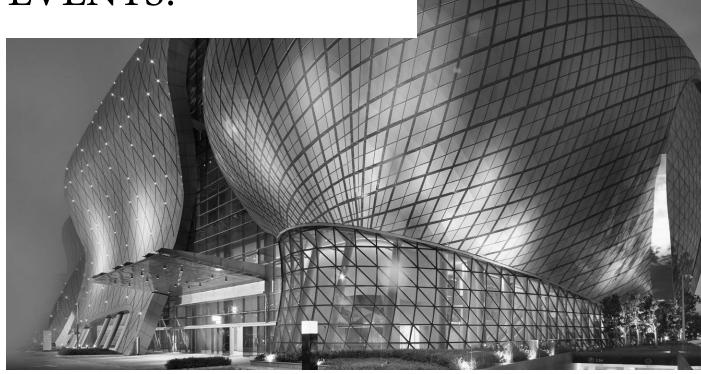
"We consider the tools and initiatives that we can provide for the patient, such as Deprexis®, an online version of Cognitive Behavioural Therapy (CBT). This is a computer-based programme designed by a German partner company. The psychiatrist can provide a code to the patient, who can go online and receive psychological counselling. This is one of our products related to E-health. We envisage this product being helpful for a number of reasons. Firstly, patients are averse to visiting the psychologists for therapy in person, again linked to the stigma. Secondly, the availability of psychologists in Malaysia is sparse. Our vision is to work with both patient groups and doctors so that patients understand their conditions." :

— Kshitij Panse SERVIER









the Malaysian pharmaceutical industry expands and develops greater links with its Southeast Asian neighbors, a significant need has emerged for a space where key stakeholders can meet, interact and promote their business offerings.

One organization aiming to fulfill this role is the Malaysia International Trade and Exhibition Center (MITEC), established in 2017, which is branding itself as 'The Venue of Choice for Medical Exhibitions.' CEO Günther Beissel explains that MITEC is "the largest trade and exhibition venue in Malaysia with 45,000 sqm of space. MITEC is strategically located less than 7.5 km away from Kuala Lumpur city center, less than 65 km from the Kuala Lumpur International Airport and is being positioned as an economic catalyst and gateway to Southeast Asia."

Beissel is keen to highlight MITEC's strong governmental ties and its role in helping achieve national goals. He points out that, "MITEC is owned by the Malaysia External Trade Development Corporation (MATRADE), a national trade promotion agency under the Ministry of International Trade and Industry (MITI). This synergy brings many advantages to the venue ... our ultimate vision is to see Malaysia becoming the leading Meetings, Incentives, Conferences and Exhibitions (MICE) destination in Southeast Asia."

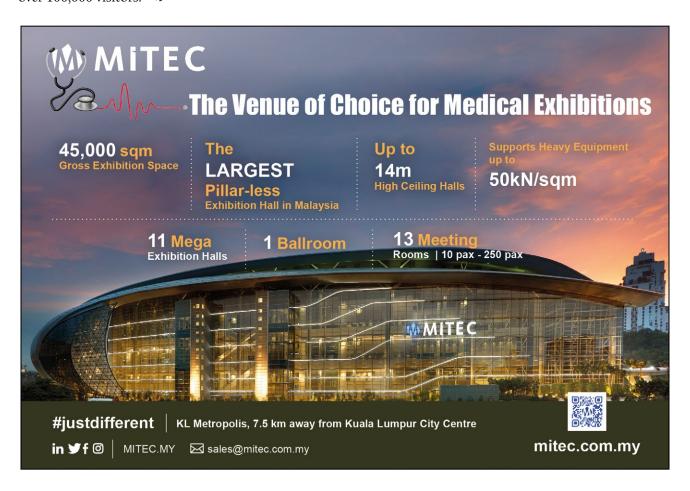


Having already played host to two major medical events in its short history - the Malaysia Medical Device Expo 2018 and the Malaysian International Scientific Congress of Obstetrics and Gynecology 2018 - Beissel feels that MITEC can continue to capitalize on the dynamic Malaysian and Southeast Asian healthcare



