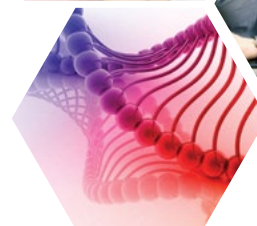


# ADVANCING THE HEALTH OF A FORWARD MOVING NATION



**INDUSTRY FACT BOOK**  
**2018 EDITION**

**A**s a rapidly developing nation, Malaysia is a country with a robust and fast-changing healthcare landscape. As the population grows and literacy improves, so does the demand for better healthcare and quality of life. In keeping with the demands for better healthcare, the pharmaceutical industry continues to invest in the discovery, research and development as well as production of newer drugs, biologics and vaccines for the treatment and prevention of diseases. Malaysia, through its attractive investment schemes and supportive economic infrastructure, has been able to attract leading global pharmaceutical companies to set up base here so that Malaysians can benefit from timely access to innovative world-class medicines.

In this Industry Fact Book, the Pharmaceutical Association of Malaysia (PhAMA) will provide greater insights into how the Malaysian pharmaceutical industry has been working closely with various stakeholders to address the many health-related challenges faced by the nation.



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Note: Figures and data presented in PhAMA's Industry Fact Book 2018 are derived from sources published in 2013–2017 and include a selection of latest available data from 2018.

# FORGING A HEALTHY NATION THROUGH COOPERATION & INNOVATION

## A message from the Minister of Health

The importance of health cannot be overstated – a healthy nation is the anchor to our economic stability and the engine that propels us towards the status of a developed, high-income nation. Importantly, laying the foundation for a healthy nation is only possible through a close cooperation between the Ministry of Health and various healthcare stakeholders in this country.

Malaysia is an aging nation with a high incidence and prevalence of noncommunicable diseases. The proportion of population aged 65 years and above has grown from 3.9% in 2000 to 5.1% in 2015, and it has been estimated that the total elderly population in Malaysia will hit 2.4 million people by 2020. This means that we continuously face a host of health-related issues that require active interventions from healthcare providers, and the Ministry is committed to proactively address these challenges by enhancing healthcare facilities and services in this country.

Moving forward, our emphasis is to support primary healthcare services in this country by allocating appropriate resources to empower the public health delivery system. We will need different expertise, medications and tools to address the overall healthcare needs of the rakyat. In order to provide a holistic and quality-assured healthcare delivery system, we seek incremental budgetary allocation to build integrated health facilities across the country and to improve patient access to medicines. Nonetheless, the Ministry is aware that to realise our visions, we must actively and strategically collaborate with private healthcare players.

To deliver the best healthcare services to Malaysians, we strongly believe in the value of public-private partnerships. As you will see in

this Fact Book, PhAMA, its members, and MoH have successfully worked together through various initiatives to improve access to novel and innovative treatments that target acute diseases and chronic conditions, in addition to addressing the threat of infectious diseases by making new and improved vaccines available to the public. Moreover, we have also introduced disease prevention measures through public education campaigns on healthy living. These positive developments would not have been possible without the participation and support of the pharmaceutical industry.

The Ministry understands that it must also address the welfare and workload of MoH's staff to enhance the delivery of healthcare services. Therefore, apart from existing collaborations, we welcome ideas and engagements from the private sector on how we could pool our resources together to achieve more. Recognising the high volume of investment in research and development and the importance of intellectual property rights, we will continue to support the pharmaceutical industry by laying down proper regulatory framework to facilitate its growth and expansion. In return, we welcome investments in capital and talent to elevate the standard of Malaysian healthcare services so it could become one of the best in this region.

By working together, we can foster a healthier and more vibrant Malaysia. ■



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



## ENVISIONING OPPORTUNITIES FOR FUTURE GROWTH

### A message from the President of PhAMA

**W**e may currently be living in the most exciting and productive years since the birth of modern medicine. Scientific advances and multidisciplinary collaborations, paired with well-planned investments and risk-taking endeavours, have accelerated the process of drug discovery and development in several key areas, resulting in new therapeutic agents and more treatment strategies employed for prolific noncommunicable diseases as well as rare genetic disorders.

In Malaysia, the healthcare system is unique in that public and private sectors co-exist at the primary, secondary and tertiary levels. This system forms the route for the delivery of pharmaceutical products in the country, enabling originator, generic and over-the-counter medicines to be made accessible to the public. In 2018, the total sales of these products amounted to RM7.5 billion, with the figure being segmented into 55%, 21% and 24% for originator, generic and over-the-counter medicines, respectively.<sup>1</sup>

The country's healthcare system also ranks among the best in the world, having achieved Universal Health Coverage despite being a relatively young nation.<sup>2</sup> In 2016, the combined total of public and private expenditure on health amounted to RM51.7 billion, with RM26.6 billion (51.5% of the total health expenditure) spent on the public sector – a reflection of the government's commitment in safeguarding the well-being of the nation.<sup>3</sup> More importantly, public and private healthcare sectors have successfully reduced many inefficiencies in recent years, as life expectancy continues to improve and infant mortality drops.<sup>4,5</sup> These are all critical

markers of success in our journey towards achieving the status of a developed nation.

Nonetheless, as with any other nations in the world, we face the challenge of increasingly prevalent noncommunicable diseases as well as an ageing population, among others. As such, the challenges in working towards Malaysia's aspiration of achieving a truly sustainable universal healthcare financing model is – funding. We applaud the government for being cognizant of the situation and acknowledge the increase in budget allocation for the Ministry of Health by 7.8% or RM2 billion, from RM27 billion in 2018 to RM29 billion for year 2019.<sup>6</sup> Aligned with the Pakatan Harapan government's government manifesto, the industry believes that strengthening our present healthcare system financially would enhance access to healthcare innovation and the delivery of improved health outcomes to patients.

Over the years, both the public and private healthcare sectors have seen the benefits of collaboration in many public-private partnership (PPP) initiatives and programmes. These initiatives were implemented in the spirit of developing better research and development capabilities, elevating the skills of healthcare professionals and enhancing patients' access to medicines, in addition to lifting the nation's economy. Examples of PPP initiatives include the Provisionally Registered Pharmacist



**Chin Keat Chyuan**  
President of PhAMA



(PRP) programme and collaborations in Patient Access Scheme (PASc). All these initiatives were conducted in manners which embody the spirit of transparency and accountability, as advocated by the Pakatan Harapan government.

It has been a long-term vision of ours to provide the best available treatments to those in need and we strongly believe in investing our resources in sustainable research and development activities. Thankfully, the Malaysian government has taken steps to create a conducive ecosystem towards enhancing research capabilities in Malaysia and our members have reciprocated positively by bringing in industry-sponsored research and contributed not less than RM186 million in revenue to the country.

PhAMA has experienced first-hand the rapidly changing landscape of the Malaysian pharmaceutical industry. We launched our inaugural Industry Fact Book in 2012 with the objective of highlighting the contributions made by PhAMA member companies to both the health of the Malaysian public and the wealth of our nation, and much have changed in the past 6 years. On our current list of 45 member companies, PhAMA has welcomed 14 new members since the publication of our

last Industry Fact Book and witnessed various organisational changes that consolidated previous members via rebranding, merger and acquisition initiatives – developments that truly reflect the dynamism of our industry.

In addition to our long-established role as an industrial liaison, PhAMA is currently developing new guidelines and authoring position papers to share valuable experiences and promote industry best practices. Besides, we have also introduced various training programmes that are targeted towards fresh graduates and current healthcare professionals in an effort to promote a stronger research culture in Malaysia. This new edition of the Industry Fact Book incorporates updated statistics and new information to inform and educate the general public and healthcare policy stakeholders on the development of the pharmaceutical industry in Malaysia.

In closing, I take this opportunity to extend my invitation to you to join us in our efforts to support the government's vision for a healthier nation by improving access to innovative medicines, and to promote the growth of the pharmaceutical industry. ■

**References:** 1. Data from IQVIA. Accessed on 30 Nov 2018. 2. National Transformation Programme Annual Report 2016. Available at: [https://www.pemandu.gov.my/assets/publications/annual-reports/NTP\\_AR2016\\_ENG.pdf](https://www.pemandu.gov.my/assets/publications/annual-reports/NTP_AR2016_ENG.pdf). Accessed on 30 Nov 2018. 3. Ministry of Health's Health Facts 2018. Available at: <http://www.moh.gov.my/english.php/pages/view/56>. Accessed on 30 Nov 2018. 4. Abridged Life Tables, Malaysia, 2015–2017 (Department of Statistics Malaysia). Available at: [https://www.dosm.gov.my/v1/index.php?r=column/cthemeByCat&cat=116&bul\\_id=dkdvKzZ0K1NiemEwNlJteDBSUGorQT09&menu\\_id=L0pheU43NWJwRWVSZklWdzQ4TlhUUT09](https://www.dosm.gov.my/v1/index.php?r=column/cthemeByCat&cat=116&bul_id=dkdvKzZ0K1NiemEwNlJteDBSUGorQT09&menu_id=L0pheU43NWJwRWVSZklWdzQ4TlhUUT09). Accessed on 30 Nov 2018. 5. Infant Mortality Rate, Malaysia, 1922–2014 (Department of Statistics Malaysia). Available at: [http://www.data.gov.my/data/ms\\_MY/dataset/vital-statistics-malaysia-1054/resource/58f18d83-128e-43bf-af9d-98f175e4a1a9](http://www.data.gov.my/data/ms_MY/dataset/vital-statistics-malaysia-1054/resource/58f18d83-128e-43bf-af9d-98f175e4a1a9). Accessed on 30 Nov 2018. 6. Ministry of Finance Malaysia's Annual Budget 2019. Available at: <http://www.treasury.gov.my/pdf/budget/speech/bs19.pdf>. Accessed on 30 Nov 2018.

# MALAYSIA'S PHARMACEUTICAL LANDSCAPE

Malaysia has a strong pharmaceutical industry, which has worked in close partnership with the government to support the national healthcare system via the delivery of innovative healthcare solutions to fellow Malaysians. It is a robust and dynamic industry, overseen and regulated by the National Pharmaceutical Regulatory Agency (NPRA) under the Ministry of Health Malaysia.

In Malaysia, the pharmaceutical industry comprises two key players: local companies and research-based multinationals, each with its own foci and interests. Local companies focus primarily on traditional medicines, vitamins, supplements, over-the-counter (OTC) drugs and generics, while research-based multinationals (also known as innovators) are responsible for ensuring that Malaysia

has access to internationally-tested and accepted drugs whose safety, efficacy and quality have been proven, backed by strong research and development capabilities. Collectively, the Malaysian pharmaceutical industry has made thousands of therapeutic agents available to the people of this country.

Members of PhAMA have consistently strived to promote timely access to quality-assured and innovative medicines in an ethical manner, and encourage the research and development of pharmaceutical products locally via the formation of strategic partnerships with various stakeholders to advance the public health agenda. Importantly, PhAMA is vested in empowering both healthcare professionals and consumers to make important decisions that will improve the quality of healthcare in this country.



## DISTINCT CATEGORIES OF PHARMACEUTICAL PRODUCTS IN MALAYSIA

## ETHICAL PRODUCTS

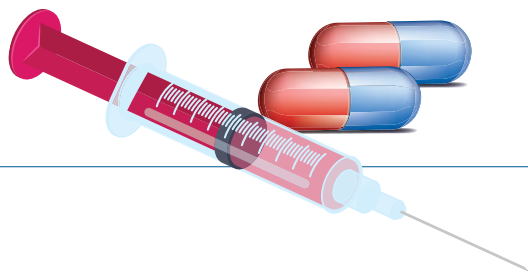
## BIOLOGICS

Biologics/Vaccines

Biosimilars

INNOVATIVE  
MEDICINESCHEMICAL  
ENTITIESNew Chemical  
Entities

Generics



## SELF CARE PRODUCTS

Over-the-Counter  
(OTC) Medicines

Supplement

Patient Care  
ProductsPersonal Care  
Products



## FACTORS INFLUENCING THE GROWTH OF THE PHARMACEUTICAL INDUSTRY

Like the rest of the world, Malaysia faces a rising incidence of medical conditions commonly associated with urbanisation, such as noncommunicable diseases (NCD). The 2015 National Health and Morbidity Survey (NHMS) focusing on NCD, risk factors and other health problems reported that the overall prevalence of diabetes mellitus, hypertension and hypercholesterolaemia is increasing among adults aged 18 years and above.<sup>1</sup> Unsurprisingly, this has created a vibrant consumer market for health products, particularly among savvy consumers who are concerned about the threat of such chronic diseases.

With increasing health literacy and rising disposable income, there has also been a noticeable growth in the consumption of self care products. While a wide range of self care products are already available in the market, the demand is expected to continue growing for more of such products.

**References:** 1. National Health and Morbidity Survey 2015. Non-communicable diseases, risk factors & other health problems. Volume II. Available at: <http://www.iku.gov.my/images/IKU/Document/REPORT/nhmsreport2015vol2.pdf>. Accessed on 18 Jan 2018. 2. NPRA (MoH). QUEST List of Manufacturers. Available at: <https://www.npra.gov.my/index.php/information/quest-list-of-manufacturers-wholesalers-importers/quest-list-of-manufacturers>. Accessed on 30 Nov 2018. 3. NPRA (MoH). QUEST List of Importers. Available at: <https://www.npra.gov.my/index.php/information/quest-list-of-manufacturers-wholesalers-importers/quest-list-of-importers>. Accessed on 30 Nov 2018.

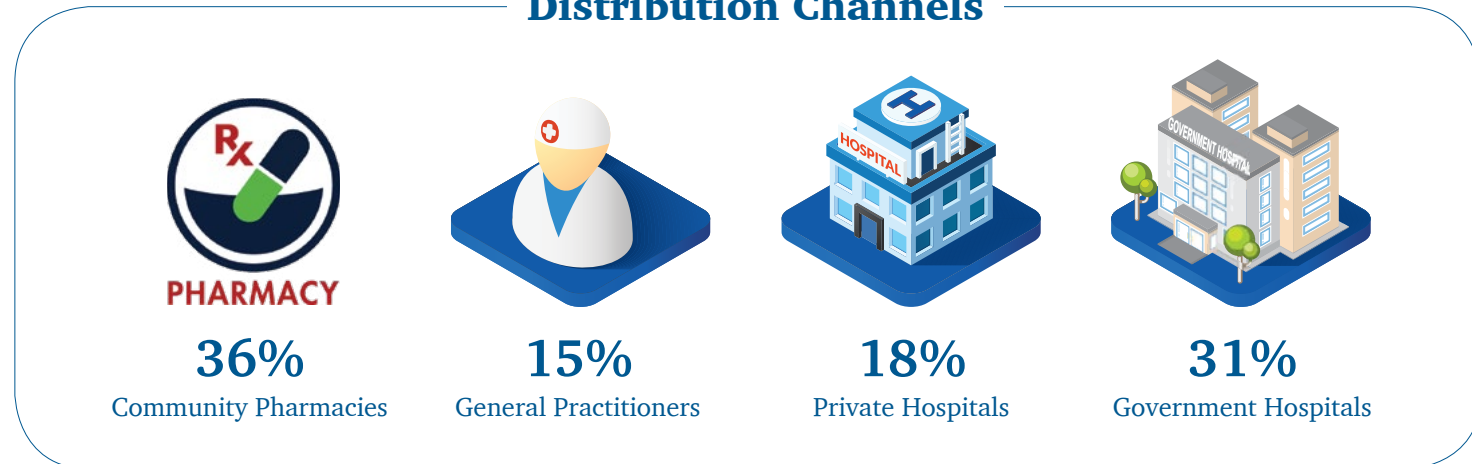




## Malaysia's Pharmaceutical Market at a Glance

- Over 445 pharmaceutical companies (excluding wholesalers), including representation by most of the world's largest pharmaceutical companies<sup>2,3</sup>
- Total market value estimated at RM7.5 billion as of Quarter 3 – 2018
- Grew between 8% and 10% annually over the last decade

### Distribution Channels



Source: NPRA; IQVIA

## PhAMA: AN ODYSSEY & A LEGACY

“Since its registration in 1972, PhAMA has been one of the major driving forces in improving Malaysians’ access to quality healthcare and healthcare products.” – Chin Keat Chyuan, President, PhAMA.

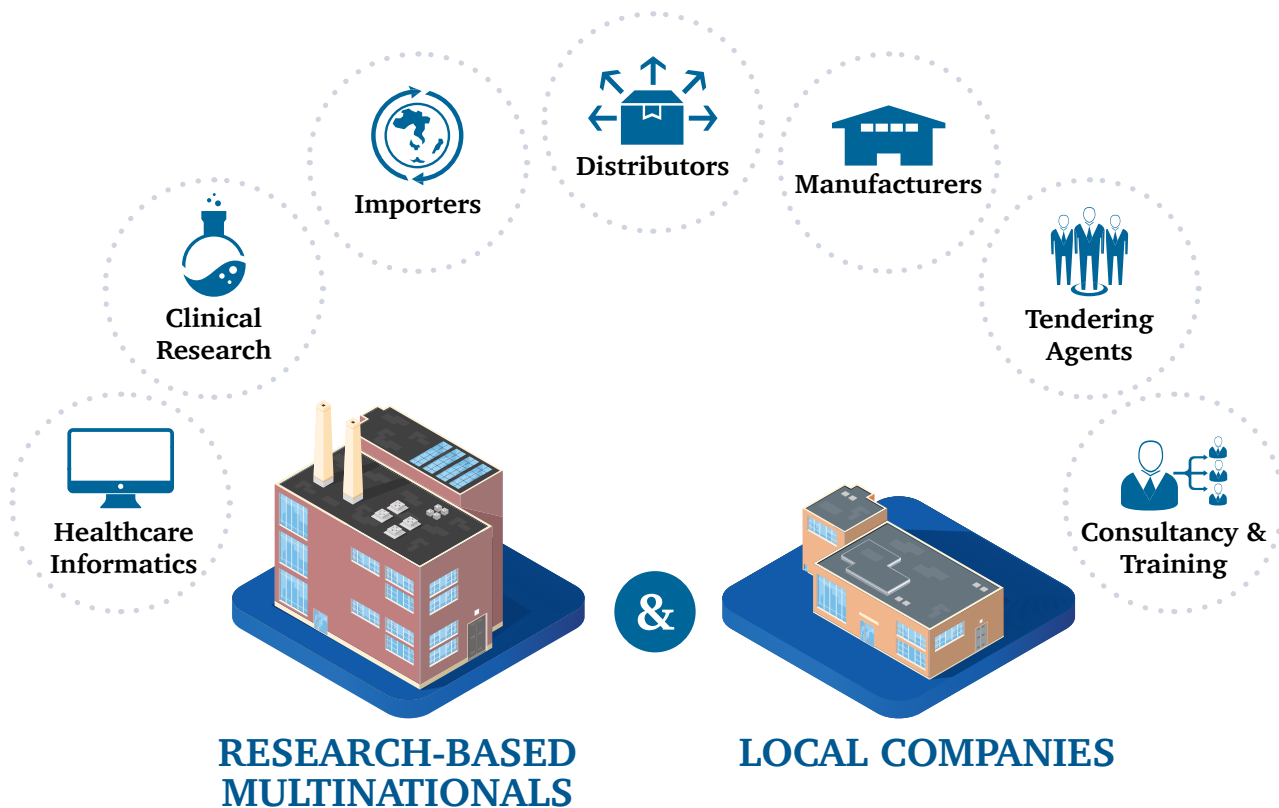
The Pharmaceutical Association of Malaysia (PhAMA) comprises 45 local and research-based multinational companies. Most of our member companies represent major global innovative pharmaceutical companies, with vast networks of local and international expertise and resources at every level – encompassing research and development, medical information, finance, information technology, human resources, legal and compliance, as well as logistics and ethical marketing. They also have decades of experience in coordinating with global and local authorities in matters related to the regulation of innovative medicines and the delivery of healthcare system. Additionally, PhAMA members offer invaluable experience in working closely with various governments and healthcare authorities across the globe in managing and providing medications and/or vaccinations during disease outbreaks.

With all these expertise and information at its disposal, it is unsurprising that PhAMA has become the voice of Malaysia’s major research-based pharmaceutical companies. The association serves as an important liaison among member companies, as well as between association members and key stakeholders of the healthcare industry, which include the government, consumers, healthcare providers, hospitals (both public and private), regulators and the mass media in promoting, supporting and strengthening a better delivery system that prioritises the health outcomes of patients.