OUR ULTIMATE VISION IS TO
SEE MALAYSIA BECOMING THE
LEADING MEETINGS, INCENTIVES,
CONFERENCES AND EXHIBITIONS
(MICE) DESTINATION IN
SOUTHEAST ASIA. — Günter Beissel MITEC

industries. He concludes, "MITEC is a game changer in the business events industry, giving Malaysia the capability to compete and meet demand in emerging markets, including for regional and international exhibitions, particularly for 'mega-exhibitions,' which attract over 100,000 visitors." ::





## MALAYSIA'S UNEXPECTED HEALTH REFORM **PROGRAM**

After 61 years of single-party rule, the May 2018 electoral victory of the populist Pakatan Harapan (PH) coalition sent shockwaves through the Malaysian political landscape. This has been keenly felt within the healthcare sphere, where industry players are broadly supportive of PH's plans to increase low-income Malaysians' access to treatments but concerned as to how these measures will be funded and implemented.



pon taking office, PH pledged to abolish an unpopular goods-and-services tax (GST), reintroduce subsidies on petrol and investigate recent big-ticket investment projects which had received foreign funding. Though popular with the electorate, these measures could precipitate a fall in the national purse; the GST having brought in MYR 45bn (EUR 9.5bn) alone in 2017.

However, Roberto Benetello,

CEO of the EU-Malaysia Chamber of Commerce and Industry (EUMCCI), feels that PH's plan - if carried out in full - could be a huge boost to the nation. "This is a massive historical change... The new government has a sensible plan for reform. We have studied in detail the PH manifesto which, if realized, will be of great benefit to the country. It addresses issues ranging from transparency and public procurement to healthcare spending and green energy adoption."

In terms of healthcare, PH has designated the field one of 12 National Key Economic Areas (NKEA), with a particular emphasis on pharmaceuticals, under the Economic Transformation Programme (ETP) to bring



#### THIS IS A MASSIVE HISTORICAL CHANGE... THE NEW GOVERNMENT HAS A SENSIBLE PLAN FOR REFORM.

— Roberto Benetello EUMCCI

Malaysia to high-income status by 2020. Within this framework, Malaysia plans to invest heavily in health infrastructure, clinical research, medical tourism promotion, promotion of the use of generic drugs, and the production of drugs in Malaysia for export.

#### **B40 SPENDING SPREE**

Eye-catchingly, the plan also includes a healthcare scheme to allocate MYR 500 (EUR 106) per year to Malaysia's three million low-income families (the



so-called 'B40' group, the bottom 40 percent of earners) to receive basic healthcare in private clinics. This programme should prove popular with both patients and clinics as the B40 families will get access to treatment and private clinics can encourage these families to use their insurance for other screenings, investigations and treatments through advertisements. Minister of Health Datuk Seri Dr. Haji Dzulkefly bin Ahmad notes that "the federal B40 health protection scheme will be focused on the health protection of the B40 group, with allocation provided, so they won't have to pay."



#### A SYSTEM RIPE FOR REFORM

Datuk Dr Noor Hisham Abdullah, director general of health at the Ministry of Health, outlines some of the issues currently facing Malaysian patients as well as the reforms planned and already underway.



#### ON CONGESTION...

"Our clinics are congested and are subject to a vicious cycle: as the quality increases, more patients visit the clinics, which in turn creates more congestion. We are investigating the possibility of bringing primary care back to the community and to patients' homes, for example reviving the concept of family doctors... We believe that outcomes will be better if patients can avoid admission into hospital."

**DATUK DR NOOR HISHAM ABDULLAH** 

director general of health, Ministry of Health

#### ON NCDS...

"Our clinics are not designed to handle non-communicable diseases. We have initiated a pilot project in 30 clinics where patients are followed by the same medical team every time they visit the hospital, so that they become well acquainted. The initial results of this scheme have shown a stronger patient engagement. We hope that this improved engagement will be translated into improved control."

#### **ON OPTIMISING RESOURCES...**

"One way to lower costs is to optimise the resources we already have. Of 143 hospitals, only 55 have specialists in place, while the others are run by medical officers. To accommodate all patients, we have created hospital clusters, meaning that the lead state hospital will also bear responsibility for the district hospitals."

#### ON OUT-OF-HOSPITAL SERVICES...

"We are taking some of the services out of the hospital. An example is the alternative birth centre that will allow normal childbirth to be made in adapted community centres instead of hospitals to lessen the burden on the latter. They are situated near hospitals so that patients can be taken there quickly in the case of complications."

#### ON WASTAGE...

"We have to cut wastage. We are tackling unnecessary prescriptions, along with the purchasing of drugs that expire before being used by having a system that can allocate the drugs to areas where they are needed."

#### ON PRIVATE SECTOR COLLABORATION...

"We are looking into collaborations with the private sector and NGOs. We have increased the cost-effectiveness and efficiency of minor surgeries, such as cataract surgery by partnering with outside organisations. They have a theatre and conduct cataract operations daily. In a normal theatre, seven operations can take place per day, whereas the new facility can conduct 15."



Dato' Sri Dr Mohammed Azman, CEO at PERKESO, the Malaysian Social Security Organization, highlights the greater levels of inclusivity within the new government's healthcare strategy, noting that, "With the new government, we have already made immediate changes such as the inclusion of the spouse of the owner of the enterprise sole proprietorship or partnership into our coverage, who had previously been excluded. In the pipeline, the coverage for housewives is currently being prepared and hopefully will be approved soon. The most immediate impact in healthcare policy is the manifesto on the introduction of a new health service - Skim Peduli Sihat - from a state-based program in Selangor to a nationwide program. The program will definitely be beneficial to ordinary citizens, especially those in the B40s where support in obtaining primary care is part of the social security requirement for medical coverage."

#### **CO-OPTING THE PRIVATE SECTOR**

Such a comprehensive reform programme will necessitate close collaboration between the public and private sectors. Minister Dzulkefly bin Ahmad suggests that this collaboration needs to go beyond merely making use of private hospitals and their facilities: "The focus now is on leveraging the capacity of the private sector, involving them in consultations on policy matters and trouble-shooting. Moreover, we could also agree to gain access to the private sector's facilities at a discount price. There is expensive equipment such as MRI scanners un-utilised in the private sector. With a synergy of the systems, we could optimise resources and the private sector could alleviate some of the congestion and bottlenecks in the public sector hospitals."

#### **INDUSTRY: CAUTIOUSLY OPTIMISTIC**

The PH government is planning a significant hike to healthcare spending, as Lance Duan, Roche's general manager notes, ""In Malaysia, healthcare expenditure only accounts for around 4.5 percent of GDP. In regard to drug expenditure, we have seen a decreasing trend going from RM 2.4 billion in 2014 to RM 1.9 billion currently. The new government has stated that they aim to double public spending, increasing the GDP percentage from 4.5 to six or seven percent."

However, industry actors, while welcoming this potential funding injection, are raising questions as to how it will be sourced and the feasibility of the government's plan. Duan warns that, "we have yet to see any specific agenda created. While we are excited to see the ambition for monetary investment, discussing the specific steps to be taken in order to achieve these goals is critical."



#### WHILE WE ARE EXCITED TO SEE THE AMBITION FOR MONETARY INVESTMENT, DISCUSSING THE SPECIFIC STEPS TO BE TAKEN IN ORDER TO ACHIEVE THESE **GOALS IS CRITICAL.** - Lance Duan ROCHE

Tunku Naquiyuddin, executive chairman of Antah Healthcare Group, strikes a similar tone, noting that "The new government was voted in for their progressive thinking to avoid monopolies and build an even-playing field in various sectors. Up until now they have done very well but what is causing concern in the industry is that while we are aware that change will occur, we don't know yet how reforms will be implemented."