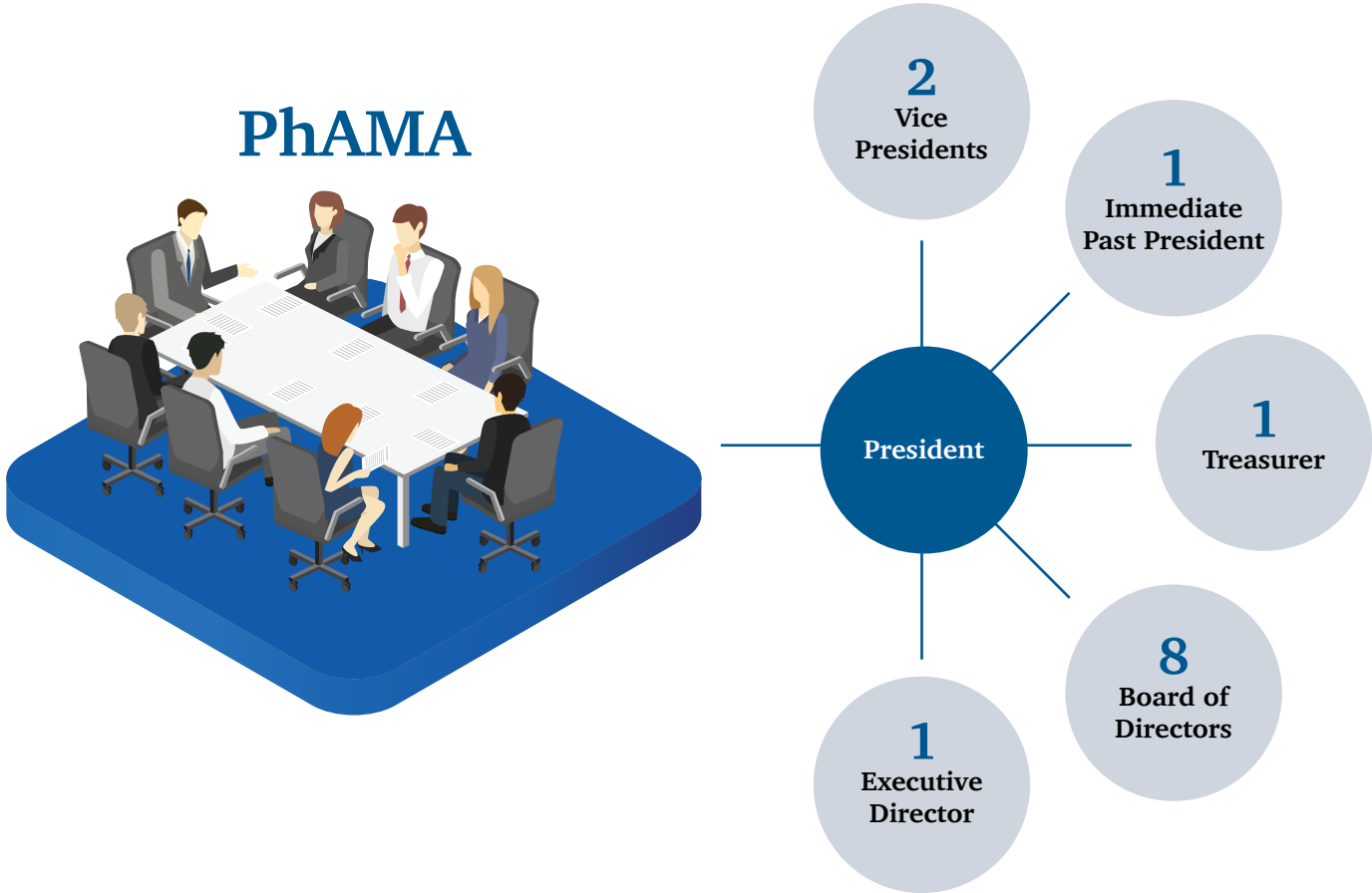




## ROLES AND ACTIVITIES OF PHAMA MEMBERS



AN OVERVIEW OF PhAMA'S GOVERNANCE



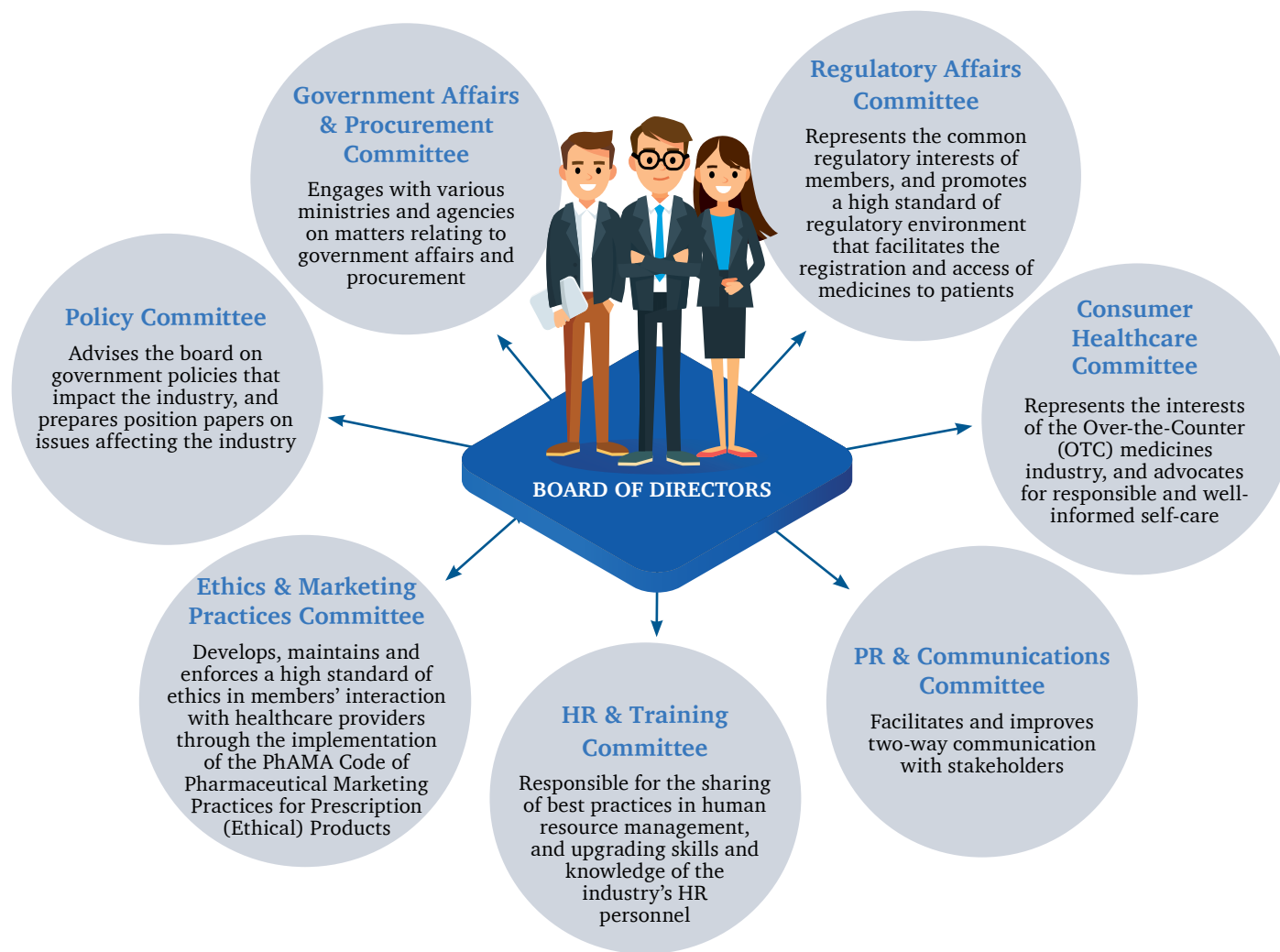


## FORGING COOPERATION THROUGH COMMITTEES

PhAMA has several committees that are dedicated to improving (i) the services provided to its members and the public, as well as (ii) the levels of expertise and professionalism in the pharmaceutical industry.



## PhAMA COMMITTEES AND THEIR RESPECTIVE ROLES IN THE ASSOCIATION



## FOSTERING AN ALLIANCE OF COOPERATION

PhAMA foster affiliations with various local, regional and global organisations to keep our members abreast of the latest developments and best practices within the pharmaceutical industry. Being a rigorous and highly regulated industry, our members must strictly adhere to the latest regulatory requirements to ensure and enhance patient safety, as well as access to medicines.

The association engages in continuous dialogues with the Pharmaceutical Services Programme (PSP) and the National Pharmaceutical Regulatory Agency (NPRA) to partake in discussions on technical issues aimed at strengthening regulatory capacity and standards, in addition to providing feedback and input on the implementation of policies concerning the pharmaceutical industry. Areas of discussions include, but are not limited to, supply chain security, storage guidelines, accessibility of medicines, guidelines on clinical practices, as well as the governance of medicines. Among others, the latest discourse on the Pharmaceutical Track & Trace system was conducted to ensure appropriate alignment and readiness of the pharmaceutical industry in meeting drug serialisation and tracing requirements.

### Enhancing Regulatory Knowledge within the Industry

PhAMA has collaborated with NPRA and Taylor's University periodically to enhance the competency level of the pharmaceutical industry's regulatory professionals. Since 2014, the association has also been working together with PSP and Monash University Malaysia to build a local talent pool on pharmacoeconomics, an area that uses cost-benefit, cost-effectiveness, cost-minimisation, cost-of-

illness and cost-utility analyses to compare pharmaceutical products and treatment strategies.

### Towards the Harmonisation of Pharmaceutical Regulations and Healthcare Integration

PhAMA also works towards achieving the harmonisation of pharmaceutical regulations and healthcare integration through regional partnerships with the ASEAN Pharmaceutical Research Industry Association (APRIA) and the Asia Partnership Conference of Pharmaceutical Associations (APAC). In addition, by working with trade chambers, the association actively engages industry players in discussions on trade and industry policy matters, and strives to address barriers towards the realisation of an optimum healthcare delivery system.

### International Affiliation

PhAMA is affiliated with the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and the World Self-Medication Industry (WSMI). Through our affiliation with IFPMA, we are not only connected to the global pharmaceutical industry, but are also aligned to the values of fostering innovation, promoting resilient regulatory system and high standards of quality, upholding ethical practices, and advocating sustainable health policies to meet global needs. Meanwhile, as a member of WSMI, we advocate the development of responsible self-medication through the use of safe and effective consumer healthcare products.



Participants of the PhAMA-Monash Health Economics and Health Technology Assessment Workshop



## PROVIDING TIMELY ACCESS TO QUALITY-ASSURED & INNOVATIVE MEDICINES

Malaysia has achieved a commendable standard of living as a result of the rapid economic development that began in the 1970s.<sup>1</sup> In the present day, more than 75% of the country's total population resides in urban areas, and approximately 25.5 million people are expected to become urban dwellers in Malaysia by the year 2020.<sup>2</sup>

While Malaysians in general continue to enjoy an improving quality of life, we are simultaneously facing an increasing prevalence of lifestyle-related diseases, such as hypertension, hypercholesterolemia, type 2 diabetes and cardiovascular diseases. In addition, ever-present infectious diseases like dengue, hepatitis B, tuberculosis and influenza also pose serious threats to the health and well-being of Malaysians.

### Noncommunicable Diseases

Noncommunicable diseases (NCDs) or chronic diseases differ from infectious diseases in that they slowly develop over a prolonged period and present a long-term, at times lifelong, disease burden on patients. The World Health Organization (WHO) has identified four main types of disease as the leading causes of premature NCD deaths globally.<sup>3</sup> They are cardiovascular diseases (eg, heart attack,

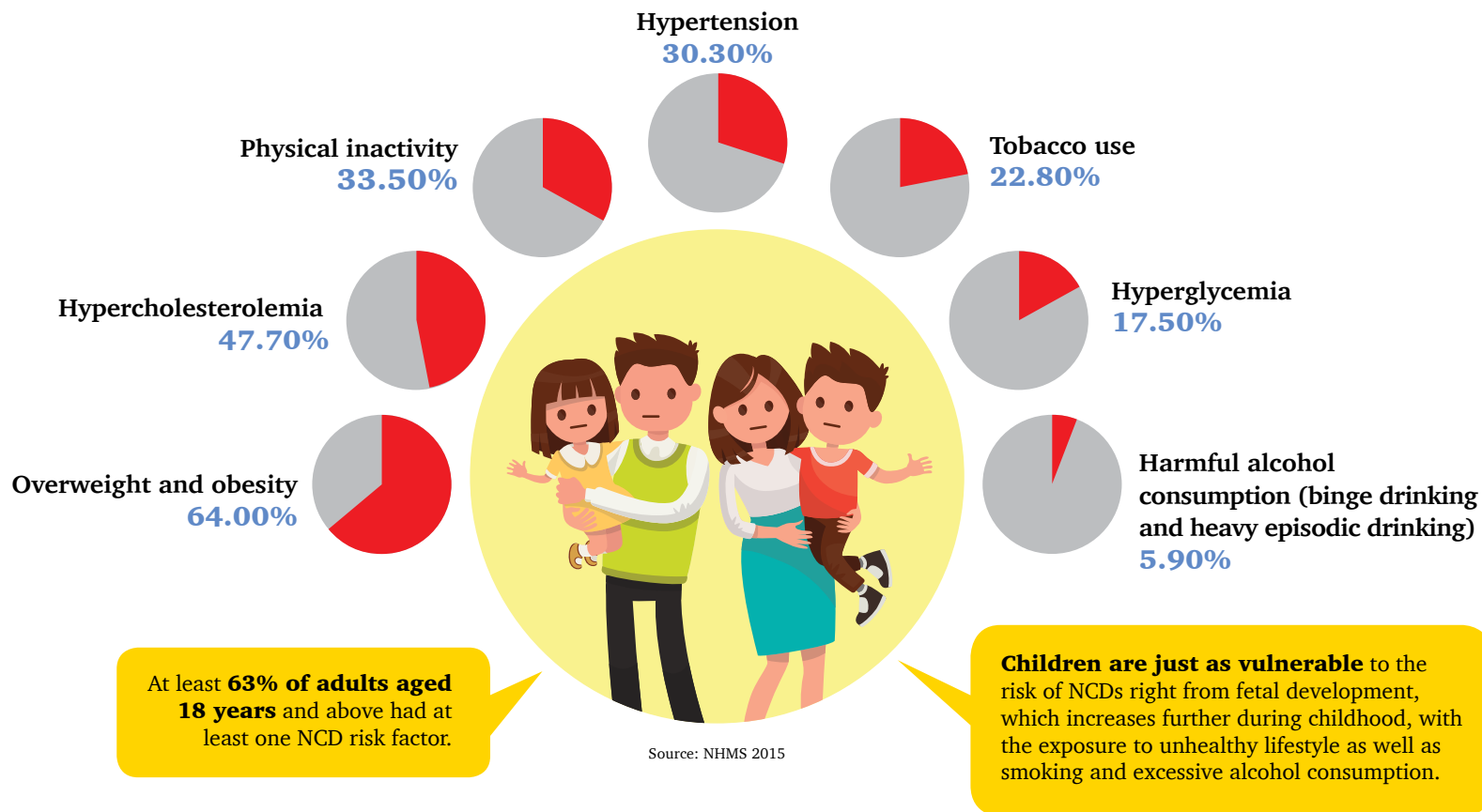
stroke), cancers, chronic respiratory diseases (eg, chronic obstructive pulmonary disease, asthma), and diabetes.

In Malaysia, it has been estimated that NCDs contributed up to 68% of the burden of premature deaths, with the majority of premature mortality occurring in the 45–59 age group (26%), comprising members of the working population.<sup>4</sup> Meanwhile, the *Second Burden of Disease Study for Malaysia*, published in 2012 by the Institute for Public Health, found ischaemic heart disease, cerebrovascular disease (stroke) and diabetes mellitus to be the biggest contributors of disability adjusted life-years (DALY) in this country.<sup>5</sup> DALY is defined as the sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability.<sup>6</sup>

Deaths due to NCDs are generally preventable as these diseases are associated with unhealthy lifestyles, lack of physical activities and the excessive consumption of nutrition-poor foods and beverages. As this has become a worldwide issue, WHO advocates proactive intervention on multiple fronts to address the aforementioned risk factors, and urges international communities to provide improved healthcare services, early detection and timely treatment to patients to reduce the burden of NCDs on the society at large.<sup>7</sup>



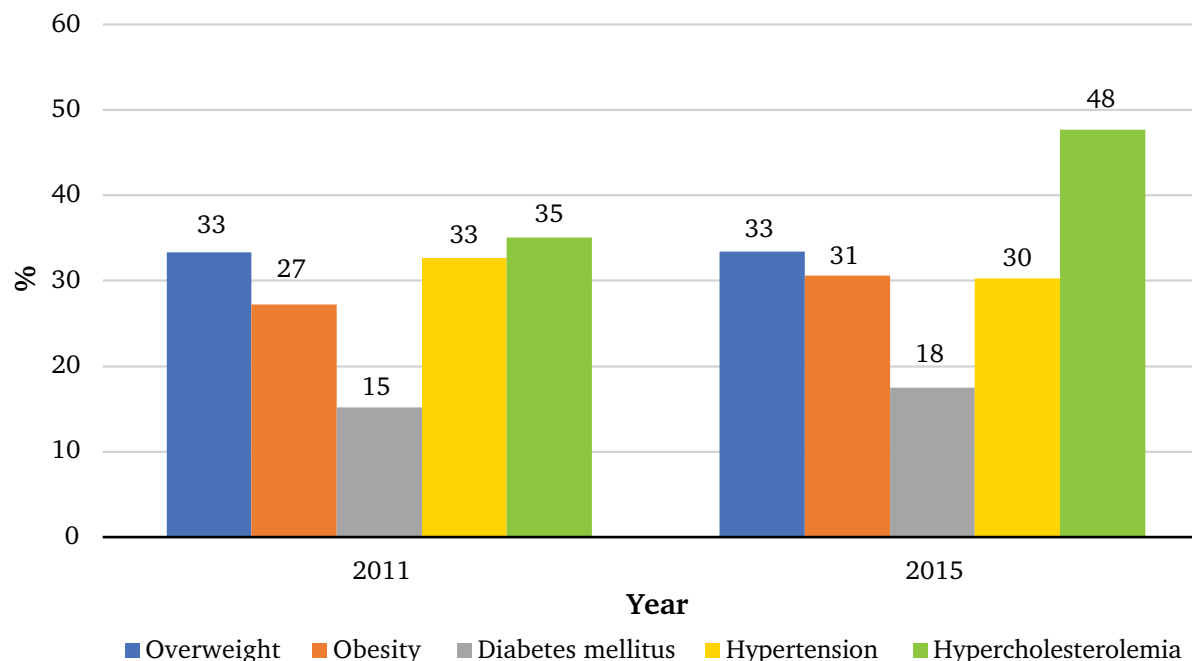
## PREVALENCE OF NCD RISK FACTORS



Data from the 2015 National Health and Morbidity Survey (NHMS) conducted by the Ministry of Health (MoH) revealed an increasing trend for NCD risk factors among Malaysians.<sup>8</sup> Worryingly, many of these risk factors remain undiagnosed in a high proportion of the population, which often leads to severe complications and hence, more costly treatments. In 2014, the

prevalence of obesity in Malaysia was alarmingly higher than that of the world. NCDs and the obesity epidemic not only substantially drain the finances of an affected individual, but also present a significant economic burden on society owing to the long-term nature of these conditions that require extended periods of treatment.

**Figure 1** Percentage of adults aged 18 years and above in Malaysia with NCD risk factors. The criteria of evaluation for overweight and obesity were based on the Malaysian Clinical Practice Guidelines of Obesity.<sup>8</sup>



## Communicable Diseases

Communicable diseases, also known as infectious diseases, are any infection-related illnesses that are caused either by exposure to disease vector either – by ingesting contaminated food or water, bites from insect, or by direct contact with an affected individual – or their

discharges (eg, body fluids).<sup>9</sup> According to MoH, the incidences and mortality rate of communicable diseases affecting Malaysians include the following disease areas.<sup>10</sup>

**Table 1** Incidence and mortality rates of communicable diseases in Malaysia (2017).<sup>10</sup>

Incidence Rate and Mortality Rate of Communicable Diseases, 2017 (per 100,000 Population)		
Communicable Diseases	Incidence Rate	Mortality Rate
<b>Food and Water Borne Diseases</b>		
Cholera	0.01	-
Dysentery	0.37	0.00
Food Poisoning	42.25	0.01
Hepatitis A	0.47	0.00
Typhoid	0.59	0.02
<b>Vector Borne Diseases</b>		
Dengue	257.60	-
Dengue Haemorrhagic Fever	1.25	0.55
Malaria	12.70	0.04
Plague	-	-
Typhus	0.06	-
Yellow Fever	-	-
<b>Vaccine Preventable Diseases</b>		
Acute Polomyelitis	-	-
Diphtheria	0.10	0.02
Hepatitis B	15.41	0.17
Measles	5.28	0.01
Neonatal Tetanus*	0.03	0.01
Other Tetanus	0.08	0.01
Whooping Cough (Pertussis)	1.09	0.04

Incidence Rate and Mortality Rate of Communicable Diseases, 2017 (per 100,000 Population)		
Communicable Diseases	Incidence Rate	Mortality Rate
<b>Sexually Transmitted Diseases</b>		
Chancroid	0.01	-
Gonorrhea	10.39	-
Syphilis	8.00	0.02
<b>Other Infections Diseases</b>		
AIDS	3.98	2.13
Ebola	-	-
Hand, Food & Mouth Disease	90.64	-
Hepatitis C	9.54	0.29
HIV	10.33	0.62
Leprosy	0.66	-
Leptospirosis	13.48	0.08
Other Specified Viral Hepatitis	0.07	-
Rabies	0.02	0.02
Relapsing Fever	-	-
Tuberculosis	80.78	6.47
Viral Encephalitis	0.09	-

\* Per 1,000 live births (2015)  
(-) No case

Source: Disease Control Division, MoH

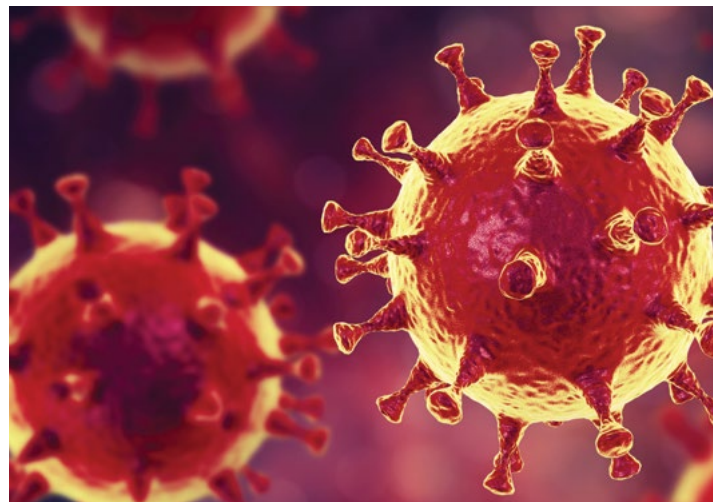
From its established list of communicable diseases, WHO further segregates them into “emerging” as well as “re-emerging” diseases.

### Emerging Diseases

WHO identifies diseases that are likely to cause severe outbreaks but have few or no countermeasures as emerging diseases; among the diseases identified under this category are Chikungunya and Zika.<sup>11</sup> The list of emerging diseases is reviewed by WHO as necessary, with diseases like HIV/AIDS, tuberculosis, malaria, avian influenza and dengue being excluded from this list owing to the existence of viable intervention measures and treatment options.

In order to produce effective interventional and countermeasures to address a potential epidemic situation, WHO advocates for a comprehensive and cohesive approach involving close cooperation between governing bodies, regulators and the pharmaceutical industry, as well as with representatives from other relevant industries. As the pharmaceutical industry has steadfastly invested in the research and development (R&D) of multiple disease areas, it plays a significant role in providing much-needed diagnostic tools, vaccines and therapeutic agents to meet various healthcare challenges.