The EUMCCI's Benetello underlines the fact that it will take time for the PH to get their feet under the table and properly implement their reform programme, positing, "It must be acknowledged that the governing party now was the opposition for many years, never having been exposed to running a country. Here in Malaysia, the previous party had been in power for 60 years. What we are seeing is that is it taking time for the new government to get established, which is understandable."

Benetello continues, "Malaysia's governance is established by plethora of ministries, agencies and government-linked corporations that engage in not just policy making but funding and implementation. These multiple stakeholders have their own set of policy instruments and framework which may lead to fragmentation of resources, overlapping competencies and redundancies. Also, ministries and agencies were given the freedom to set their own priorities and tend to perform in silos. Therefore, the current challenge is transitioning into such an intricate system. We just hope that the transition time will not take too long!" 👯

## THE RELATIONSHIP BUILDERS

Tunku Naquiyuddin and Tunku Mohamed Alauddin, respectively executive chairman and managing director of pharma distributor, Antah Healthcare Group, highlight the importance of close business relationships between stakeholders in Malaysia and how the Group goes about choosing partners.



NAQUIYUDDIN

executive chairman,
Antah Healthcare



TUNKU MOHAMED ALAUDDIN managing director, Antah Healthcare

**HCLS:** What makes Antah Healthcare Group unique compared to other distributors in the country?

TUNKU MOHAMED ALAUDDIN (TMA): The company was formed 57 years ago, and we have been growing year on year. This year we experienced positive growth and it is partly due to the growing population and new medical infrastructures being built, but it is also thankful to a very strong distribution network of about 12,000 hospitals, clinics and pharmacies that we have developed over the years. Our strength has always been from the perspective of warehousing, marketing and distribution; however, we are small compared to DKSH and Zuellig which are global companies with much more resources. As a family company, our focus is to build our business through a reliable, friendly and successful relationship with our principals and customers. Our partners can have direct access to the management in short notice and we offer a lot less bureaucracy than other companies.

**TUNKU NAQUIYUDDIN (TN):** Ever since TMA took over the operations of Antah Healthcare Group, the company's culture has changed. He has been focusing on talent management in order to build up value of the company to make a difference. We have been focused on organic growth by limiting our investments into the company and this method allowed us to reconsider our way of doing business as we understand that multi-tasking encourages better efficiency from employees.

## **HCLS:** How do you choose your business partners and the products that will be distributed in Malaysia?

**TMA:** In choosing our partners, we do not look at areas where big companies have similar products but at

niche products that our product specialist has identified after much analysis. As we know mostly all the pharmacies, hospitals and doctors in the country, this speeds up the process compared with other players when answering the need of the market. We are the soldier on the ground, we understand and anticipate all possible shortcomings and ensure that a needed product can be immediately distributed in the market upon approval. We also have a good working relationship with the government so as we may anticipate and fulfill requirements where necessary.

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IN CHOOSING OUR PARTNERS, WE DO NOT LOOK AT AREAS WHERE BIG COMPANIES HAVE SIMILAR PRODUCTS BUT AT NICHE PRODUCTS THAT OUR PRODUCT SPECIALIST HAS IDENTIFIED AFTER MUCH ANALYSIS.

- Tunku Mohamed Alauddin ANTAH HEALTHCARE GROUP

## **HCLS:** What are your main priorities for the next three years?

**TMA:** The name Antah is well known in Malaysia as we have always been very Malaysia-centric and as such, our goals are to expand into the ASEAN region. Locally for Antah Sri Radin we are entering into a new customer segment such as private hospitals, dentists and relevant medical institutions. We are also looking out for products for the retail market such as ECG devices, Time Machine for pain management and acquiring more consumables. As for Antah Pharma, we are looking to include wider coverage in East Malaysia and will be involved with bio-pharmaceutical technology such as stem cell treatments, media culture and finally, acquiring IPs for our own range of products including generic drugs.



## SEA CUCUMBERS: MORE THAN JUST A DELICACY

Sea cucumbers - odd-looking marine animals with leathery skins and elongated bodies - can be found on ocean floors worldwide. Although more famous as a culinary delicacy in East and Southeast Asia, one Malaysian company - Healwell - is using these primitive creatures to save lives.