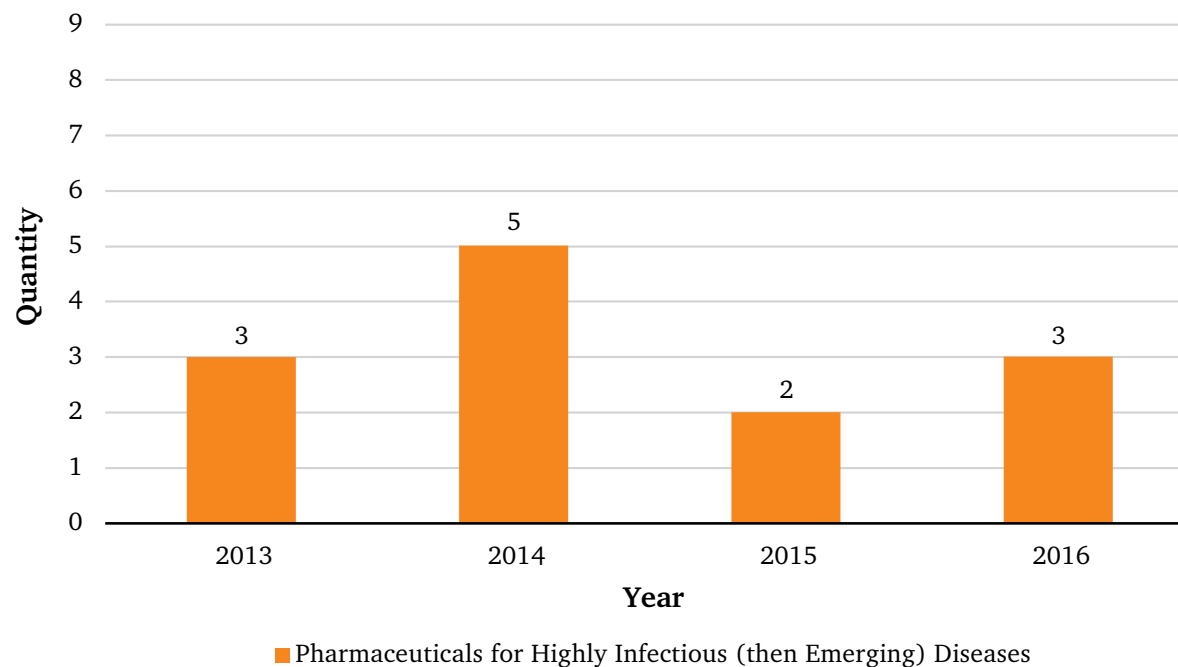
It is a fact that R&D activities do not stop once an innovative treatment is made available as the first-line defence of target diseases. Oftentimes, further R&D activities are undertaken to elucidate the nature of these diseases (eg, epidemiology, mechanism of infection), thus enabling the development of better treatment options to combat the threat of constantly evolving disease agents or vectors. To support the growth of the pharmaceutical industry, it is necessary to create



and nurture a healthy and conducive ecosystem to encourage the proliferation of sustainable R&D activities.

Between 2013 and 2016, seven PhAMA member companies brought a total of 13 therapeutic agents into Malaysia for the treatment of highly infectious diseases that were previously considered as emerging diseases according to WHO's definition (Figure 3).<sup>12</sup> By consistently making dedicated financial, time, manpower and infrastructure investments, these companies are committed to ensuring the availability of innovative medicines in preventing an epidemic outbreak globally.

**Figure 3** Number of new treatment options/new anti-infectives registered in Malaysia by surveyed PhAMA member companies for the treatment of highly infectious (then emerging) diseases between 2013 and 2016.<sup>12</sup>





### An Ageing Population

Although Malaysia has a relatively young population, the proportion of the population below the age of 14 years has fallen from 33.3% in 2000 to 23.8% in 2018.<sup>13,14</sup> On the contrary, the proportions of the working age population (15–64 years) and those aged 65 years and above during the same period have increased from 62.8% to 69.7%, and 3.9% to 6.5%, respectively. Consequently, the Malaysian population's median age has increased from 23.6 years to 28.6 years within close to two decades.

Based on statistical projections, the total population of the elderly in Malaysia is expected to reach 2.4 million people in the year 2020.<sup>15</sup> This observation reflects the gradual transition of the country's population towards an ageing society and its impact will be increasingly noticeable in the coming years.

As Malaysia's population ages, there will be a significant shift in the types of ailment diagnosed, from acute to chronic diseases, such as Alzheimer's disease, heart disease and osteoporosis. Chronic diseases require long-term treatment, and the focus of medical intervention can also be expected to progress from the treatment of a single condition to the treatment of multiple comorbidities. Such developments are expected to place considerable strain on any country's healthcare sector delivery system.

Backed by the pharmaceutical industry's strong R&D capabilities, PhAMA members play an essential role in addressing the various chronic diseases faced by an ageing population. Member companies are directly involved in introducing and providing access to innovative medicines, keeping healthcare professionals continuously updated on relevant disease areas and available treatment options, create public awareness on increasingly prevalent diseases and educate patients through disease management education programmes.







## TIMELY DELIVERY OF QUALITY-ASSURED MEDICATIONS FOR DISEASE PREVENTION & TREATMENT

It has always been one of PhAMA's focal points in ensuring Malaysians have access to high-quality medications for preventive, management and curative purposes. Over the years, PhAMA has undertaken various initiatives for the benefits of patients. Several significant initiatives include:

### Drug Registration & Commercial Availability

Between 2010 and 2016, PhAMA member companies registered and launched a total of 247 innovative medicines in Malaysia (top 10 drug classes listed in Table 2).<sup>12</sup> In addition to a total of 73 ethical products launched between 2013 and 2016, a further 156 products in the same category are expected to be introduced between 2017 and 2022 (Figure 4; Table 3). As Malaysia continues to see a rising prevalence of cancer, PhAMA members are responding proactively by increasing the public's accessibility to innovative cancer medicines, as demonstrated by the number of anticancer agents introduced into the country.



TABLE 2. TOP 10 CLASSES OF PHARMACEUTICAL PRODUCTS LAUNCHED IN MALAYSIA BETWEEN 2010 AND 2016<sup>12</sup>

Drug Classes	Number of Pharmaceutical Products Launched (2010–2016)
Anticancer agents	22
Vitamins	20
Central nervous system agents	17
Antihypertensives	16
Hormones	14
Antidiabetics	10
Antidepressants	10
Vaccines	8
Antibiotics	7
Antivirals	6

**Figure 4** Number of ethical products launched by surveyed PhAMA member companies between 2013 and 2016, and the projection for new launches between 2017 and 2022.<sup>12</sup>

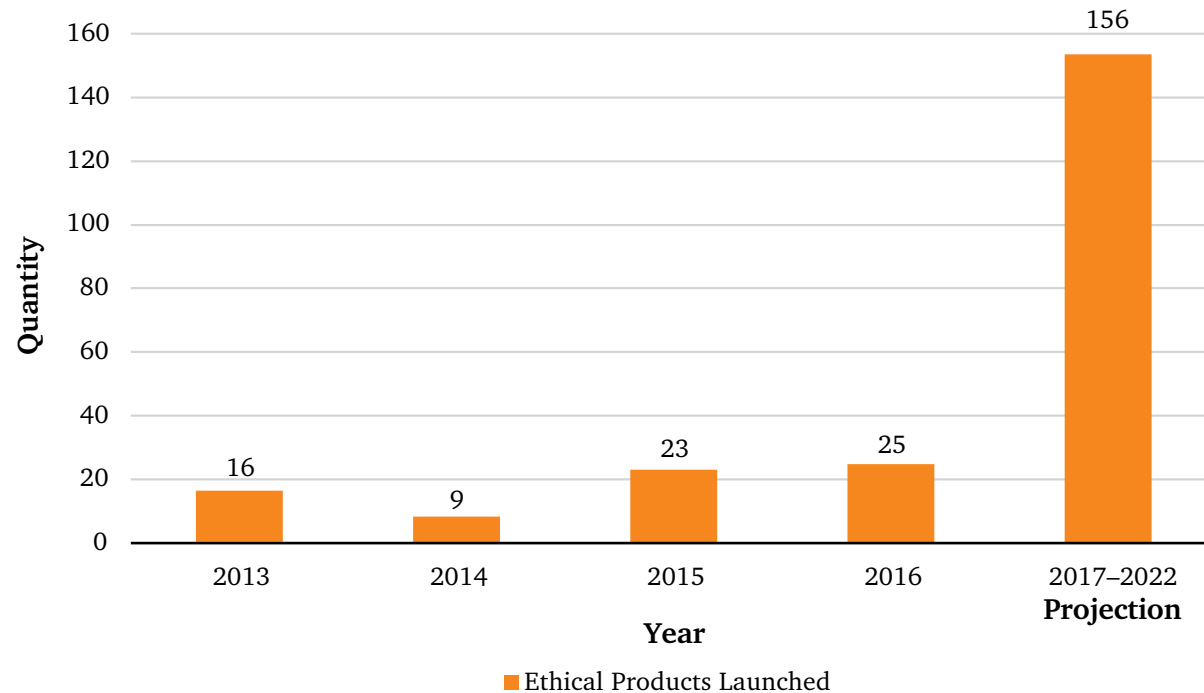


TABLE 3. TOP 10 CLASSES OF ETHICAL PRODUCTS TO BE LAUNCHED IN MALAYSIA BETWEEN 2017 AND 2022<sup>12</sup>

Drug Classes	Number of Ethical Products* to be Launched (2017–2022)
Anticancer agents	24
Central nervous system agents	19
Antidiabetics	16
Diagnostic agents	10
Anti-infectives	10
Vaccines	9
Immunologic agents	9
Cardiovascular agents	8
Smoking cessation agents	5
Others	11

\*Ethical products are those that are available only with a prescription from a qualified healthcare professional.



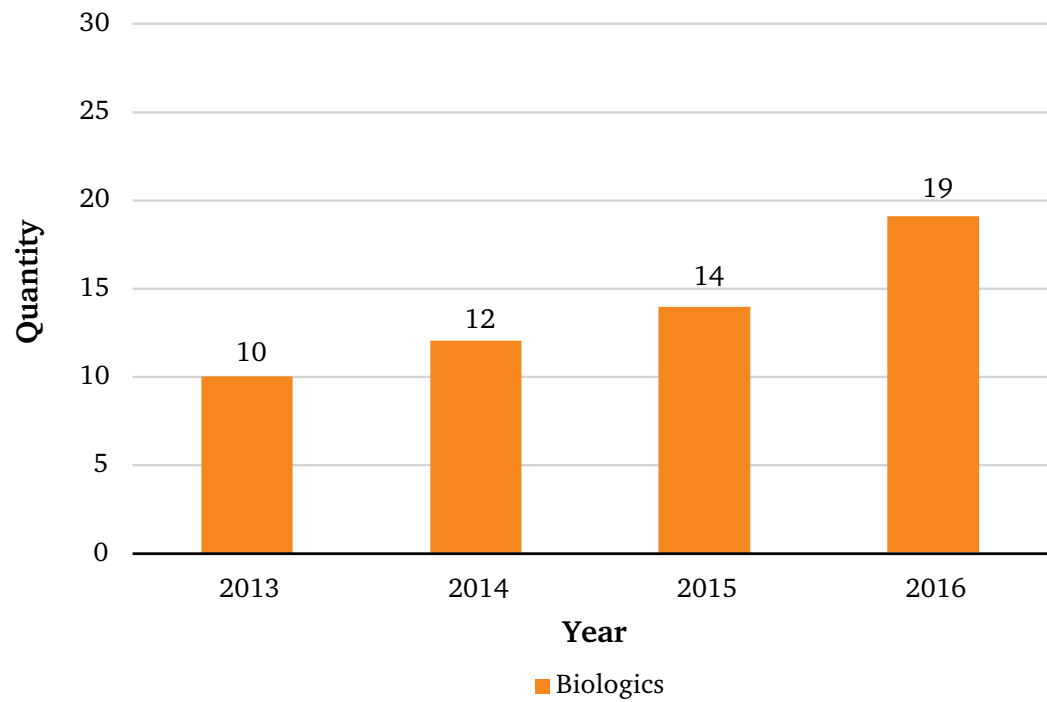
## Biologics

Biologics (also known as biological products) are therapeutic agents containing large, complex molecules that are isolated from a variety of natural sources (eg, plants, animals or microorganisms).<sup>16</sup> They are produced using state of the art biotechnologies and comprise a wide range of products, including vaccines, blood and blood components, allergenics, genes, somatic cells, tissues, and recombinant therapeutic proteins.

In recent years, a growing number of PhAMA member companies have made significant efforts to improve the availability of biologics in Malaysia. This is an important endeavour in ensuring Malaysian patients have equal access to the latest medicines that are readily available to patients in high-income countries. Between 2013 and 2016, a total of 55 biologics were made available to Malaysian patients (Figure 5).<sup>12</sup>



**Figure 5** Biologics made available to Malaysian patients between 2013 and 2016.<sup>12</sup>



### Self-Care: More than just Over-the-Counter Medicines

Appropriate self-care offers many advantages to a healthcare system, and the WHO recognises that responsible self-medication (being the most accessible form of healthcare) is an important component of self-care.<sup>17</sup> In line with the philosophy of individual participation and empowerment, self-care can help to prevent and treat symptoms and ailments that do not require medical consultation; reduce the increasing pressure on medical services for the relief of minor ailments, especially when financial and human resources are limited; increase the availability of basic healthcare to those living in rural or remote areas, where access to medical advice may be difficult; and enable patients to control and manage their own chronic conditions.

A country that fully encourages self-care can expect to have a healthier population and redeploy scarce resources in priority areas. In general, the benefits of practising self-care include empowering patients to take actions, improving wellness and life expectancy, and reducing the use of core healthcare services.<sup>18</sup> Additionally, self-care can also play a crucial role in the prevention and post-treatment management of noncommunicable chronic illnesses such as cardiovascular diseases, cancer and diabetes.

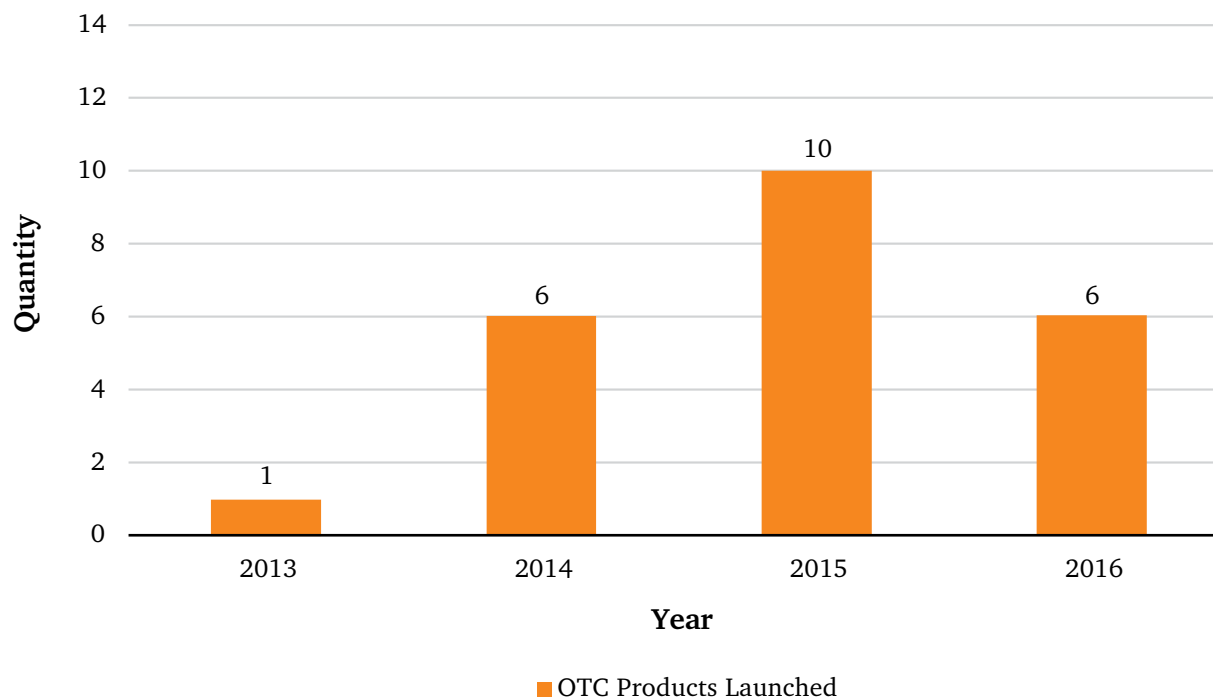
PhAMA members contribute to the development of the self-care sector in Malaysia by facilitating the availability of Over-the-Counter (OTC) products (eg, supplements and medications) to consumers at large. Between 2013 and 2016, a total of 23 OTC products were launched by PhAMA member companies (Figure 6).<sup>12</sup>

### Counterfeits & Countermeasures

As with most commodities with an intrinsic monetary value, pharmaceutical products inevitably face the threat of counterfeiting. In the 2017 PhAMA Fact Book Survey, three member companies reported the discovery of counterfeits involving their products.<sup>12</sup> Being part of an industry with strict inbuilt guidelines and proper audit and response systems, these affected companies took the necessary multilevel countermeasures to notify their respective head offices, and provided critical analyses and technical support to the relevant law enforcement authorities.

Meanwhile, PhAMA has worked closely with the Royal Malaysian Customs Department to address the issue of counterfeit medicines by providing technical training to enforcement officers, as and when necessary.

**Figure 6** Number of OTC products launched by surveyed PhAMA member companies between 2013 and 2016.<sup>12</sup>



## BREAKING DOWN BARRIERS TO MEDICINE ACCESSIBILITY

While PhAMA and its members have been working tirelessly to ensure the availability of innovative and OTC products for all Malaysians, there are barriers that still stand in way of full consumer accessibility. Therefore, a number of initiatives have been introduced to further improve patient access to innovative medicines, such as the Patient Access Programme.

### Patient Access Programme

The Patient Access Programme (PAP) is a global practice that aims to improve patient access to innovative medicines and is implemented under various formats and names.

To enable public health institutions to fully benefit from such programme, the pharmaceutical industry constantly welcomes engagements and multilevel dialogues with various stakeholders of the healthcare system. In Malaysia, PAP has helped thousands of eligible patients who are financially constrained to access costly innovative medicines while receiving treatment in public healthcare facilities.<sup>1</sup> Oftentimes, patients under PAP receive their treatment either free of charge or at a reduced cost based on the recommendations given by their healthcare professionals. Through a strong public-private partnership, PhAMA has been collaborating with MoH to implement PAP in Malaysia in order to provide patients, especially those in public health institutions, greater access to innovative treatment options that can improve their quality of life.

In May 2018, MoH in collaboration with the pharmaceutical industry

officially rolled out its Patient Access Scheme (PASc).

### PAP: Featured Members

#### Johnson & Johnson

As highlighted in Our Credo, the cornerstone of Johnson & Johnson's beliefs that outlines a common set of values, Johnson & Johnson is committed to patients around the world. In realising this, the company's Patient Access Programme (PAP) allows accessibility of innovative medicines to patients who need them most. Johnson & Johnson Malaysia's PAP provides accessibility to seven types of therapeutic medicines in various diseases, from prostate cancer and multiple myeloma to Crohn's disease and psoriasis. To date, more than 270 patients in Malaysia have benefited from J&J Malaysia's PAP. With the PAP, J&J Malaysia hopes to continue to care for the world, one patient at a time.

#### Roche (Malaysia) Sdn Bhd

Roche's Patient Assistance Programme is part of Roche's commitment to help eligible patients access the Roche medicines they are prescribed with. The Roche Assist team is dedicated to providing value-added support and services under this programme. The Roche Patient Assistance Programme is for patients whose medical expenses are not fully covered by insurance, corporate benefit or any other funding from third parties, as advised and justified by physicians. Since 2007, more than 5,000 Malaysian patients have benefitted from this on-going initiative.

## IMPACT OF THE PATIENT ACCESS PROGRAMME ON THE MALAYSIAN HEALTHCARE SYSTEM<sup>12</sup>

Between 2013 and 2016, **> 10 PhAMA member companies offer PAP**



**Approximately 12,000 patients** have benefited from PAP offered by 9 member companies (2013–2016)



Total value of PAP offered by 8 PhAMA companies amounted to approximately **RM99 million** (2013–2016)





## LOOKING AHEAD

PhAMA has made significant inroads into improving the access of medicines for all Malaysians; however, there is still room for improvement in ensuring that patients in Malaysia continue to receive the best treatment options available. Here, PhAMA offers some observations on challenges faced in this country and the corresponding propositions on how these challenges can be overcome together.

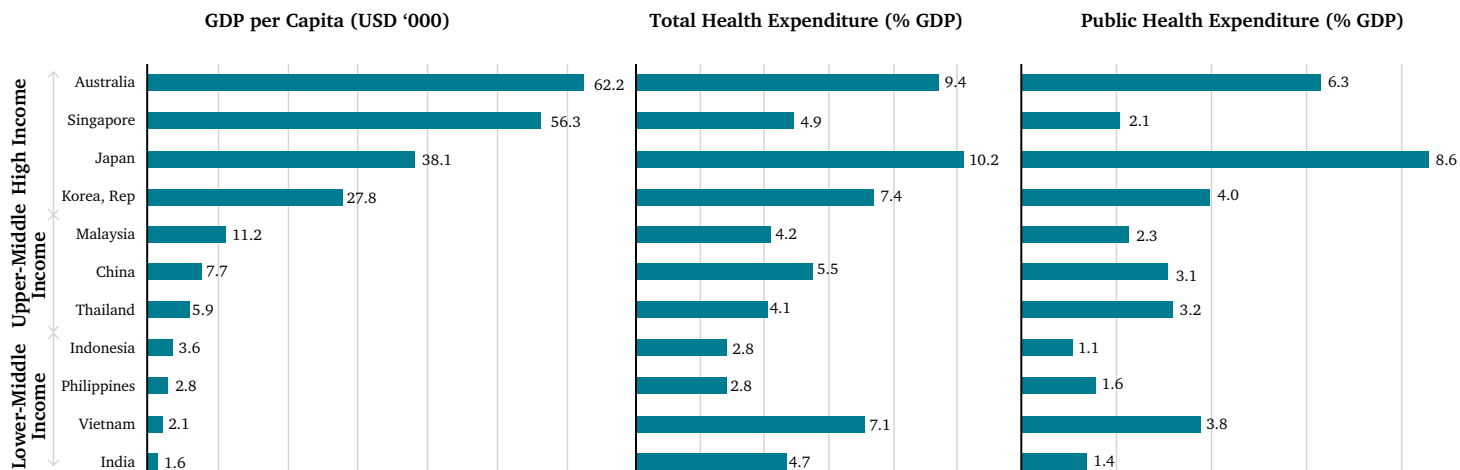
### Improving Malaysians' Access to Innovative Medicines

As an upper-middle income country, Malaysia has a comparatively low total healthcare expenditure. In 2014, Malaysia spent 4.2% of its Gross Domestic Product (GDP) on total health expenditure (with 2.3% on public healthcare), well below the average value (ie, 6.2%)

Figure

7

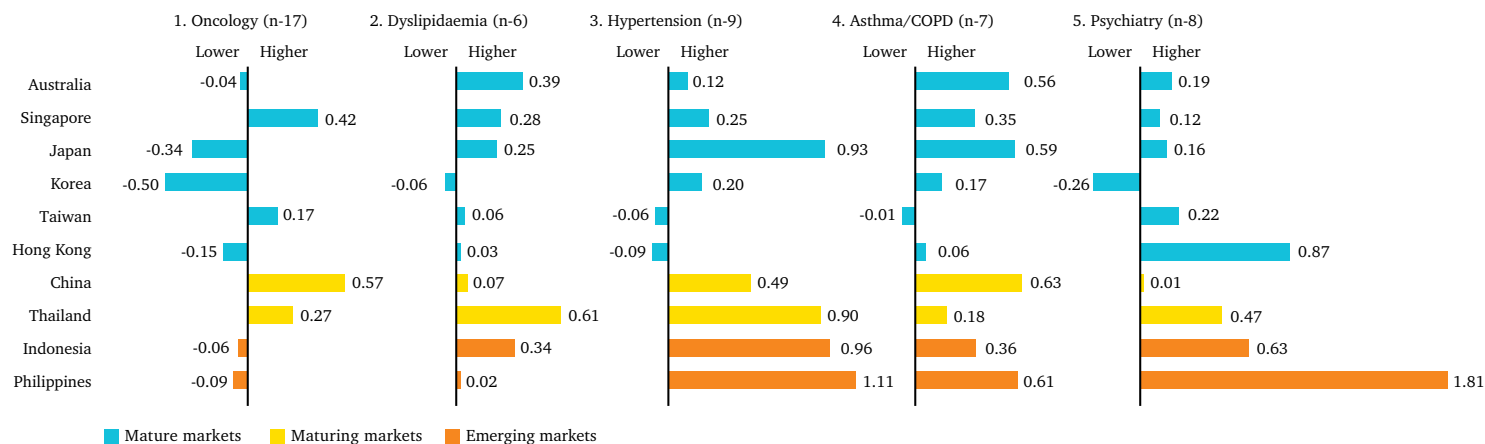
Comparison of Gross Domestic Product (GDP) per Capita, total and public health expenditures of selected Asia Pacific countries in 2014.<sup>19</sup>



of upper-middle income countries (Figure 7).<sup>19</sup> During this period, global spending on medicines reportedly surpassed USD1 trillion per year and accounts for up to 67% of total health expenditures in some countries, mostly as out-of-pocket (OOP) expenses borne by consumers.<sup>20</sup> In Malaysia, 40% of the average individual's total

healthcare expenditure in 2016 constituted of their OOP payments.<sup>13</sup> Interestingly, the pricing of medicines in Malaysia are, in fact, not significantly higher than that of our neighbouring countries, even when branded innovative medicines in high-cost therapeutic area such as oncology is taken into consideration (Figure 8).<sup>21</sup>

**Figure 8** Comparative pricing analysis of top five therapeutic areas in selected Asia Pacific countries.



Source: IMS PADDs data, MAT Q1 2014

Note: Includes prescription products from all channels, including public and private sectors; Common products available in the same form(s) across markets

PhAMA opines that a free pricing model would be beneficial as it will encourage effective competition and foster a more demand-oriented local pharmaceutical market. The pricing of, and access to, costly innovative medicines should be governed by clinical and cost-effectiveness criteria, and evaluated using a systematic, evidence-based approach (ie, health technology assessments) to ensure that each medicine is given a fair value for money. In a PhAMA position paper, it has been suggested that MoH should utilise tools other than reference pricing to ensure that a sustainable and balanced approach is used to achieve cost savings while safeguarding patient's access to the medicines they need.<sup>21</sup>

While MoH has a Drug Formulary Listing, the range of availability and the uptake of drugs in the public sector remain limited. Surveys have found that Malaysians' access to innovative medicines was consistently lower than those of Koreans and Taiwanese.<sup>22</sup> For instance, according to data published in 2014, the proportion of patients in Malaysia with access to dipeptidyl peptidase-IV (DPP-IV) inhibitors (for the treatment of type 2 diabetes) – at 0.4% – was significantly lower compared with patients in Korea (9.8%) and Taiwan (10.8%). The same was observed for the treatment of rheumatoid arthritis, where only 0.21% of Malaysian patients have access to biological therapies, compared with 4.92% in Korea and 9.2% in Taiwan (Figure 9).<sup>22</sup>

**Figure 9**

Patient volume analysis illustrating the accessibility of innovative medicines for the treatment of chronic diseases in selected Asian countries.<sup>22</sup>

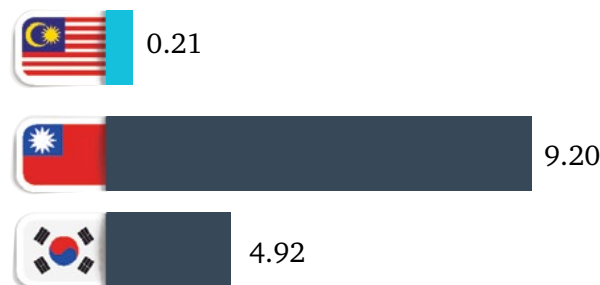
### Type 2 Diabetes

Estimated percentage of patients who were treated with listed DPP-IV inhibitors (%), MAT Q1 2014  
N=4



### Rheumatoid Arthritis

Estimated percentage of patients who were treated with listed biological therapies (%), MAT Q1 2014  
N=4



PhAMA believes that a mutual goal of providing equitable and sustainable access to innovative medicines would be of tremendous advantage to the public, the government, and other relevant stakeholders. The institution of a united network of stakeholders to work towards this goal, utilising a multi-criteria decision analysis (MCDA) model, to increase transparency and predictability of decisions is thus recommended.<sup>23</sup> Additionally, PhAMA also advocates for the personalisation of value measurement by incorporating broader measures of value for each patient. The association is confident that the implementation of these suggestions will deliver results that outweigh the perceived disadvantage (ie, price-related) of innovative medicines. Thus, PhAMA seeks and welcomes active engagements with other stakeholders in exploring alternative access schemes.

PhAMA recommends all relevant stakeholders to review and consider the following points:

- Equity, efficiency and effectiveness in the context of healthcare decision-making
- Alternative methodologies or pathways for the articulation of cost-effectiveness and promotion of associated challenges
- The current threshold approach being applied in Malaysia, as well as associated challenges
- WHO's position on cost-effectiveness thresholds that place incremental cost-effectiveness ratios (ICERs) in the context of other public health options available, or already adopted in relevant Malaysian settings, as well as in the context of budget
- New frameworks such as MCDA to improve on the use of simple thresholds and their relevance to Malaysia

**References:** 1. Speech by Tan Sri Nor Mohamed Yakcop, Minister in the Prime Minister's Department. Launch of the Malaysian Quality of Life Index Report, 2011. Available at: <http://www.vodpod.upm.edu.my/uploads/docs/Malaysia-%20A%20Model%20of%20Quality%20Growth.pdf>. Accessed on 23 Jan 2018. 2. United Nations. World Urbanization Prospects. The 2014 Revision. New York; 2015. Available at: <https://esa.un.org/unpd/wup/Publications/Files/WUP2014-Report.pdf>. Accessed on 23 Jan 2018. 3. World Health Organization Fact Sheets – Noncommunicable diseases. Available at: <http://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases>. Accessed on 3 Sep 2018. 4. Yusuf UN, et al. Int J Public Health Res 2013;3:249–256. 5. Institute for Public Health. The Second Malaysian Burden of Disease Study. Available at: <http://www.iku.gov.my/index.php/research-eng/list-of-research-eng/iku-eng/bod-eng>. Accessed on 23 Jan 2018. 6. World Health Organization. Available at: [http://www.who.int/mental\\_health/management/depression/daily/en](http://www.who.int/mental_health/management/depression/daily/en). Accessed on 3 Sep 2018. 7. World Health Organization. Global status report on noncommunicable diseases 2010. Available at: [http://www.who.int/nmh/publications/ncd\\_report\\_full\\_en.pdf](http://www.who.int/nmh/publications/ncd_report_full_en.pdf). Accessed on 3 Sep 2018. 8. Institute for Public Health (MOH). National Health and Morbidity Survey 2015. Non-communicable diseases, risk factors & other health problems. Volume II. Available at: <http://www.iku.gov.my/index.php/research-eng/list-of-research-eng/iku-eng/nhms-eng/nhms-2015>. Accessed on 23 Jan 2018. 9. World Health Organization Technical Guidelines. Available at: <http://www.who.int/hac/techguidance/phit/commdisease/en>. Accessed on 3 Sep 2018. 10. Ministry of Health Malaysia. Health Facts 2018. Available at: <http://www.moh.gov.my/english.php/pages/view/56>. Accessed on 30 Nov 2018. 11. WHO publishes list of top emerging diseases likely to cause major epidemics. Available at: <http://www.who.int/medicines/ebola-treatment/WHO-list-of-top-emerging-diseases/en>. Accessed on 23 Jan 2018. 12. PhAMA Fact Book Survey 2017 13. Ministry of Health Malaysia. Country Health Plan. 10<sup>th</sup> Malaysia Plan 2011–2015. Putrajaya, Malaysia: Kementerian Kesihatan Malaysia. ISBN 978-983-3433-96-4. 14. Department of Statistics Malaysia. Current Population Estimates, Malaysia, 2017–2018. Available at: [https://www.dosm.gov.my/v1/index.php?r=column/cthemeByCat&cat=155&bul\\_id=c1pqTnFjb29HSnNYNUptTmNWZHArdz09&mnu\\_id=L0pheU43NWJwRWVSZklWdzQ4THUUT09](https://www.dosm.gov.my/v1/index.php?r=column/cthemeByCat&cat=155&bul_id=c1pqTnFjb29HSnNYNUptTmNWZHArdz09&mnu_id=L0pheU43NWJwRWVSZklWdzQ4THUUT09). Accessed on 30 Nov 2018. 15. Department of Statistics Malaysia. Population Projection 2020–2040. Available at: <http://pqj.stats.gov.my/searchBL.php?tahun=2020-2040&kodData=3&kodJadual=2&kodCiri=3&kodNegeri=00>. Accessed on 30 Nov 2018. 16. USA Food and Drug Administration. What Are “Biologics” Questions and Answers. Available at: <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm>. Accessed on 23 Jan 2018. 17. World Self-Medication Industry. What is self-care? Available at: <http://www.wsmi.org/about-self-care-and-self-medication/what-is-self-care>. Accessed on 23 Jan 2018. 18. World Health Organization. The Role of the Pharmacist in Self Care and Self Medication. Available at: <http://apps.who.int/medicinedocs/en/d/Jwhozip32e/3.3.html>. Accessed on 23 Jan 2018. 19. The World Bank. GDP per capita & Health Expenditure 2014. Available at: <https://data.worldbank.org/indicator/SH.XPD.PUBL.ZS>. Accessed on 23 Jan 2018. 20. Keynote address by Director General of Health Malaysia (Balancing access, quality, affordability & sustainability). 7<sup>th</sup> Asia Pacific Future Trends Forum 2014. Available at: <https://kpkesihatan.com/2014/09/20/medicine-expenditure-accounted-for-11-4-of-the-operating-budget-of-the-ministry-in-2012>. Accessed on 23 Jan 2018. 21. PhAMA. Is Reference Pricing Right for Malaysia? An analysis of proposed pricing reforms for pharmaceuticals in Malaysia. September 2015. Available at: <http://phama.org.my/index.cfm?&menuid=87&parentid=6>. 22. PhAMA. Building Greater Access to Innovative Medicines – What is Next for Malaysia? An analysis of proposed reforms and a review of possible access schemes. September 2015. Available at: <http://www.phama.org.my/index.cfm?&menuid=86&parentid=6>. 23. PhAMA. Value Pricing for Improved Patient Access in Malaysia – White Paper. September 2016. Available at: <http://phama.org.my/index.cfm?&menuid=93&parentid=6>.

## CULTIVATING A STRONGER PHARMACEUTICAL LANDSCAPE

“No one in the pharmaceutical industry can exist independently of each other. The growth of the industry is reliant on the efforts of all stakeholders and has a positive ripple effect on the rest of the economy. Conversely, positive growth and development in other economic areas also benefit the pharmaceutical fraternity. Thus, it is vital that we explore opportunities to grow, and to view this growth as a component of Malaysia’s progress as a whole.” – Chin Keat Chyuan, President, PhAMA.

The Malaysian government recognises healthcare, of which the pharmaceutical industry is a key component, as one of the National Key Economic Areas (NKEA) to be developed under the Economic Transformation Programme (ETP), in tandem with other government programmes such as the 11<sup>th</sup> Malaysia Plan (which commenced in 2016).

PhAMA is proud to contribute towards the NKEA’s Entry Point Projects (EPP) 2 of the ETP (Healthcare), which focuses on creating a supportive ecosystem to grow clinical research in Malaysia through the transfer of knowledge via industry-sponsored research (ISR) activities.<sup>1</sup>

### Positive Changes Begin from Within

As the Malaysian pharmaceutical industry continues to grow, it becomes increasingly vital that industry players observe a common standard of conduct in their engagement with healthcare professionals (HCPs). To meet this objective, PhAMA has developed the PhAMA Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products and the PhAMA Code of Conduct for Non-Prescription (OTC) Products. The scope of both codes, whilst being extensive in order to

provide guidance beyond the dissemination of scientific information, observe the legal boundaries established by the government. Importantly, both codes owe their existence to the voluntary adoption and compliance by PhAMA members. PhAMA also encourages the adoption of these codes by other industry organisations.

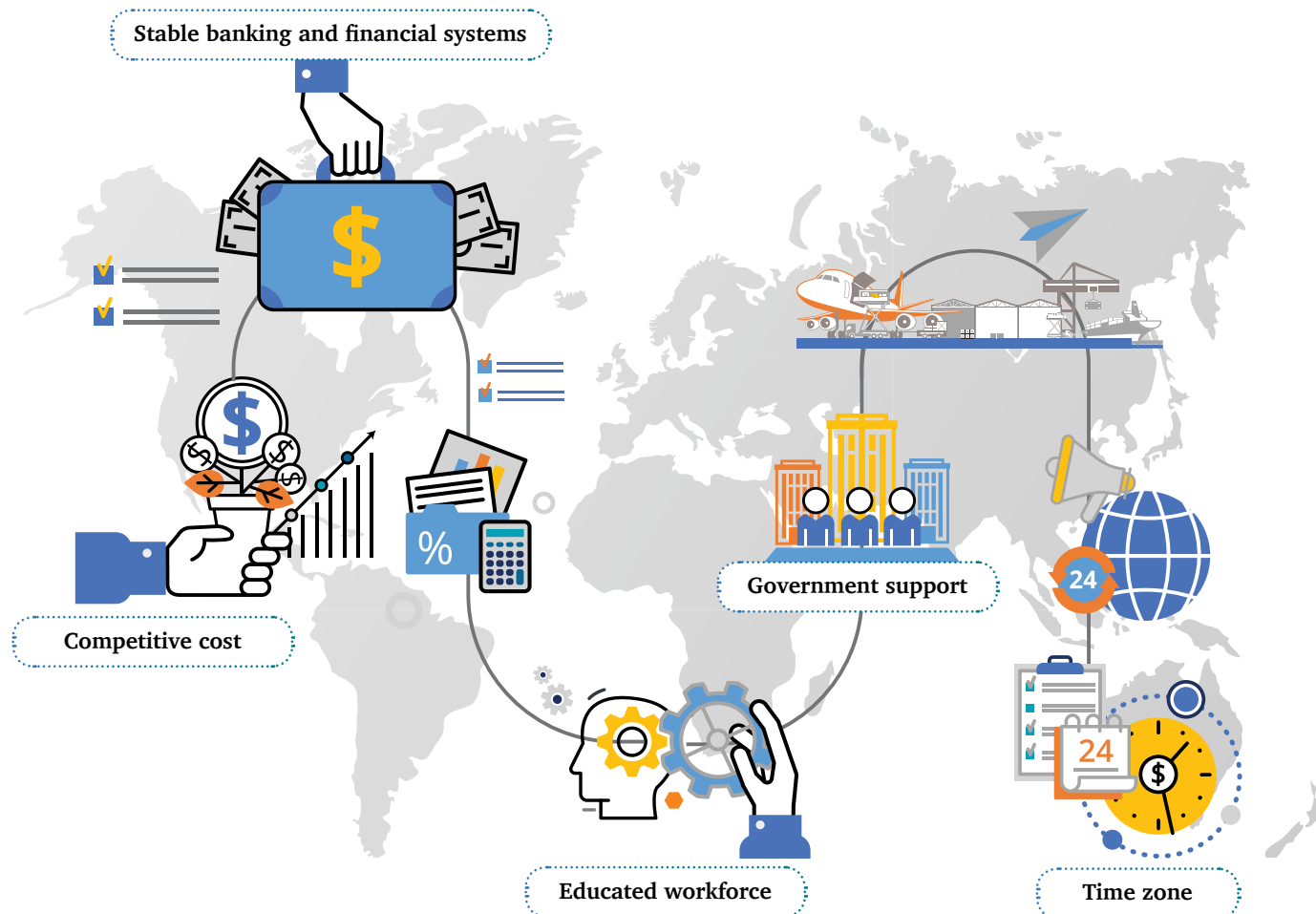
### PhAMA Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products

The **PhAMA Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products** was first drawn up and adopted by fellow members in 1978. It was developed to provide clear guidance on industry members’ conduct and to establish a standard for the dissemination of accurate, fair and objective information to the medical and allied professions in promoting rational prescribing decisions. The code has since been reviewed by the association on a regular basis and amended when necessary to ensure clarity and current relevance, on par with the pharmaceutical industry’s global standards.

### PhAMA Code of Conduct for Non-Prescription (OTC) Products

The **PhAMA Code of Conduct for Non-Prescription (OTC) Products** provides guidelines on marketing activities for medical products which are used for self-medication to treat minor ailments, not requiring a doctor’s prescription. The PhAMA Code of Conduct for Non-Prescription (OTC) Products complements the various government acts and regulations, and supports responsible self-medication.

## KEY STRENGTHS THAT FACILITATE THE CREATION OF GLOBAL SHARED SERVICES HUBS IN MALAYSIA





## IMPROVING PRODUCTIVITY & GROWTH

Identifying key areas for improvement and implementing strategic business practices are vital to the growth and advancement of PhAMA members. To accelerate the country's economic growth, PhAMA members are committed to the development of manpower capacities and capabilities with the aim of improving labour market efficiency. This is in line with the message of “accelerating human capital development for an advanced nation” – one of the key pillars listed in the 11<sup>th</sup> Malaysian Plan (2016–2020).<sup>2</sup>

### Local Plants of Research-Based Multinationals

Having a local manufacturing facility enhances a company's portfolio and presence. Additionally, it also promotes the local economy by generating employment opportunities.

### Shared Services Unit

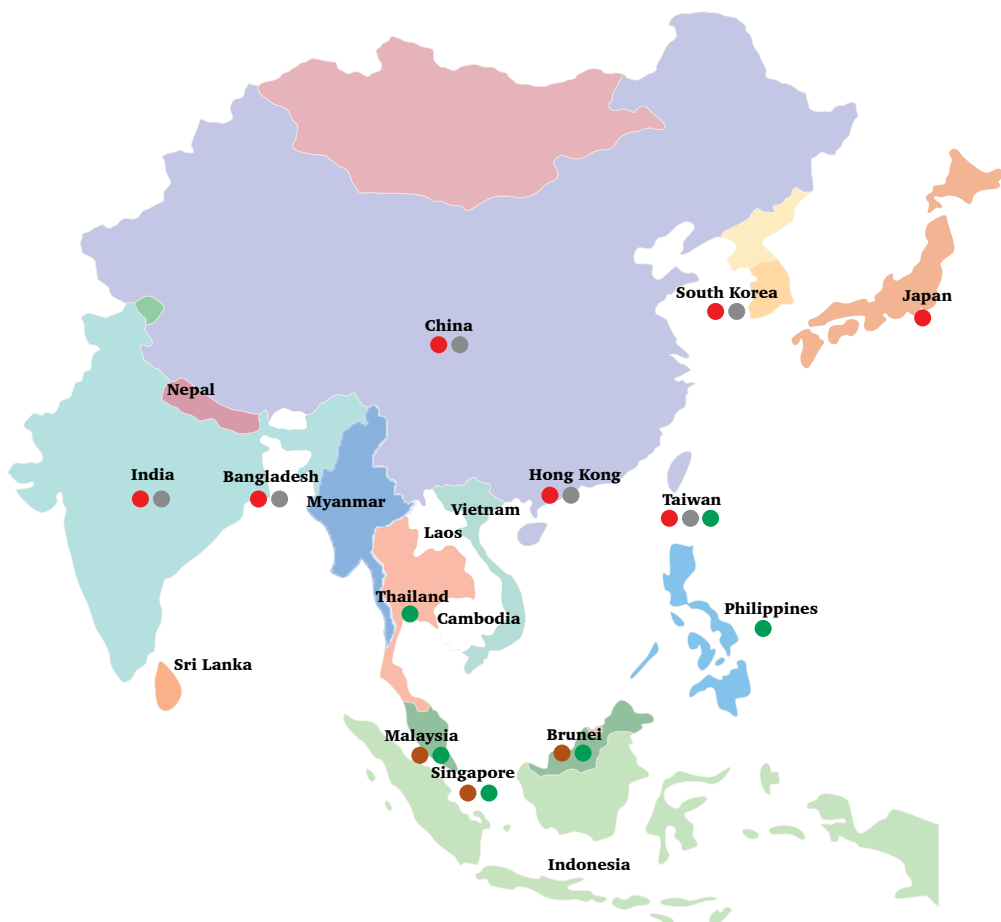
The Shared Services Unit (SSU) is an organisational structure that sees a centralised centre servicing various parts of a company across a wider region. Focusing on the strategic use of key human resource personnel and information technology (IT) solutions within a regional hub, such arrangement allows for improved efficiency via the streamlining of standard operating procedures (SOP) and

promotes a stronger inter-regional cooperation within a company. Furthermore, the establishment of a regional hub eliminates the need for specific functional support staff in each region, thus reducing the company's global operational costs.

Nine PhAMA member companies offer shared services to their respective business units within the region, as well as globally.<sup>3</sup> One SS hub has been in operation since 2009, while the most recent hub was established in 2018. Depending on the functional role of these SS hubs, the number of staff employed ranges from 6 personnel/unit to as high as 400 personnel/unit. The establishment of these hubs within Malaysia is a recognition of the country's human resources expertise.