Hassan Yaakob, Healwell's founder explains. "Our products sit between traditional and modern medicine. When there were claims about a special type of primitive sea cucumber which only came out at night and would melt if exposed to sunlight, we conducted research on it, discovering it contained collagens and polysaccharide."

#### **OUR PRODUCTS SIT BETWEEN** TRADITIONAL AND MODERN MEDICINE

Yaakob continues. "When heated under a certain temperature, it degrades into polypeptide. That polypeptide is a molecule which is a rejuvenating agent which prevents sickness. It has shown remarkable successes treating a number of hereditary diseases. For example, a baby was born with a hereditary disease affecting one in five million babies, causing parts of the body to become necrotic,

and usually leading to death by the age of eight years old. Her family was considering amputating one of her legs, but we let her consume our product, and within less than one week, she showed signs of recovery. A full recovery was observed after three months. She is still alive today, 18 years later, although she is reliant on our star product Gamogen."

Despite this proven success, Healwell has found seeking registration for its unusually-sourced products challenging. Yaakob notes, "Since our first research, we have conducted clinical trials in Japan over a period of one year, and we continue to conduct



clinical research on our products in Japan. After the

clinical trials, we even planned to register the product with the US FDA. However. this was not deemed possible by the FDA, who claimed that our product was food. For this reason, we could not register the process."

However, Yaakob is sanguine about this FDA rejection, noting that "In spite of this, it may, in fact, be preferable not to register with the FDA, as the processes

we use would have to be publicized ten years after registration. We want our processes to remain the proprietary knowledge of the company, as there are a number of companies attempting to imitate our products that have been unsuccessful in replicating our quality." 🛟

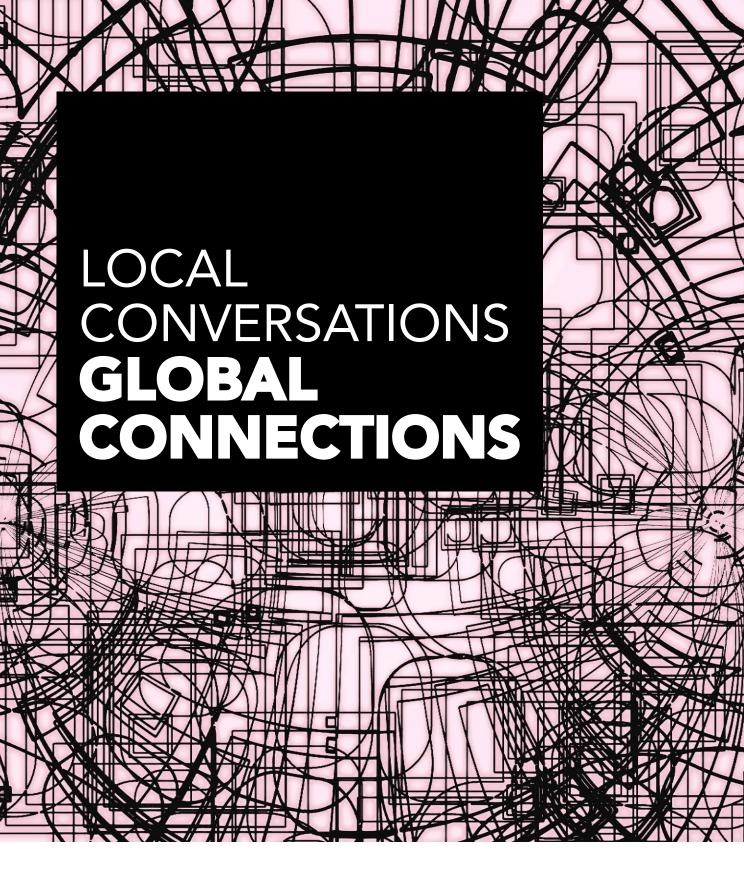




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