Key strengths such as the competitive cost of doing business, a strong presence of commercial businesses, stable banking and financial systems, the availability of a young, multilingual and educated workforce, coupled with the affordability of these high-value talents, strong government support and incentives, good infrastructure, and time zone alignment to a majority of the countries served – all contributed to the creation of global SS hubs in Malaysia. The existence of these hubs also encourages the transfer of knowledge and skills at the international level.

## AREAS OF SERVICES OFFERED BY SHARED SERVICES HUBS IN MULTIPLE COUNTRIES ACROSS THE GLOBE



- Finance process & services
- Clinical research services
- Information technology
- Legal/Control & compliance
- Medical information

SS hubs by PhAMA member companies operating in ASEAN member countries offer all of the services listed above.

- Human resource services
- Marketing & other back office support

### Note:

● Finance process & services provided in the ASEAN countries exclude Cambodia and Laos. The SS hub for this functional role also covers Australia, New Zealand and the UK.

● Information technology services provided in the ASEAN countries exclude Brunei, Cambodia and Laos. The SS hub for this functional role also covers Australia and New Zealand.

**Other areas of services offered** include – Controllership, taxation, support & training, financial planning, global clinical office, global business performance analysis, FRA operations, procurement, facility management, record management, employee experience, and purchase-to-pay

ASEAN member countries: Malaysia, Singapore, Indonesia, Myanmar, Laos, Thailand, Cambodia, Vietnam, Brunei, Philippines

Other serviced countries: East Asia (China, South Korea, Japan, Taiwan, Hongkong), South Asia (India, Bangladesh), Oceania (Australia, New Zealand), Europe (United Kingdom)

## Shared Services: Featured Members

### AstraZeneca

AstraZeneca Asia-Pacific Business Services Sdn Bhd (AZ APBS) has been operating since 2008, and employed a total of 220 employees as of 2017. The areas of expertise supported by AZ APBS include controllership, controls and compliance, finance and accounting transactional processing activities, financial planning and analysis, finance process management and improvement services, global business performance analysis, information and report production, information technology support services, support and training services, as well as tax services.

It serves a number of countries, including Australia, China, Hong Kong, India, Indonesia, Japan, Malaysia, New Zealand, Philippines, Singapore, South Korea, Taiwan, Thailand, UK and Vietnam. In 2016, it was the gold winner of the Excellence in Customer Service Awards presented by Shared Services Outsourcing Network (SSON).



Launching of Project Pearl by AstraZeneca's Global Finance Services (KL) to move to world-class standards in finance processes

### DKSH

DKSH's global IT platform is centrally managed from the DKSH Corporate Shared Services Center (CSSC) at Technology Park Malaysia, Kuala Lumpur. Established in 2003, CSSC operates one of the largest SAP platforms in Asia, driving growth for DKSH's business partners in many diverse market sectors. CSSC's portfolio of services include IT application and infrastructure management, business intelligence and analytics, consulting and advisory, as well as business process operations for finance.

With more than 300 specialists, CSSC offers global support services for the DKSH Group, spanning 825 business locations in 37 countries across the world. A centralised IT backbone is essential in enabling DKSH Group to outgrow the market and increase overall productivity. Furthermore, locating IT headquarters in Malaysia provides access to excellent talent and a reliable infrastructure to drive sustainable business success.



DKSH CSSC, one of Asia's largest operator of SAP platform, commemorating SAP's 25<sup>th</sup> anniversary in the market in 2017

**GlaxoSmithKline**

GlaxoSmithKline Business Service Centre Sdn Bhd (GSK BSC KL) was established in 2008. With approximately 400 employees servicing around 469 global sites regionally and globally, it supports the following areas of expertise – financial services, global application and development, information technology for R&D and manufacturing infrastructure and facilities, global tax and statistics, procurement, and supply chain.

BSC KL invests mostly in local talents and has a key value proposition in talent management, with a core focus on developing its employees' hard and soft skills, particularly leadership capabilities. Additionally, its Talent Management Programmes provide high performers with opportunities to work within GSK's global network of companies. GSK BSC's APAC Finance Services (Kuala Lumpur) was given the bronze award for Excellence in Transformation at 2015's 18<sup>th</sup> Annual Asian SSON Excellence Awards.



GSK Business Service Centre KL supports around 469 global sites in a number of areas of expertise

**MSD**

Effective from April 2018, MSD will be investing in a regional Business Service Centre (BSC) aimed at providing diversified, higher value services in the areas of finance and accounting, supported by approximately 220 people. Once established, BSC's operational scope will expand to include a wide range of other enterprise services.

**Pfizer**

Pfizer Malaysia Sdn Bhd established its SSU in 2012, and it is currently supported by six staff. It provides medical information services to Australia, Brunei, Malaysia, New Zealand, Philippines and Singapore. Members of Pfizer Malaysia's SS team have the capability of working across many cultures and markets in Asia Pacific and beyond, owing to their experience of studying and/or working in other countries outside of Asia.

**Roche**

Officially known as Roche Services (Asia Pacific) Sdn Bhd, Roche SSC KL is a central hub that provides key finance, IT and procurement services to the Roche group, with an emphasis on Asia Pacific. It is one of Roche's three Global Shared Service Centres, along with SSC Budapest and SSC San Jose. In Asia Pacific, SSC KL provides Roche affiliates across 15 countries with shared-service efficiencies, optimisations and value-added functions in finance, IT and procurement.

Globally, SSC KL also provides IT application development to support the Roche Group's core business areas. This includes innovative, cutting-edge IT-based solutions in the research and manufacture of Roche's medicines and diagnostic equipment, as well as the ongoing development of personalised healthcare IT applications. SSC KL was officially opened in October 2016 and as at October 2018, has more than 500 employees from 14 countries. It intends to grow further, staying dedicated to Roche's purpose of "Doing now what patients need next".



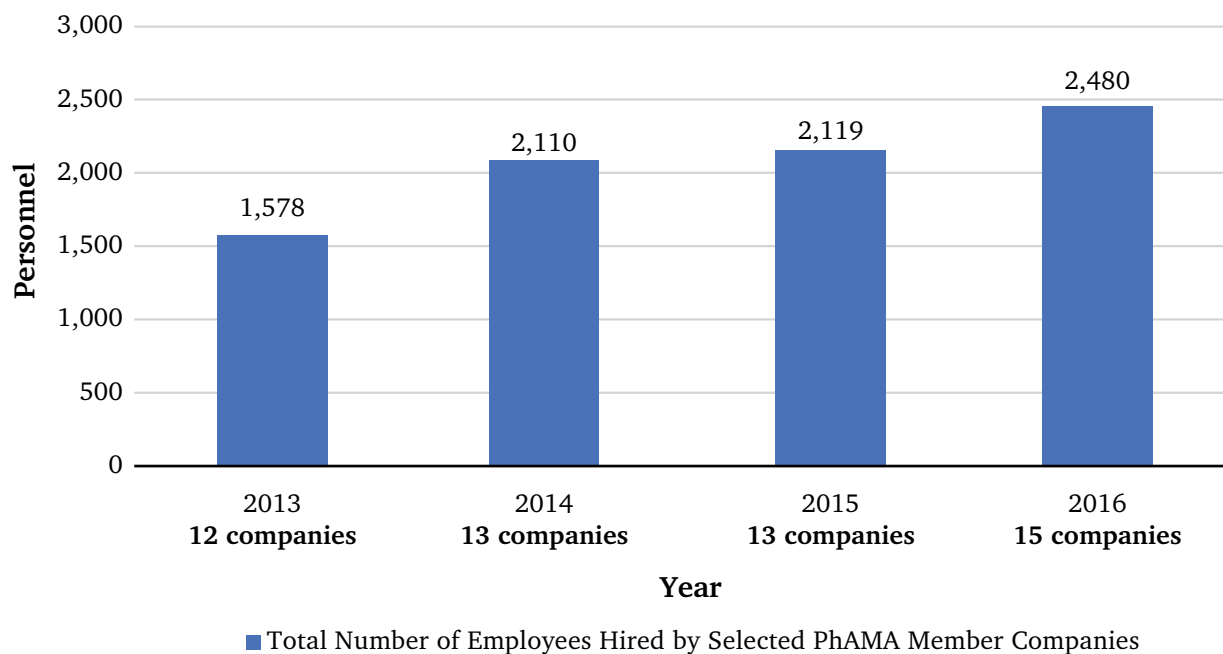


## PROMOTING THE GROWTH OF THE NATION

The ETP Annual Report 2014 reported that the Malaysian government aims to generate RM35.5 billion in gross national income (GNI) and 181,000 new jobs via the healthcare sector by 2020.<sup>1</sup> There were 41 projects providing 25,633 jobs in 2014, and the total investment value is expected to reach RM4.96 billion over a period of 6 years. In 2014 alone, the healthcare sector had achieved 28.8% of the RM17.2 billion investments targeted as per the government's 2020 roadmap. Given that pharmaceutical products form the treatment and management backbone of the healthcare sector, PhAMA members have and will continue to play a significant role in helping the government achieve its economic transformation goals.



**Figure 10** Total number of employees hired by selected PhAMA member companies between 2013 and 2016.<sup>3</sup> The number of companies varies between the listed years due to the selective responses submitted by survey respondents.



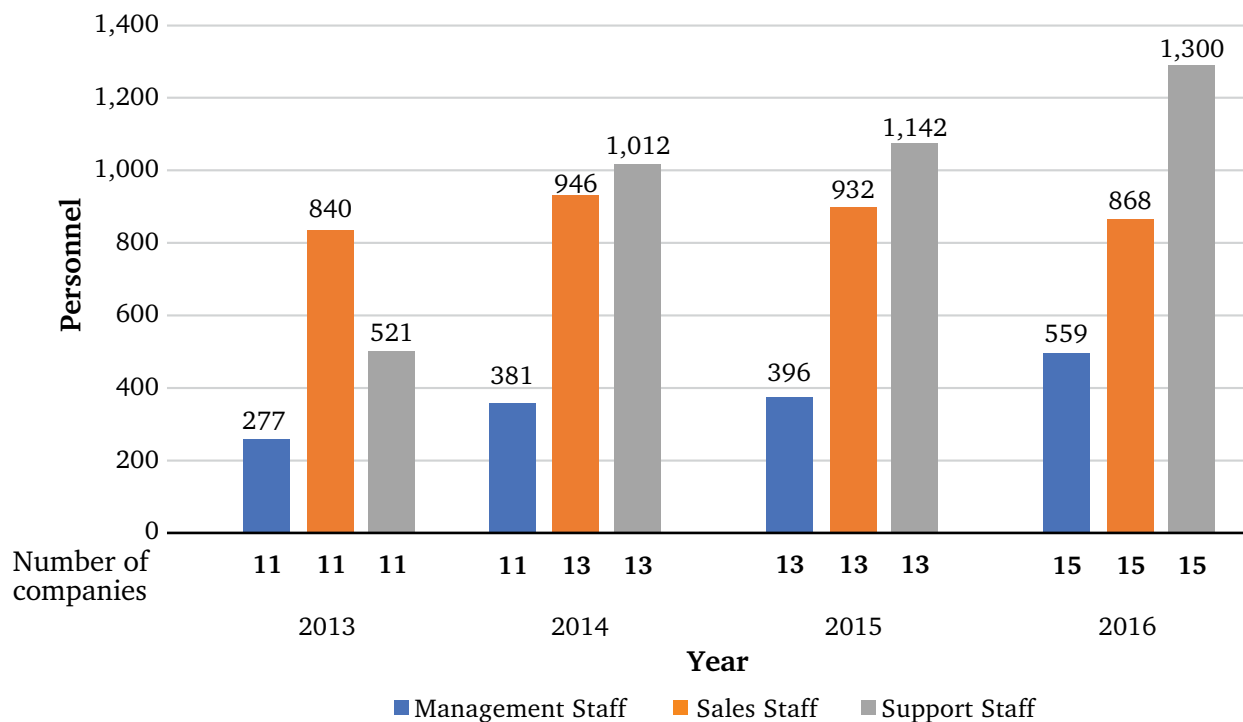


## Taxation & Employment

Activities generated by PhAMA member companies contribute to the growth of other supporting industries, and create pools of income for the country. Notably, pharmaceutical companies also provide employment opportunities and tax contribution that are essential in sustaining the national economy. Since 2013, there has been a year-on-year increase in hiring among PhAMA member companies (Figure 10), and a total of close to RM31 million in tax was paid by 10 member companies in 2016.<sup>3</sup> When analysing the breakdown of employees as per their functional roles, there was a noticeable increase in the number of management staff from 2014 to 2016 owing to the creation of SSU, which necessitated the hiring of additional manpower and expertise to support local, regional and international operations (Figure 11). This contributed towards the 11<sup>th</sup> Malaysian Plan's aspiration to reach a total employment number of 15.3 million by 2020.

**Figure 11**

Total number of employees, as per functional role, hired by selected PhAMA member companies between 2013 and 2016.<sup>3</sup> The number of companies varies between the listed years due to the selective responses submitted by survey respondents.





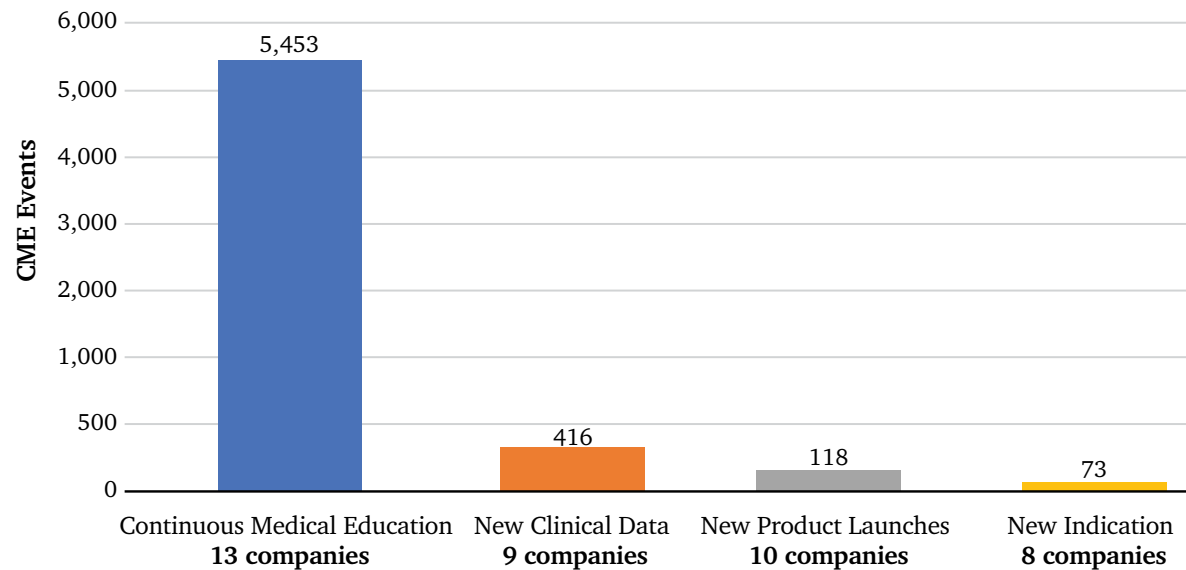
## BUILDING & DEVELOPING EXPERTISE

A country's typical healthcare delivery framework comprises many components, encompassing policy makers, regulators, health institutions, HCPs, research institutions, producers of medicines, as well as entities from other supporting industries.

Relationships among the stakeholders are multi-layered and cut across horizontally, with a number of them assuming more than a single role. Members of the research-based pharmaceutical industry not only make treatment options available to Malaysians, but also share the latest specialised knowledge in medicine and biotechnology with healthcare providers. One way they do this is through partnerships with the Ministry of Health (MoH) Malaysia in providing postgraduate training to pharmacy graduates.

**Figure****12**

A total of 6,060 CME events in four distinct categories were held by selected PhAMA member companies between 2013 and 2016.<sup>3</sup> The number of companies varies due to the selective responses submitted by survey respondents.



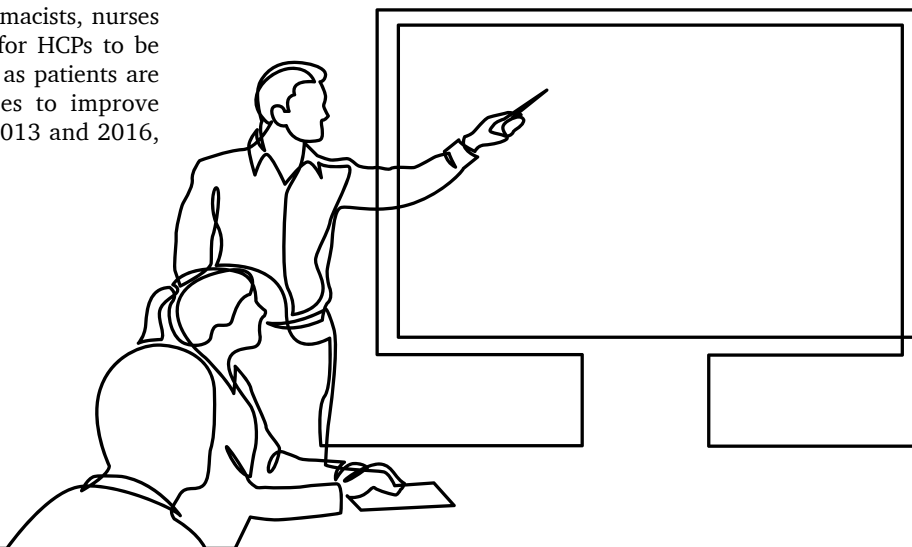
### Continuous Medical Education

Continuous Medical Education (CME) plays a pivotal role in updating HCPs on new developments in the healthcare industry, such as updated disease information and new treatment options. It also provides a platform for Malaysian HCPs to share their experiences and exchange know-how with their local and international colleagues. This ensures that the skills and knowledge of local HCPs are on par with that of their peers from other countries. Moreover, the presence and participation of Malaysian HCPs at international events also help to elevate the reputation of the country as an authority in medicine and health sciences.

As a central figure in the pharmaceutical sector, PhAMA advocates the advancement of scientific knowledge and medical information among general practitioners, specialist doctors, pharmacists, nurses and lab technicians in the country. It is important for HCPs to be attuned to current developments in medical science as patients are constantly looking for the latest treatment choices to improve their quality of life and overall lifespan. Between 2013 and 2016,

14 PhAMA member companies invested a total of RM83.92 million in CME events catered to Malaysian HCPs (Figures 12 & 13).<sup>3</sup>

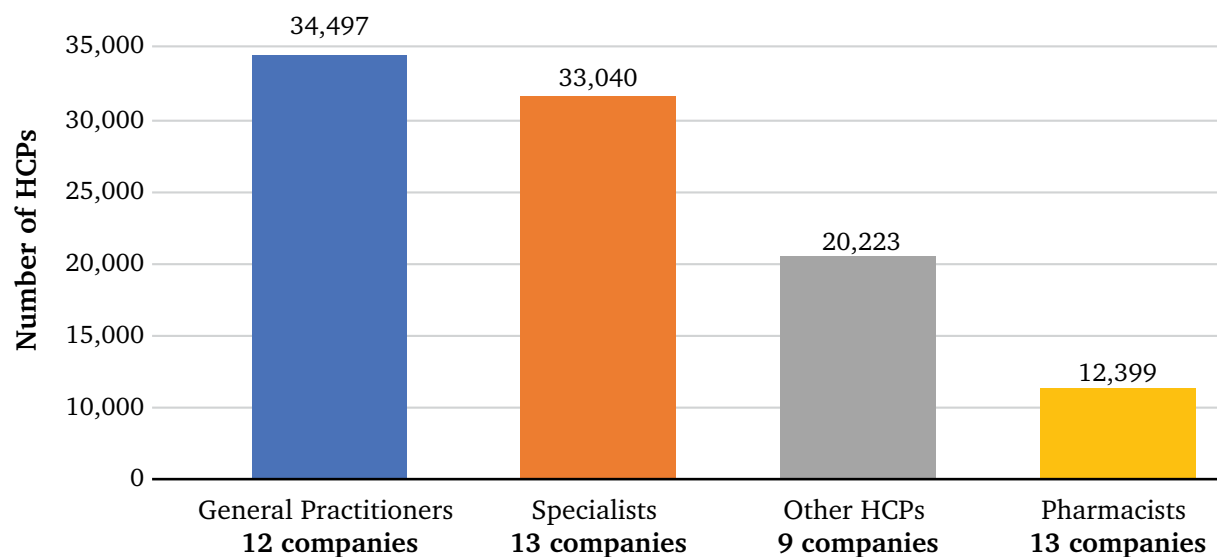
Each PhAMA member company is guided by its own global internal ethical code, accompanied by the PhAMA Code of Marketing Practices. CME activities are audited annually by their respective head offices to ensure strict compliance and transparency. These internal guidelines may differ between one company and another but a common guiding principle applies – participations of all HCPs at CME events should be conducted in a transparent manner. CME programmes or events should be free of any conflicts of interest, and no parties should be subjected to any kind of obligations.





**Figure 13**

A total of 100,159 HCPs in four occupational categories attended CME events organised by selected PhAMA member companies between 2013 and 2016.<sup>3</sup> The number of companies varies due to the selective responses submitted by survey respondents.



### 'Provisionally Registered Pharmacist' Training Programme

The Provisionally Registered Pharmacist (PRP) programme is a one-year training programme that enlists pharmacy graduates in preparation for their registration as Fully Registered Pharmacists (FRP). The programme is an MoH initiative designed in collaboration with the pharmaceutical industry. It provides an opportunity for participants to develop professionally and personally from interactions with different departments within a pharmaceutical company, as well as from projects, assignments and workshops.

Participants are expected to discover new roles outside of the standard occupational model for pharmacists such as, but not limited

to, medical science liaison, policy manager and compliance officer. Such exposure will enable them to explore and determine whether they are interested in and/or qualified for these roles.

Concurrently, the PRP training programme benefits pharmaceutical companies. It provides a platform for these companies to promote their employment opportunities to dynamic new talents, in addition to highlighting their brand, vision and corporate image. Furthermore, it provides a means for pharmaceutical companies to build a strong relationship with future pharmacists and other skilled professionals in the industry.

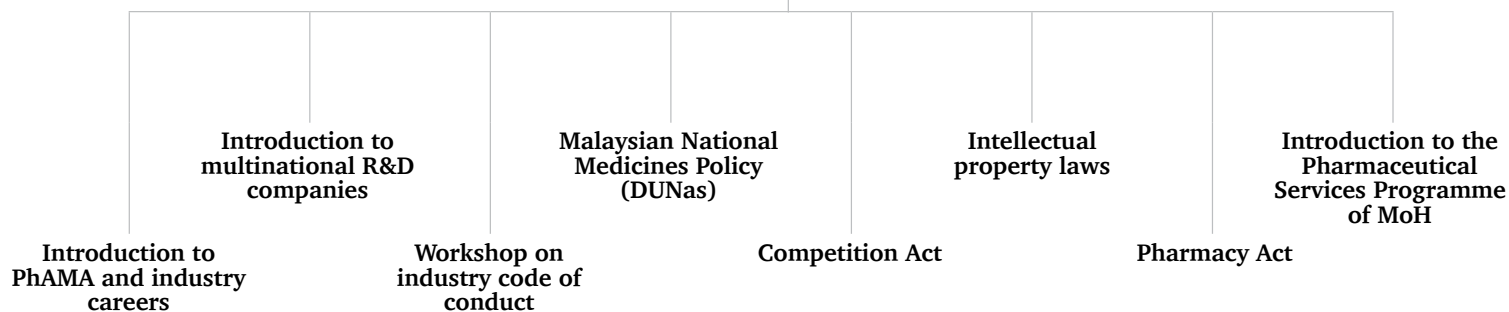
As of October 2018, there are 15 approved training premises within PhAMA members, with a total of 37 trained Preceptors and 32 PRPs.



### PhAMA MEMBER COMPANIES RECOGNISED BY PHARMACY BOARD MALAYSIA TO CONDUCT PRP TRAINING



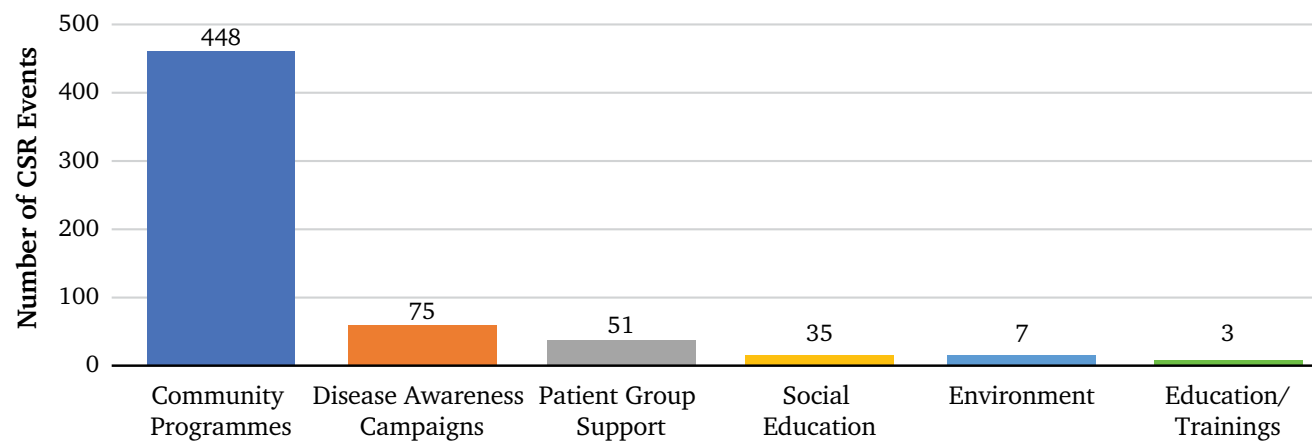
### TOPICS COVERED DURING A ONE-WEEK TRAINING SESSION AT PhAMA



### Corporate Social Responsibility

Globally, pharmaceutical companies are actively involved in community-centric programmes, and PhAMA member companies have taken the initiative to lead a number of local Corporate Social Responsibility (CSR) activities. This reflects PhAMA members' commitment in enriching the lives of Malaysians by empowering local communities with the knowledge to better manage their health, providing positive experiences, undertaking environmentally friendly projects and providing nonscientific learning opportunities – all with the objective of making a difference in the community that they operate in. A total of 619 CSR events were organised by selected PhAMA members between 2013 and 2016. While each company has its own focus areas, CSR activities in Malaysia revolve around six main areas (Figure 14).<sup>3</sup>

**Figure 14** A total of 619 CSR events, across six areas, were organised by selected PhAMA member companies between 2013 and 2016.<sup>3</sup>





### Disease Awareness Campaigns

As the core focus of pharmaceutical companies revolves around the treatment and management of diseases, disease awareness campaigns play an important role in helping the public better understand the nature of diseases and their impact, along with prevention and management strategies. Public health campaigns such as these not only create greater awareness on the importance of leading a healthy lifestyle, but also create a long-term impact in terms of healthcare cost saving as a result of reduced disease burden.

#### GSK Consumer Healthcare's *Melawan Denggi* Programme

**GSK Consumer Healthcare**, in partnership with MoH, Malaysian Medical Association (MMA), Malaysian Pharmaceutical Society (MPS) and Guardian Health & Beauty, initiated the Allied Against Dengue (AAD or *Bersama Melawan Denggi*) programme, a

multilateral platform to empower and educate local communities to fight against dengue. By pairing mainstream and social media with ground activation efforts, the programme mobilised approximately 7,000 HCPs to educate patients and caregivers on the detection of dengue fever at its onset and the provision of appropriate treatment. The AAD coalition has outlined a 3-year roadmap to achieve its goal in reducing the impact of dengue in the region.

#### GSK Pharma's Awareness Campaign on HIV and AIDS-Related Issues

Additionally, GSK established a community partnership with the Malaysian AIDS Foundation (MAF) in 2017 to raise awareness on HIV and AIDS-related issues in Malaysia. A multipurpose grant of RM1.25 million was allocated towards supporting a Paediatric AIDS Fund, creating HIV-friendly workplaces in Malaysia through the Malaysian Business Consortium on HIV/AIDS, and promoting disease awareness and education programmes among general HCPs.



Participants of the Allied Against Dengue programme



### Johnson & Johnson Malaysia's 'People Living with HIV' Programme

Similarly, **Johnson & Johnson Malaysia** has also been actively involved in a series of local HIV and AIDS programmes to raise funds and destigmatise issues surrounding people living with HIV (PLWH). From May to September 2017, J&J's Global Community Impact in Malaysia took part in the International AIDS Candle Light Memorial (led by Kuala Lumpur AIDS Support Services) and the Hot & Cold Charity Run 2017 (jointly organised by MAF and University of Malaya's Faculty of Medicine), and visited the shelter homes for PLWH in Setapak, Kuala Lumpur (in association with MAF).

### Johnson & Johnson Malaysia's mQuit Services – Smoking Cessation Programme

Working alongside MoH, Universiti Sains Malaysia, Universiti Malaya and Malaysian Academy of Pharmacy in a public-private partnership endeavour, J&J launched mQuit Services – a smoking cessation programme aimed at helping 390,000 people quit smoking over a period of 3 years – in 2016. The programme not only has an official website ([www.jomQuit.com.my](http://www.jomQuit.com.my)) that provides relevant information on smoking cessation, but the Universiti Sains Malaysia Tobacco Quitline was also launched in Penang as part of the mQuit Services. It is a telephone facility that offers continuous assistance and advice to smokers throughout their quitting journey.



Managing Director of J&J Malaysia, Chin Keat Chyuan, delivering a speech at the launch of the 'mQuit Services' programme

**MSD's 'Living Well with Diabetes' Campaign**

**MSD Malaysia** conceptualised and launched the Living Well with Diabetes (LWWD) campaign, together with Persatuan Diabetes Malaysia, to promote the message that diabetes can be managed with proper food intake, exercise and the right kind of care. Since coming into existence, the LWWD campaign has seen the introduction of sugar-light *teh tarik*, a healthy cooking media workshop and themed cookbooks, as well as a public educational event themed 'Race to Goal'. On the same note, the MSD Ramadan Campaign has been in place since 2011 to raise awareness about the possible complications faced by Muslim patients with type 2 diabetes while fasting during Ramadan.

**MSD's 'It's Your Life, Why Take A Chance' & Immunise For Life Campaigns**

MSD also ran the 'It's Not Worth The Pain Campaign', which provides information on shingles and post-herpetic neuralgia; the 'Live My Sunshine HPV' campaign, an integrated campaign with a digital focus on human papillomavirus and cervical cancer education; and the 'Immunise For Life Campaign', which raises awareness on the importance of immunisation, specifically with regard to HPV-related cancers and diseases via a digital platform.

**Relay For Life**

MSD Malaysia takes part at the annual Relay For Life, an event spearheaded by the National Cancer Society Malaysia (NCSM), to show support for cancer survivors, patients and caregivers alike in their fight against the disease.

At MSD, it is a commitment of the company's employees to "Fighting with You Every Step of the Way from Prevention to Treatment", which showcases MSD's support towards cancer and those affected by the disease.



'Facts about Fasting During Ramadan' information booklet that complemented the MSD Ramadan Campaign

### Mundipharma's 'Hand, Foot and Mouth Disease' & 'H5N1' Programmes

Meanwhile, Mundipharma Malaysia Sdn Bhd took on the responsibility of educating the public on Hand, Foot and Mouth Disease (HFMD) in February 2017 by conducting a media round table discussion on disease symptoms and preventive measures through the use of hand hygiene products. The initiative included a series of public education programmes delivered via talks, social media and other healthcare professional channels.

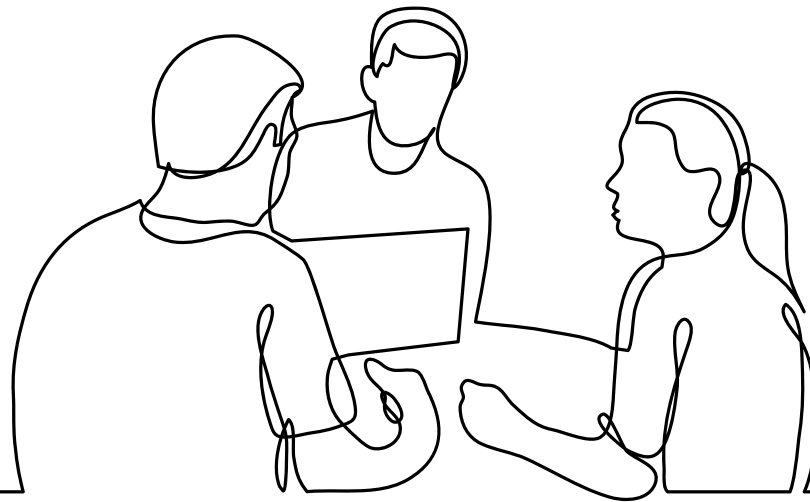
A month later, the company took the lead in working closely with doctors in Kelantan to deliver antiseptic products and information brochures on avian influenza to 1,000 families in areas affected with the H5N1 outbreak. Subsequently, tips on proper hand and oral hygiene were shared via social media to educate the public on disease symptoms, modes of transmission and preventive measures. Notably, Mundipharma successfully broke the Malaysian record for the largest gathering of children in performing correct hand washing steps, to mark the World Children's Day in October 2017. Suresh Pragasam, Regional General Manager of Mundipharma South East Asia said, "We must teach children the correct steps to wash their hands to instill healthy hygiene habits and prevent infections."



The largest gathering of children in performing correct hand washing steps, to mark the World Children's Day in October 2017

**Novartis Corporation Malaysia's Donation Drive for Malaysian Rare Disorders Society & 'Novartis Community Partnership Day'** Novartis Corporation Malaysia has organised a donation drive for the Malaysian Rare Disorders Society (MRDS) to support patients and caregivers of families with rare disorders. According to the European Society of Paediatric Oncology, 75% of rare diseases affect children, of whom 30% die before reaching their fifth birthday. Even though Malaysia has yet to provide an official definition for rare diseases, MRDS (a voluntary organisation that represents patients and families affected by rare diseases) defined the condition as any disease that

affects less than one per 4,000 in the community. Owing to the small population size of rare disease patients, treatment options and medical information are not widely available. As more can be done to raise the awareness on rare diseases, Novartis is committed to this cause in celebration of Novartis Community Partnership Day, which symbolises Novartis' commitment to serving and improving the health of its local community. Community Partnership Day gives associates the opportunity to participate in a variety of activities that would create a positive impact in the local communities where they live and work.



### Novo Nordisk's 'World Diabetes Day' Programme

Finally, **Novo Nordisk** celebrated the 2014 World Diabetes Day (WDD) by organising a variety of public and company-level activities from 9 to 14 November 2014. The list of events included the World Diabetes Day Charity Run & Walkathon (in collaboration with the Malaysian Endocrine and Metabolic Society), the DiabCare National Seminar, the Changing Diabetes Village, and the lighting of the Petronas Twin Towers in blue at the KLCC Esplanade. The DiabCare seminar gave medical professionals fresh insights into the current status of diabetes care in Malaysia, providing robust evidence towards forming effective strategies and action plans to address increasing

diabetes prevalence. Meanwhile, the Changing Diabetes Village was an on-ground community initiative to encourage urbanites to undergo health checks and screening for diabetes, and the lighting of the Petronas Twin Towers was a symbolic event to commemorate WDD, highlighting the need to address the rising prevalence of urban diabetes.



Health screening at the Changing Diabetes Village



Inauguration of the Petronas Twin Towers lighting by event partners: Novo Nordisk, Kuala Lumpur City Hall, MoH, and Malaysian Danish Embassy

## Community Programmes

It has been a long-standing tradition for pharmaceutical companies to reach out to the less-privileged and communities with limited resources to help them improve their living condition. In this area, PhAMA members have always been exemplary in introducing community programmes that deliver a real impact on the life of their beneficiaries.

### Abbott's 'Sponsor a Child' Programme

The DASH committee at **Abbott** initiated the 'Sponsor a Child' programme in December 2016, with the aim of helping children in need. Centering on the theme of 'Back to School', the Sweet Care Welfare Society in Selayang was chosen as the programme's beneficiary. Staff members from the Established Pharmaceutical Department Kuala Lumpur visited the underprivileged children at the Sweet Care Orphanage, and donated schooling essentials to these children. During the visit, over 60 children were involved in paper origami crafting, decorating Christmas tree and painting temporary tattoos. Additionally, they were given presents and treated to a small Christmas buffet during tea time. The initiative shows that it is possible for corporate employees to give back to the society despite leading a busy schedule.



### Eli Lilly's 'Global Day of Service' Programme

**Eli Lilly** launched the Lilly's Global Day of Service in 2008 as one of the company's contributions to make life better for people around the world. The company's employees have collectively given more than 825,000 hours through its Global Day of Service initiatives, making it one of the largest single-day volunteer programmes in the world. In 2016, more than 24,000 Lilly employees in over 70 countries participated in the one-day event. In Malaysia, employees of Lilly and Elanco carried out community work throughout the country by helping charitable organisations clean their respective facilities in Klang and Perak, while assisting those in Penang to clean their kitchens and distribute food to the hungry. Moreover, they also participated in making new educational materials for autistic children in Kuching, and conserving the environment by cleaning up public beaches in both Melaka and Kota Kinabalu.



Eli Lilly's logo of Global Day of Service



### MSD's 'Lend-A-Hand' Programme

MSD Malaysia launched the Lend-A-Hand programme, dedicated to establishing long-term commitments with various organisations to help make a difference in local communities. Community and charitable activities organised under this programme aim to foster volunteerism among MSD employees across the nation, and to promote the spirit of giving back to the community. In conjunction with the 125<sup>th</sup> global anniversary of MSD in 2016, MSD Malaysia's employees created a total of 125 bookmarks in December, under the Lend-A-Hand programme, to commemorate the company's milestone. These bookmarks were then presented to the children from the Praise Emmanuel Children's Home (PECH) and Children's Home of Hope (CHH) to encourage them to read and learn. During their visit to PECH, MSD employees presented the home with a donation, grocery items and other necessities, and engaged the children in a T-shirt-painting activity. Meanwhile, the staff of MSD treated children from CHH to a batik/T-shirt-painting day trip at Batik Conlay.



A visit to PECH under the Lend-A-Hand programme

### Roche's 'Deepavali Cheer' Programme

In the meantime, staff from Roche Malaysia Sdn Bhd brought Deepavali cheer to children with cancer at Hospital Kuala Lumpur's Paediatric Oncology ward in November 2017. The children had a fun time eating burgers and potato chips while being entertained by Roy, the clown who performed magic tricks for them. Roy and his friend also created various balloon sculptures in the form of swords, guns and flowers for the children, which put a huge smile on their faces. Leading the Roche team was the Managing Director, Lance Duan, who said that this is part of Roche Malaysia's corporate responsibility of giving back to the communities where it operates. In addition, the children also received goody bags containing toiletry kits, towels and food items.



Visiting children with cancer at Hospital Kuala Lumpur's Paediatric Oncology ward in conjunction with Deepavali

### Roche Children's Walk

One of Roche's signature employee projects, the Roche Children's Walk, is a global fund-raising project to elevate and improve the quality of life of underprivileged and disadvantaged children. Roche matches the contributions raised, which is then channelled to global children's initiatives related to education, nutrition, primary healthcare and social development. In Malaysia, Roche has raised funds for eight children's projects throughout the country since 2011.

## Education, Trainings & Social Education

Pharmaceutical companies play a notable role in educating both HCPs and the communities that they serve in. PhAMA members are invested in increasing the level of scientific knowledge among HCPs, whilst providing broad educational opportunities to members of the society.

### GSK's 'myPharmAssist™' Programme

In 2016, GSK collaborated with MPS to launch the myPharmAssist™ programme, a dynamic educational platform targeted at approximately 8,000 pharmacists nationwide, that provides tailored content and training for community pharmacists. The modular programme covers various topics, such as pain relief, cough, flu, oral and skin health, allergy, and nutrition and digestive health, in addition to providing tools that facilitate interactions with patients and counselling guide. Furthermore, in collaboration with MoH, the company also recruits PRPs in an effort to nurture talents and promote career prospects within the pharmaceutical industry.



Launching the myPharmAssist™ programme that provides tailored content and training for community pharmacists

### Bayer Malaysia's 'Bayer Science Festival' Programme

**Bayer Malaysia** initiated the Bayer Science Festival in 2014 as the company's corporate social engagement programme. It is a company-wide initiative that advances science literacy through hands-on, inquiry-based science learning, employee volunteerism and public education. Through the festival, Bayer employees take time out to visit schools, malls and science fairs to perform hands-on science, such as experiments that schoolchildren can try out themselves in hope of piquing their interest to understand the science behind the experiments. As of today, around 70 Bayer employees have been involved in the programme as volunteers, helping thousands of children discover science through fun and practical experiments as they hope to inspire the next generation to be passionate about science.



Bayer Science Festival is an initiative that advances science literacy through hands-on, inquiry-based science learning, employee volunteerism and public education

**Johnson & Johnson Malaysia's 'English Crib' Programme**

Meanwhile, **Johnson & Johnson Malaysia** initiated The English Crib programme in 2016, in line with its strategic pillar of saving and improving the lives of women and children. As part of the programme, J&J employees turned a classroom in SMK Seri Sepang (Selangor) into an English-learning resource centre by equipping it with a myriad of learning materials, such as English-language books, board games and DVDs. The English Crib aimed at improving the command of the English language among students of the school. The setup of the centre was followed by group activities and contests organised for students of the school.



Employees of J&J Malaysia at 'The English Crib'

## PhAMA: LEADING THE WAY FORWARD VIA STAKEHOLDER ENGAGEMENTS

PhAMA has played an important role in strengthening the local pharmaceutical landscape by promoting a culture of continuous, proactive engagement with members of the Malaysian healthcare industry. This includes actively engaging various ministries and government agencies, such as MoH, Ministry of Finance, Ministry of International Trade and Industries, and Ministry of Domestic Trade and Consumer Affairs.

These engagements have resulted in a better understanding, as well as collaborations and partnerships, between MoH and the pharmaceutical industry. One such example is the Provisionally Registered Pharmacist Training Programme that was launched in 2015.

Other PhAMA initiatives include providing access to global experiences and sharing of best practices as well as industry reference data. The pharmaceutical industry also shares MoH's aspiration in increasing and strengthening clinical research activities in Malaysia.





## PhAMA Position Papers

From 2014 to 2017, PhAMA has released at least one position paper each year, on topics that are inextricably linked to the stakeholders of the pharmaceutical industry.<sup>4,5</sup> They highlight the dynamic market conditions that pharmaceutical businesses operate in, and the impact of healthcare policies and decisions on Malaysian consumers.

The **Intellectual Property (IP)** position paper (2017) conveys the importance of IP, and how it encourages more development and introduction of new inventions. IP not only improves access of medicines into a country, but also increases foreign direct investment. The largely undiscussed additional benefit of IP includes how it indirectly facilitates technology transfers. A strong IP regime promotes access to quality medicines and faster access to new drugs. It also motivates investment in clinical research activities which in turn leads to innovation.

The **Value Pricing** position paper (2016) advocates measures and proposes recommendations towards achieving high-value medical care for patients, by targeting the optimum health outcome which can be achieved per ringgit spent. The paper strongly recommends a united network of stakeholders working towards this goal whilst addressing the common challenges faced by any healthcare system in the world. It also recommends utilising a Multi-Criteria Decision Analysis (MCDA) model to increase transparency and predictability of decisions, as well as personalising value measurement by incorporating broader measures of value for each patient. It is foreseen that this value-based system would over time deliver better health outcomes for patients.

The position paper on **‘Building Greater Access to Innovative Medicines – What is Next for Malaysia?’** (2015) provides an analysis of proposed reforms and a review of possible access schemes to improve patient access to innovative medicines, in line with the principles of the 2012 National Medicines Policy (2<sup>nd</sup> Edition). A few access schemes were covered in the paper – ie, risk-sharing agreements and coverage, along with the sharing of best practices from other countries. The paper emphasises on evidence-based, clear, transparent, and fair evaluation of medicines, coupled with high-quality communication between relevant parties.

The **‘Is Reference Pricing Right for Malaysia?’** position paper (2015) provides an analysis of proposed pricing reforms for pharmaceutical in Malaysia, by reviewing the country’s medicine pricing system in the context of the country’s macroeconomic environment and evolving healthcare trends. After analysing the prices for 47 branded original products (on- and off-patent) in the top five therapeutic areas (by sales) in public and private markets across Malaysia and 10 other Asia-Pacific countries, the paper found that medicine prices in Malaysia are not higher compared to other countries, even when considering high-cost therapeutic areas such as oncology. In fact, prices in reimbursed markets such as Taiwan are approximately 8% higher than Malaysia on average.

The position paper on **Biosimilar Medicines** (2014) sets out PhAMA’s position on biologics and biosimilars. Biologics have become an important therapeutic option with the advent of recombinant technology, which provides means of producing a variety of therapeutic proteins. This technology has revolutionised the treatment of serious

and intractable diseases such as cancer, diabetes and rheumatoid arthritis. As biologics (“large molecules”) differ from chemical drugs (“small molecules”) with respect to their manufacturing processes, size, complexity, as well as origin, composition, and nature, their generic analogues (ie, biosimilars) are not equivalent to the originator products. Specific approval guidelines and regulatory framework, as well as prescribing and dispensing guidelines, are required each for biologics and biosimilars. Therefore, PhAMA has made several recommendations to regulators, health technology assessment agencies, policy makers and HCPs regarding the use of these biological medicines.





## PhAMA Awards

Aimed at spurring innovation and acknowledging impactful community-centric initiatives, the PhAMA Awards were launched in 2014. It comprises two primary awards – the Minister of Health Innovation & Research Award (MIRA) and the PhAMA President's Community Impact & Awareness Award (CIA). MIRA recognises innovation and research by individuals or those who have contributed towards enhancing the standards of healthcare in Malaysia. Meanwhile, CIA acknowledges impactful initiatives that improve an aspect of community health, well-being, awareness, or standards of care within Malaysia.

Submissions received for these awards include local and regional/multi-country projects. HCPs, public/private institutions of higher learning, government health institutions and agencies, nongovernmental agencies, as well as industries players took part in the contest.

Winners for the awards are selected by a pool of independent judges, consisting of clinicians, key opinion leaders/HCPs and academicians from MoH's hospitals and agencies, as well as public/private institutions of higher learning. The submissions are evaluated based on the design and clarity of methodology, beneficial impact to the target group in terms of health outcomes and quality of life, cost-efficiency of the project, and practicality of implementations.

The awards are presented to the awardees at a formal ceremony by/ on behalf of Malaysia's Minister of Health. It is hoped that MIRA will create a talent pool that will continue to pursue ideas and nurture collaborations that could lead to new discoveries in the future and CIA will encourage more community centric activities.



GRAND PRIZE WINNERS OF  
MIRA BETWEEN 2014 AND 2016 AND PhAMA PRESIDENT'S CIA BETWEEN 2014 AND 2015

**MIRA 2014**

**The Decision Making in Insulin Therapy**

Universiti Malaya, Universiti Putra Malaysia and  
Ministry of Health

**PhAMA President's CIA 2014**

**Water for Life**

University of Nottingham in collaboration with  
Engineers without Borders (Malaysia) and Saccess

**MIRA 2015**

**Colorimetric Detection of Dengue by Single Tube  
Reverse Transcription-Loop-Mediated Isothermal  
Amplification**

Universiti Malaya

**PhAMA President's CIA 2015**

**Deworming Initiative for Children Aged 2 Years and  
Above in Orang Asli Village at Kampung Ulu Tual,  
Kuala Lipis**

Malaysian Pharmaceutical Society Young Pharmacist  
Chapter and Center for Orang Asli Concerns (COAC)

**MIRA 2016**

**Gut Dysbiosis and Probiotics in Persistent  
Abdominal Discomfort Following a Major Disaster**

Universiti Sains Malaysia



**References:** 1. Performance Management & Delivery Unit (Prime Minister's Department). Healthcare. In: Economic Transformation Programme's Annual Report 2014. Available at: [http://etp.pemandu.gov.my/annualreport2014/upload/14\\_NKEA12\\_ENG\\_HC.pdf](http://etp.pemandu.gov.my/annualreport2014/upload/14_NKEA12_ENG_HC.pdf). Accessed on 30 Jan 2018. 2. Economic Planning Unit (Prime Minister's Department). Eleventh Malaysian Plan 2016–2020: Anchoring Growth on People. Available at <http://epu.gov.my/sites/default/files/RMKe-11%20Book.pdf>. Accessed on 1 Oct 2018. 3. PhAMA Fact Book Survey 2017. 4. PhAMA. PhAMA Position Papers. Available at: <http://www.phama.org.my/index.cfm?&menuid=88&parentid=6>. Accessed on 30 Nov 2018. 5. PhAMA. PhAMA Position Papers. Available at: <http://www.phama.org.my/index.cfm?&menuid=6>. Accessed on 30 Nov 2018.

## SHAPING THE FUTURE OF THE INDUSTRY

Pharmaceutical research and development (R&D) activities form the core foundation for the existence of the numerous treatment options available to healthcare professionals for the diagnosis, prevention, as well as treatment and management of diseases. Such critical activities are well established in countries with a strong R&D culture to support the lengthy and laborious processes involved in pharmaceutical R&D. If the discovery of a new molecule and its development into a medical treatment are successful, the R&D process is followed by various phases of clinical trials, which may be conducted beyond the country's own geographical boundaries.

Countries with a well-developed clinical trial infrastructure have the benefits of early access to new and improved innovative treatment options. In addition, there are also economic and social spillovers arising from infrastructure development, knowledge and technology transfers, creation of new career pathways, and increased economic activities.

The Malaysian government recognises the value a strong clinical research culture and has introduced several strategies to promote the development of clinical research in this country through the Ministry of Health (MoH). Clinical Research Centre (CRC), the

clinical research arm of MoH, and Clinical Research Malaysia (CRM), a nonprofit company established by MoH in 2012, work in concert with the objectives of creating a conducive ecosystem that will nurture the growth of pharmaceutical R&D activities, and attracting more industry-sponsored research (ISR) into the country.

## DELIVERING SCIENTIFIC ADVANCEMENT & ECONOMIC CONTRIBUTION

### Clinical Trials & Industry-Sponsored Research

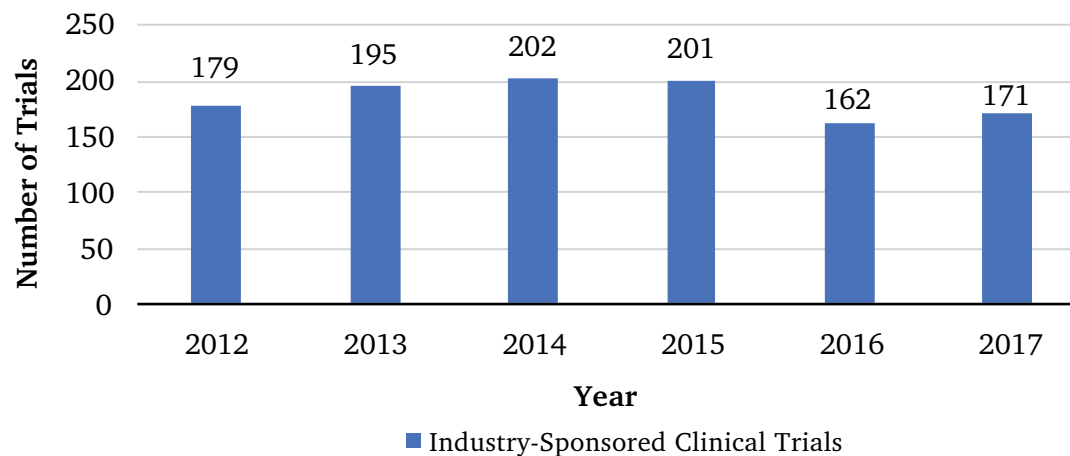
Clinical trials are research studies undertaken to assess and evaluate a particular treatment's level of safety and efficacy. It could be a medical, surgical or interventional study, evaluating for the effectiveness of a new drug or treatment option, or a new method to diagnose a disease earlier, new ways to prevent diseases or to improve the quality of life of patients with life threatening diseases, and even to study the roles undertaken by caregivers.<sup>1</sup>

Industry-Sponsored Research (ISR), in contrast, are clinical trials undertaken under contractual arrangement between an innovator and a local research organisation at local clinical trial sites under strict scrutiny and rigorous protocol, within a duration of time. Costs related to ISR include the utilisation of clinical sites' infrastructure, facilities and equipment, information technology's infrastructure,

laboratory testing, pharmacy fees, central administrative services, legal advice and implementation of procedures, as well as employment of researchers and private investigators, among others. CRM acts as a one-stop-centre to coordinate all these services in facilitating the process of conducting clinical trials in Malaysia.

With the synergised efforts of CRM and the pharmaceutical industry, a sharp increase in the number of ISR was evident with a total of 1,110 ISR conducted in Malaysia between 2012 and 2017. Of these, 900 were interventional studies, while the remainder was observational in nature (Figure 15).<sup>2,3</sup>

**Figure 15** Total number of industry-sponsored interventional and observational clinical trials conducted in Malaysia between 2012 and 2017.<sup>2,3</sup>







### Multicentre Clinic Trials

Premises for clinical trials are available both in the private and public sector, and each sector offers numerous sites across the country. Owing to the variations in population groups and expertise that are available at different sectors and sites, the same clinical trial may be conducted at different sectors and involving more than one site each. This is referred to as multicentre studies. Multicentre studies offer better data comparison on the effectiveness of a product over larger populations with varying genetics, environment, ethnic and cultural background. Figure 16 shows the breakdown of ISR conducted across different sectors and sites from 2014 to 2017.<sup>3</sup>

### Expansion of ISR Activities Beyond Phase IV

After a new molecule is successfully discovered and a treatment option developed, it usually undergoes four phases of clinical trials.

Phases I–III are mainly conducted with the purpose of evaluating a product's quality, safety and efficacy. It is also during these initial three phases that appropriate dosage and side effects are determined. A phase IV trial is conducted to find a more stable safety profile and at times, study the effectiveness of a drug or treatment for a new indication. It also involves a larger patient population.

The ISR conducted in this country was initially limited to phase IV trials. However, over the years, an increase in expertise and capacity building under CRM gave the pharmaceutical industry more confidence to extend their ISR activities to pre-phase IV trials. Conducting early phase studies drives capacity building for local ethical review, facilitates healthcare infrastructure development, increases economic activity by encouraging research into more innovative products and proactively strengthens the country's R&D capabilities.



**Figure 16** ISR conducted across private, Ministry of Higher Education (MoHE)-affiliated and MoH-affiliated sites between 2014 and 2017. For multicentre studies, the same trial may involve sites from different sectors.<sup>3</sup>

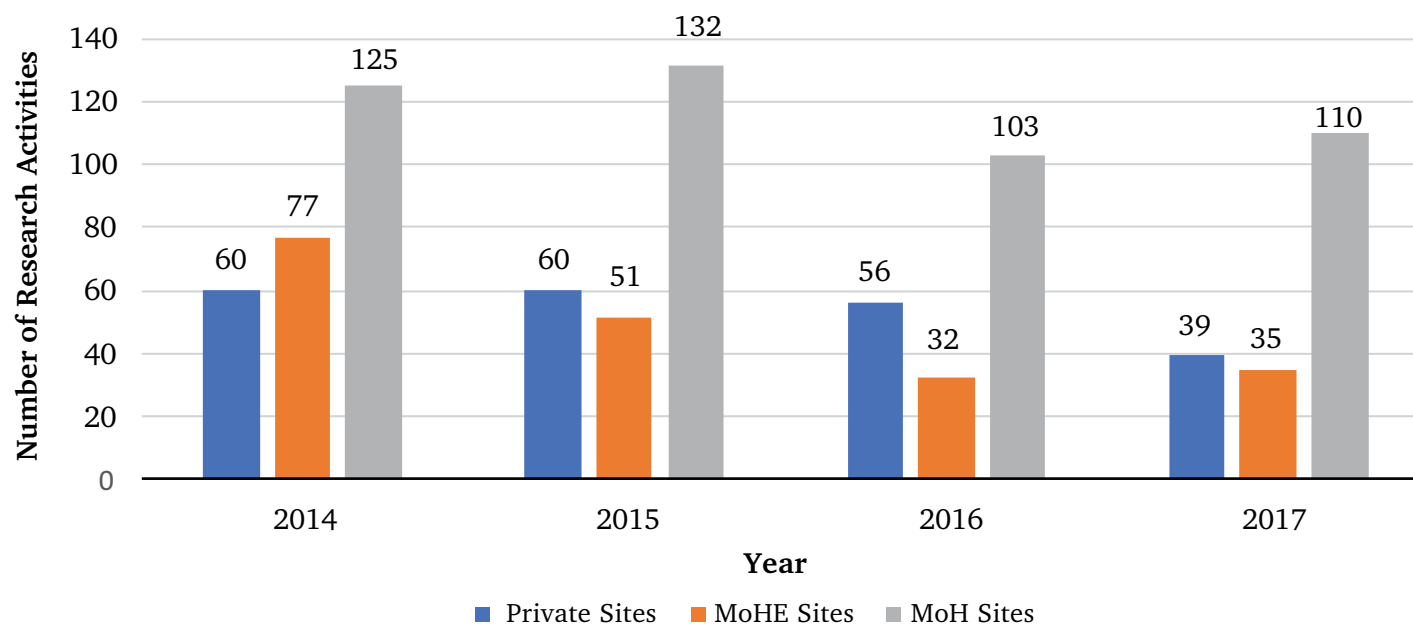
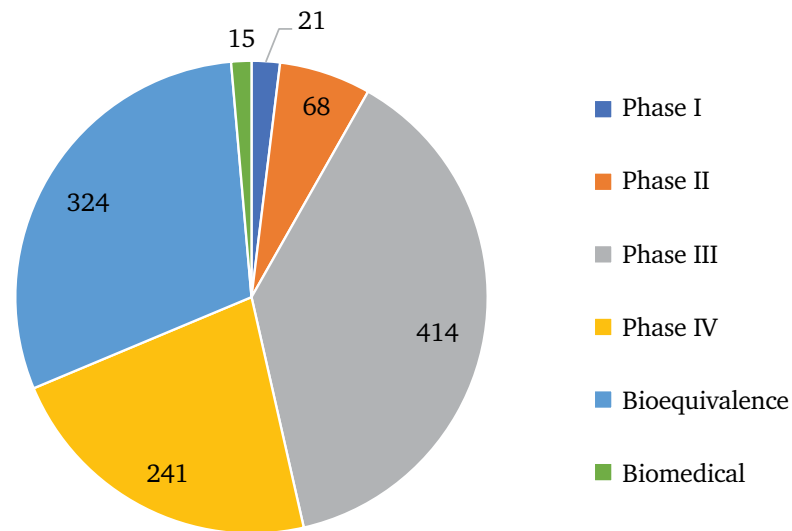


Figure 17 shows the breakdown of different types of clinical trials conducted in Malaysia between 2012 and 2017. In terms of the phases and types of clinical trials conducted, 69% consisted of phase I to IV trials, with bioequivalence studies, registry work and biomedical research making up the other 31% (Figure 17).<sup>3</sup>

### Human Resource Training & Private Investigators

CRM recruits and trains qualified study coordinators (SCs) who are later placed at trial sites throughout Malaysia to assist investigators in clinical trials. Trainings related to clinical research such as refresher courses on good clinical practice are held for doctors and support staff.

**Figure 17** Types of clinical trials conducted in Malaysia.<sup>2,3</sup>

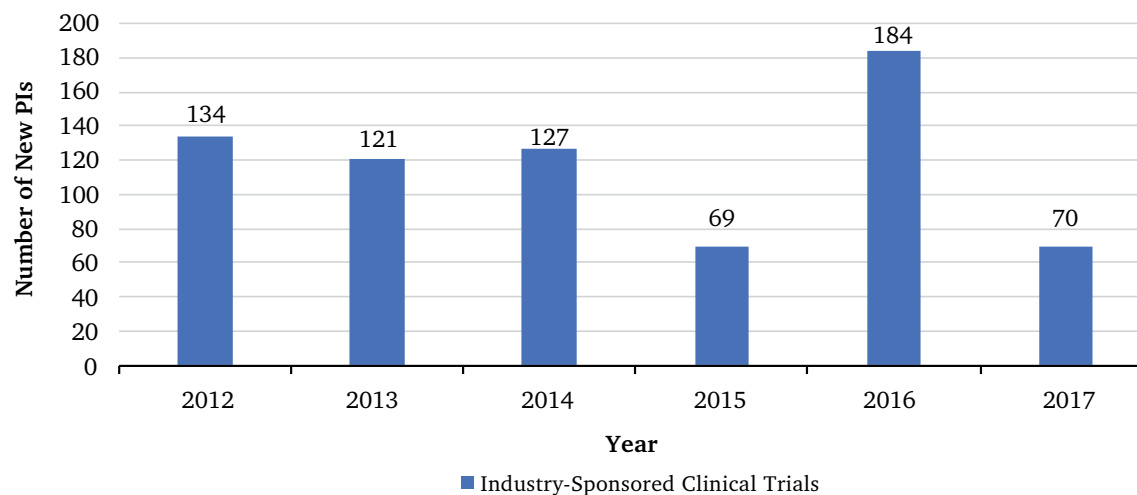


One of the key initiatives of CRM in improving the clinical research ecosystem is the recruitment and training of medical officers, with the objective of developing them into future investigators.

In its early days, CRM only had 22 SCs who serviced various ISR sites across the country, but this number has since grown to 113 coordinators as of September 2017 (Figure 18). Meanwhile, owing

to under-reporting from previous years, there was an approximately three-fold increase in the number of new principal investigators (PIs) participating in local clinical trials in 2016 compared with the preceding year, with an overwhelming majority of them being associated with MoH. In 2017, the number of new PIs returned to double digit figures (Figure 18).<sup>3</sup>

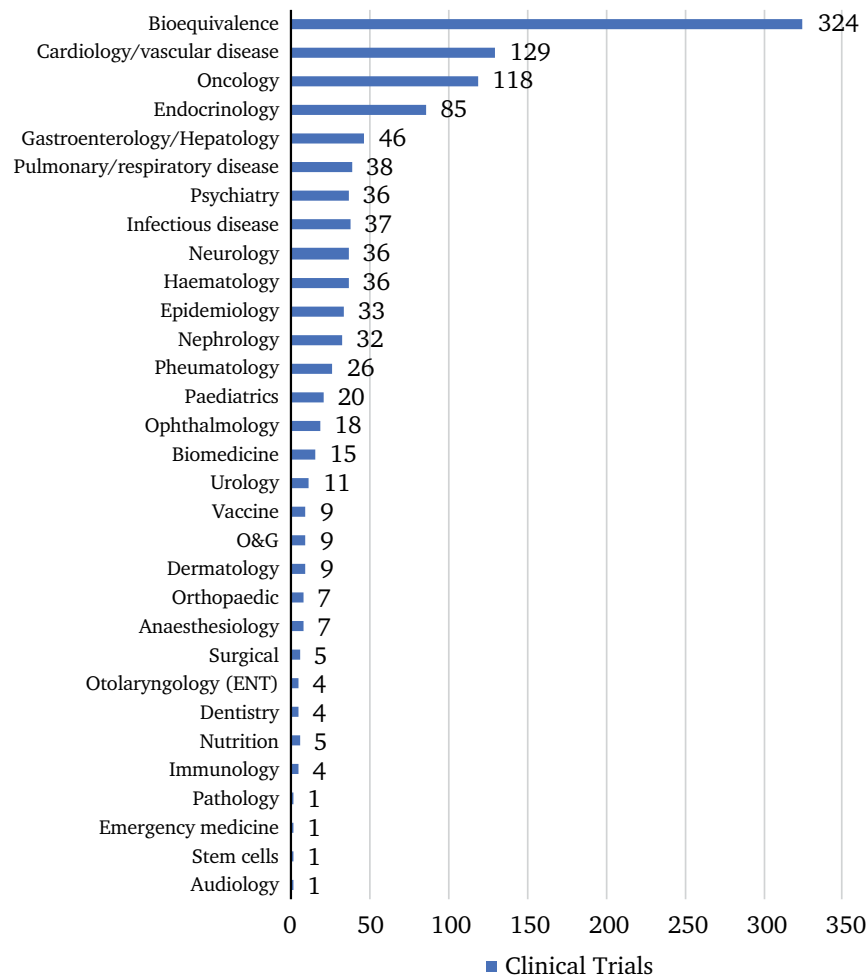
**Figure 18** Number of new principal investigators affiliated with MoH, universities and the private sector who participated in local clinical trials between 2012 and 2017.<sup>3</sup>



**Figure 19** Clinical trials conducted in Malaysia according to therapeutic areas between 2012 and 2017.<sup>2,3</sup>

### Therapeutic Areas of Clinical Trials in Malaysia

Over the years, the level of expertise and infrastructure of local clinical trial sites have increased significantly. As a testament of the industry's confidence in Malaysia's capability to conduct ISR, the total number of therapeutic areas being investigated in this country now stands at 30. Covering a wide range of therapeutic areas, 95% of the total number of trials was drug-related, while the remaining 4% and 1% involved medical devices and biomedicine, respectively (Figure 19).





### **Economic Benefits of Clinical Research**

In 2015, CRM reported a 35.6% increase in the number of full feasibility enquiries with a 100% growth in the number of contract research organisations and five times more sponsors compared to 2014. This positive growth has translated into real economic benefits – over 1,900 skilled jobs were created in 2017 and in excess of RM240 million was added to the country's gross national income (GNI) since 2012.<sup>3</sup> MoH has originally set a target to increase the total number of local clinical trials from 200 in 2012 to 1,000 by the year 2020, which is projected to contribute RM578.4 million to the country's GNI. Encouragingly, this target was achieved as early as 2017 with the active participation of the pharmaceutical industry in ISR.<sup>4,5</sup>

### **PhAMA and Clinical Research**

PhAMA has always been supportive of the government's efforts to drive the growth of clinical research. Our long-standing relationship with CRM allows us to actively contribute to the strengthening of the local clinical research culture. Armed with a global network of experience and expertise, our member companies welcome opportunities to collaborate with various stakeholders to continuously increase the quality of Malaysian clinical research capabilities.

### Clinical Trial Activities

A total of 14 PhAMA member companies participated in clinical trial activities in Malaysia between 2013 and 2016.<sup>6</sup>





### Clinical Grant

Funding is the lifeline of every clinical research endeavor, and nine of our member companies have provided grants for research and development activities that are being conducted in Malaysia. A total of RM6.4 million in grants from eight PhAMA member companies was awarded for research purposes between 2013 and 2016.<sup>6</sup>

## GREATER INTELLECTUAL PROPERTY PROTECTION

### Value of Clinical Research

The value of clinical research goes beyond direct financial impact and the creation of jobs. It spurs local innovation and also delivers other tangible benefits to patients, such as preventing disease complications and prolonging lives. These would result in fewer hospitalisation days and noticeable improvement in patients as well as their care givers' overall quality of life. It is thus crucial for the government to build a greater and more effective intellectual property (IP) protection framework to incentivise research-based multinationals to continue conducting clinical trials in Malaysia.

In addition, PhAMA believes that the product registration system should be well balanced; there must be an adequate and effective protection of patent rights for innovators, while allowing generic products to be marketed in Malaysia upon the expiry of patents. Such a mechanism not only ensures that the rights of the innovators are respected during the patent period, but also reduces the need for

complex litigation processes that would drain the finances of the parties involved. A strong IP protection mechanism can better facilitate the transfer of knowledge between well-resourced multinational companies and local stakeholders of the pharmaceutical industry, as both parties have guaranteed rights to operate in their respective niche areas without creating a predatory environment.

PhAMA has over the years recommended and proposed measures which can be implemented to reinforce and incentivise a R&D culture.<sup>7</sup>

### Patent Term Restoration

Implementation of a patent term restoration (PTR) system in Malaysia to compensate for the marketing time lost while waiting for registration approval by the authorities.

### Patent Linkage

Recommend the adoption and implementation of patent linkage system.

### Data Exclusivity

Raise the importance of data exclusivity (DE) as part of the legislation. Additionally, PhAMA urges for provisions in the law so that DE eligibility shall not be conditional upon making the application for marketing authorisation within any time limit. Meanwhile, the calculation of the DE period should be made from the date of local registration approval, thus allowing innovator companies to be incentivised by the full period of DE from when the drug product is approved for marketing locally.

### Second Medical Usage/Indication and Dosage Regimen

New and nonobvious second medical use or a new, nonobvious dosage regime should not be excluded from patent protection as inclusion would encourage further research into existing medicines which would benefit society at large.

### Compulsory Licensing & Local Working Requirement

Compulsory licensing under Section 84 of the Patents Act 1983 (Rights of Government) should only be resorted to in exceptional circumstances of genuine necessity as how it was originally intended.

PhAMA urges further amendment of the Patents Act to remove any imposition of local working requirements.

### Administrative Enforcement of IP Rights

The provision to prescribe minimum penalties that must be imposed upon conviction of an offence should be included in the relevant statutes. The minimum fine per counterfeit item found and minimum jail terms are to replace the current provisions, which prescribe only the upper limits. This will remove judicial

discretion that has, often, resulted in inadequate and nondeterrent sentences.

### Provisions to be Included in New Legislation

PhAMA strongly recommends that any new legislation should provide for a rebuttable presumption relating to offences so that the possession, custody or control of three or more quantity of the same counterfeit drug is deemed (until proven otherwise) to be for the purposes of sale, trade or commerce; where it is absent in current relevant legislation.

It should be made an offence to print, import, produce, reproduce, publish, sell, issue, circulate, distribute, or be in possession of any publication, label, printed materials or insert relating to pharmaceutical products, which reproduces or substantially reproduces, closely copies or imitates the trade mark, brand, package get-up and/or copyrighted material of another without license or consent.

### Practical Issues

PhAMA fully supports the need for a more streamlined approach in the appointment processes of key drug enforcement officers which are currently made by different authorities depending on the subject matter.

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# FUTURE TRENDS AND CHALLENGES IN THE HEALTHCARE INDUSTRY

## Big Data

The concept of 'Big Data' differs from the traditional notion of data analytics, mainly in terms of its sheer magnitude, variety and velocity.<sup>1</sup> When combined with machine learning technology, it offers the pharmaceutical industry exciting possibilities and opportunities. In the last couple of years, the capability of machine learning technology has improved significantly and early experiments in medical diagnoses, which compared the ability of doctors to that of machine-learning algorithms to accurately diagnose medical conditions, have produced remarkable results in favour of the latter.<sup>2</sup>

Machine learning technology is an application of artificial intelligence (AI), supported by a system that allows the AI to self-learn and improve with experience based on every single new data point available. The availability of huge datasets and their corresponding analyses can be expected to push the boundaries of the pharmaceutical industry by redefining the design and implementation of R&D programmes, and reducing the lead time of new product discovery. Therefore, it is increasingly likely that pharmaceutical companies will be incorporating more machine learning technology into their product development cycle to address the constantly evolving market needs.<sup>3</sup>

Meanwhile, at the patient-doctor level, Big Data is making strides not only in assisting healthcare professionals make better disease diagnoses, but also lends a hand in suggesting potentially more appropriate treatment options at a much faster rate. For instance, owing to the unique DNA profile of every individual, patients diagnosed with the same disease might respond differently to the various types of treatment prescribed. A comprehensive analysis of collated genetic data and patients' response to specific drugs will help fine-tune the application of precision medicine, thus yielding better patient outcomes post-treatment.<sup>4</sup>

Specifically, the adoption of AI is expected to change the landscape of the healthcare industry in several notable ways.<sup>5</sup> They include:

- **Multi-channel outreach.** AI will help members of the pharmaceutical industry determine optimal ways to reach key opinion leaders, as well as establish the most effective communication points and the best time to engage these experts.
- **Clinical trials.** AI can be relied upon to introduce more sophisticated algorithms and predictive analytical tools that can help find patients who would most likely respond to interventions. By aggregating primary data, family history, genetics, and social media data to predict outcomes, clinical trials will be more effective in minimising risks to patients. Operationally, AI will facilitate better patient monitoring and real-time data gathering.
- **Learning and development.** AI will personalise learning platforms and determine which learning styles are most effective for learners based on data gathered. This will presumably lead to better informed members of the pharmaceutical industry, which in turn generates more insightful discussions with external stakeholders.
- **Drug development.** Data has shown that it takes an average of USD2.6 billion to bring a drug to market.<sup>6</sup> AI will reduce the time and costs needed to make this happen. AI may also help predict a drug development process's likelihood of success by sorting through massive amounts of data more efficiently.
- **Label expansion.** By gathering large quantities of data, AI will help uncover possibilities for expanded indications of drug candidates after initial drug approval. With an abundance of data points in a postmarketing setting, AI may be able to determine if certain drugs can be used for presently-nonindicated patient populations.





### mHealth Technologies, Siteless Trial Models and the 'Basket Approach'

The move towards a more patient-centric approach in clinical trial has been made possible owing to the emergence of groundbreaking mobile health (mHealth) technology such as Fitbit® and Apple® wearable devices.<sup>7</sup> Mobile devices offer their users the convenience of capturing and transmitting basic health data (eg, blood pressure, blood sugar level, heart rate) to a central data collection system without being hooked to conventional equipment, thus minimising disruptions to their daily activities.

This development is significant as patient recruitment and retention accounts for up to 30% of the clinical product development cycle.<sup>8</sup> The availability of mHealth technology clearly reduces the burden of trial participation on patients. Such technology also allows for 'siteless' trials to be conducted. Eliminating the need for site selection and activation activities at multiple sites will save a significant amount of resources for trial sponsors. Additionally, when mHealth technology is used to complement home visits performed by skilled nursing staff, it is possible to recruit a wider and more diverse patient population to participate in clinical trials, including home-bound patients.

In the past, oncology clinical trials were typically conducted based on cancer types. These days, however, researchers are moving towards a 'basket approach' – ie, grouping patients based on genetic changes regardless of the type of tumour.<sup>9</sup> Through knowledge gained from various scientific studies over time, researchers have discovered that while tumours in patients with the same type of cancer may have different aetiologies, the genetic changes observed in patients may be the same across different cancer types. Using this approach, it is

possible to identify potential treatment options that could be used for patients with rare cancer types, which generally have very few treatment options undergoing clinical trial.

Notably, basket approach-based clinical trials are only possible as a result of improved knowledge in genome sequencing. With the advancement of science and technology, more unconventional practices may be introduced to future clinical trials.

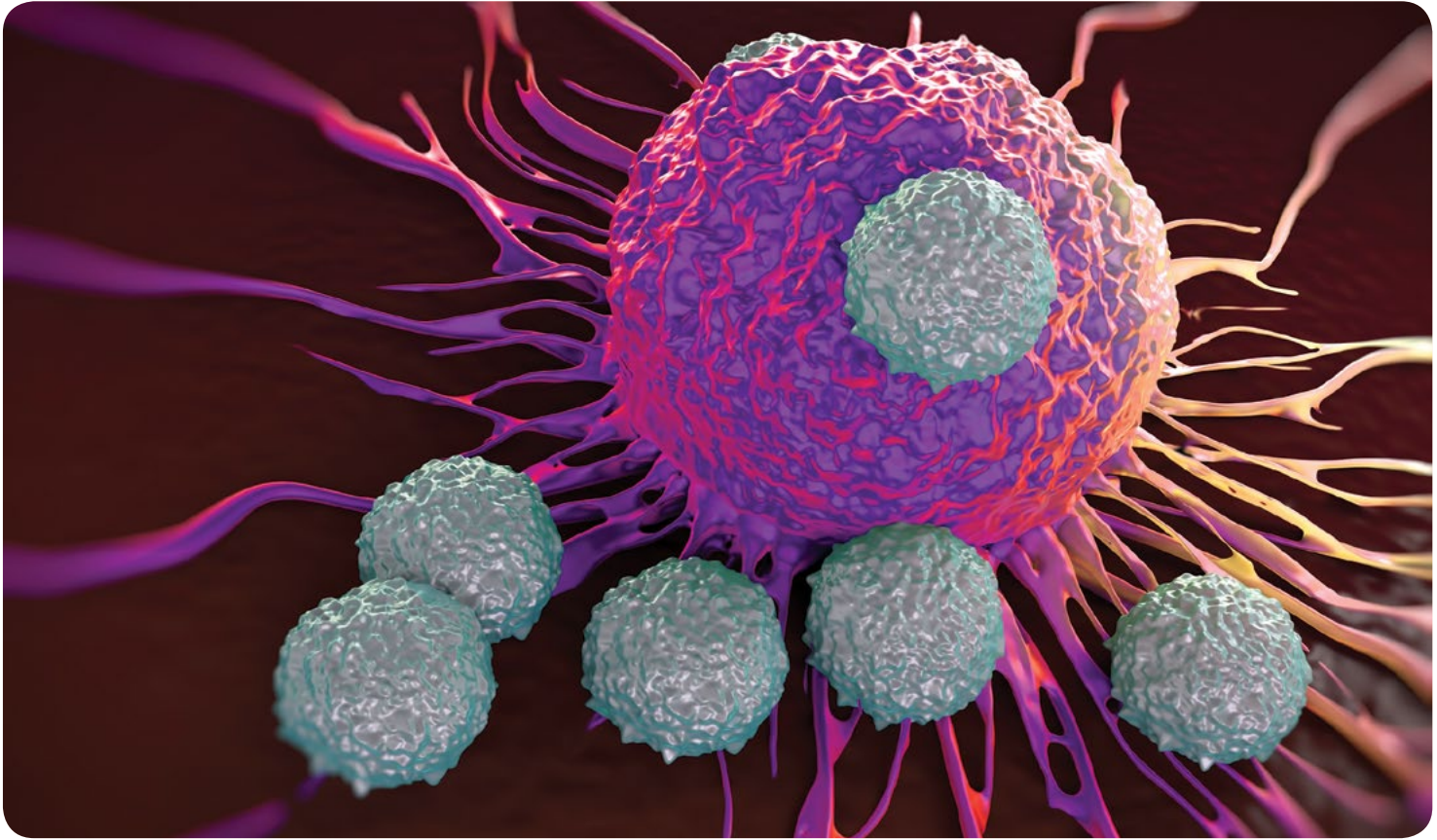
### Growing Role of Biologics

Unlike synthetic pharmaceutical agents, biologics (or biological medicines) are derived from living organisms, and they are a good alternative for patients who showed suboptimal response to conventional treatments, or for those whose conditions have no other suitable treatment options.<sup>10</sup> Biologics can interact with various systems in the body in novel ways, thus allowing for the treatment of previously untreatable or very difficult to treat medical conditions, such as cancer and autoimmune conditions (eg, rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis).

Encouraged by such progress, the pharmaceutical industry has intensified its research efforts and invested more resources into uncovering the untapped potential of biologics. Globally, biologics can be expected to play a bigger role in modern disease management owing to a growing demand for better targeted therapies from healthcare professionals and patients.

Importantly, biosimilars are not regarded as a generic of biologics due to the natural variability and more complex manufacturing of biological medicines that restrict the exact replication of molecular







micro-heterogeneity<sup>11</sup>; thus, no two products of the same category can be scientifically or technically identical to the originator product.<sup>12</sup> They are also referred to as similar biotherapeutic products, follow-on biologics, or subsequent entry biologics.

Established biological products have indications as well as specific long-term clinical and real-world data that demonstrate their quality, safety and efficacy.<sup>13</sup> This provides reassurance and certainty around the value of these treatments for patients.

In this field, pharmacovigilance (PV), which is the monitoring of drug safety via the collection, detection and assessment of adverse effects associated with pharmaceutical products, should be practised.<sup>14</sup> This is particularly important for biosimilars as they have limited safety data available at approval due to the abbreviated licensure pathway.<sup>15</sup> Stringent PV procedures can help detect potential differences in safety signals between biosimilars and their reference products to ensure unique product identification.

A total of 55 biologics were made available in Malaysia by PhAMA members between 2013 and 2016.<sup>16</sup>

### Breakthroughs in Oncology

Oncology, or the study and treatment of cancer, is one of the areas making headway in the research of targeted therapies. In the past, surgery – along with chemo- and radiotherapy – is the most frequently employed treatment for oncological diseases; however, new noninvasive treatment options have been discovered and introduced in recent years. These latest treatment options may be

grouped under the term ‘targeted therapies’.<sup>9</sup> Targeted therapies work by getting drugs to interfere with the actual proteins that cause tumour to grow or spread.

This type of approach uses either small molecule drugs that can penetrate cells easily, or monoclonal antibody drugs that cannot enter cells easily but can, nevertheless, attach themselves to specific targets on the outer surface of cancerous cells. Most targeted therapies work via the following modes of action:

- **Immunotherapy.** The immune system is modified to destroy the cancer cells.
- **Interruption of cell proliferation.** The proliferation of rapidly dividing cancer cells is halted as therapeutic agents bind to proteins on cell surface and prevent defective cells from dividing.
- **Inhibition of angiogenesis.** The growth of new blood vessels surrounding cancer cells is interrupted in order to starve cancer cells, in hope of killing the tumour or shrinking its size.
- **Targeted delivery of cytotoxic agents.** Certain monoclonal drugs are designed to bind specifically to targets on the outer layer of cancerous cells to exert their killing action. Importantly, cells lacking in the specific targets are not affected.
- **Hormonal/endocrine therapy.** Hormone-positive cancer cells are starved of their growth factor by blocking the interaction between hormone and cancer cells.

It has been observed that while some of these newer therapies may deliver excellent results to certain patients, some would respond poorly to the same types of treatment. As such, it is now increasingly common for clinicians to initiate targeted therapy, in combination with chemotherapy and radiation treatment, to reduce the risks of drug resistance and treatment failure.<sup>17</sup>

The pace of research in this area needs to be continuously intensified.

The breakthroughs made to date will pave the way towards the future availability of precision medicine that promises effective customised care, with markedly reduced side effects. Such treatment option may one day be offered to a broad base of patient populations, where treatment is designed based on individual genetic profiles and personal health histories. Between 2013 and 2016, 25 targeted drugs were launched in Malaysia, with the expected launching of another 22 agents from 2016 to 2022.<sup>16</sup>

### Glossary:

**Angiogenesis** – The development of new blood vessels

**Cell proliferation** – The process that results in an increase of the number of cells, and is defined by the balance between cell divisions and cell loss through cell death or differentiation

**Cytotoxic agents** – A group of medicines that contain chemicals which are toxic to cells, preventing their replication or growth, and so are used to treat cancer

**Drug resistance** – The reduction in effectiveness of a medication in curing a disease or condition

**Hormone/endocrine therapy** – The use of hormones in medical treatment

**Immunotherapy** – The prevention or treatment of disease with substances that stimulate the immune response

**Monoclonal antibody** – An antibody produced by a single clone of cells or cell line and consisting of identical antibody molecules

**Precision medicine** – Medical care designed to optimise efficiency or therapeutic benefit for particular groups of patients, especially by using genetic or molecular profiling.

### Emerging and Re-Emerging Diseases

Emerging diseases refer to diseases which were previously undetected or unknown, known agents which have now spread to new geographical locations or populations, known agents whose role in specific diseases was previously unrecognised, or diseases which had been eradicated previously but has since reappeared (ie, specifically referred to as re-emerging diseases).<sup>18</sup>

According to a World Health Organization report published in 2007, the rate of emergence of infectious diseases in the last 40 odd years is alarming. Since 1970s, 70 emerging diseases have been discovered, including SARS, MERS, ebola, chikungunya, avian and swine flu, and most recently Zika. In Malaysia, the Ministry of Health reported that incidence of hand, food and mouth disease (HFMD) increased from 19,398 cases in 2017 to 21,644 cases in 2018.<sup>19</sup> HFMD is highly contagious, can spread through body fluid, and mostly affect children below the age of 5 years.



For an emerging disease to become established, the agent which causes the disease has to be introduced to a vulnerable population, in addition to having the ability to spread readily from person to person, which leads to the occurrence of an epidemic. The severity of emerging diseases and the increasing rate of infection are driven by frequent cross-border travels, increased interactions between populations dwelling in various geographical areas, dense housing conditions, increased contact with wild animals, changing social interaction behaviours, unsanitary conditions during and after natural disasters or wars, as well as destructive ecological changes due to economic development and changing climate.

The growing resistance of pathogens to antimicrobial medications is also a critical factor in the equation.<sup>20</sup> Both bacteria and viruses can evolve over time and develop resistance to previously effective drugs. Intensified research on known pathogens causing emerging/re-emerging diseases is now being conducted in selected laboratories across the globe in order to better understand the risks posed by these deadly pathogens, and reduce the response time in identifying the right treatment solutions in the event of a future epidemic.

During an emergency, essential life-saving drugs that can be used to contain and control an epidemic/pandemic must be rapidly produced and distributed to the affected areas or countries. Between 2013 and 2016, 13 pharmaceutical agents that can overcome a critical disease outbreak were registered in Malaysia by PhAMA members.<sup>16</sup>

### Rare Diseases

Rare diseases are one of the most significant health challenges of our time; between 5,000 and 8,000 rare diseases have been identified to

date.<sup>21</sup> These diseases are uncommon on their own but as a group, they affect 6–8% of the global population. This presents unique problems not only for individuals living with rare diseases, but also for caregivers, researchers, policymakers, and other members of the healthcare industry. More than 80% of rare diseases are caused by genetic or congenital aberrations, and 75% present with a wide range of neurological symptoms, as well as physical and intellectual disabilities. With opportune medical intervention, some rare diseases can now be controlled.

To achieve opportune medical intervention, it is important for stakeholders to address barriers that prevent individuals with rare diseases from accessing high-quality healthcare services. This means designing health interventions that facilitate the right diagnosis early, and deliver the right care at the right time in the most effective, efficient and equitable way possible.

A number of significant global policy changes, such as the UN 2030 Agenda and Sustainable Development Goals (SDGs) and the push towards universal health coverage, have given more momentum to the investigations of rare diseases, focusing on the message of “leave no-one behind”.<sup>22</sup> More countries are now supporting the need to address the barriers to healthcare services across a broad spectrum of populations, especially those affected by rare diseases. Despite improving awareness, many countries still do not have tailored policy frameworks, which hinder fundamental medical progress.

The vision in rare disease management is to promote equitable and timely access to various medical tools, appropriate healthcare infrastructure and supportive care that patients need to manage

their diseases. Therefore, to improve the lives of patients with rare diseases, the framework for rare disease policy should be based on:

- Ensuring rare diseases are a public health priority by raising the awareness on rare diseases among policymakers, healthcare professionals and the general public.
- Empowering patients and their wider communities by enabling better disease management and allowing patients to further influence the decisions that affect them.
- Promoting continued research and development by building political commitment to drive research, innovation and policies for rare diseases, and increasing collaborative research efforts to enhance the scientific understanding of all rare diseases.
- Ensuring sustainable patient access to diagnosis, treatment and care by improving the workforce and infrastructure to treat rare diseases, and developing and strengthening legislation that enhances access to orphan drugs.





## Value of Preventive Medicines

Preventive medicines play a crucial role in ensuring the optimum quality of life is attained at different stages of one's existence.<sup>23</sup> It is especially relevant to modern times as the current life span of an average person has increased with improved accessibility to medical interventions, better diet and higher level of education.

Preventive medicines should be carefully structured in the absence of diseases. The basic components of preventive medicines include inculcating healthy habits (eg, eating on time), consuming a well-balanced diet to ensure that the body has access to essential nutrients, avoiding a sedentary lifestyle, as well as getting enough rest at night. These healthy habits act as a defence against most illnesses. Additionally, exercising regularly and adopting leisure time activities such as reading help to reduce stress, and promote a healthier state of mind, which in turn reinforces the body's natural

defence mechanism. At the same time, the consumption of tobacco, alcohol and excessive sugar should be avoided.

As we grow older, understanding the risks associated with age becomes more crucial. Thus, it is critical for us to undergo routine medical tests (eg, assessing cholesterol and blood sugar levels) and consult healthcare providers accordingly to establish our health profile. These practices will facilitate the early detection of impending chronic diseases, and enable early medical interventions to take place in order to control, manage and lessen future health complications.

The advocacy of preventive medicines does not only translate into the improvement of one's quality of life, but also indirectly reduces the long-term financial impact and social burden associated with chronic diseases. Between 2013 and 2016, 75 disease awareness and 35 social education programmes were conducted by PhAMA members.<sup>16</sup>

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## PhAMA MEMBERS



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AbbVie Sdn. Bhd.



Allergan Malaysia Sdn. Bhd.



Antah Pharma Sdn. Bhd.

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Sdn. Bhd.Astellas Pharma Malaysia  
Sdn. Bhd.

AstraZeneca Sdn. Bhd.



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Boehringer Ingelheim (Malaysia)  
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Clinical Research Malaysia

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Sdn. Bhd.

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Digital A Plus Healthcare Sdn. Bhd.



DKSH Malaysia Sdn. Bhd.



Eisai (Malaysia) Sdn. Bhd.



Eli Lilly (M) Sdn. Bhd.



EP Plus Group Sdn Bhd



Ferring Sdn. Bhd.



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Healthcare Sdn. Bhd.GlaxoSmithKline Pharmaceutical  
Sdn. Bhd.iNova Pharmaceuticals (Singapore)  
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IQVIA Malaysia



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Lundbeck Malaysia Sdn. Bhd.



Merck Sdn. Bhd.

Merck Sharp & Dohme  
(Malaysia) Sdn Bhd

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Mundipharma Pharmaceuticals  
Sdn. Bhd.

Mylan Malaysia Sdn. Bhd.

Novartis Corporation (Malaysia)  
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Reckitt Benckiser (M) Sdn. Bhd.Roche (Malaysia)  
Sdn. Bhd.

Sanofi-Aventis (Malaysia) Sdn. Bhd.



Servier Malaysia Sdn. Bhd.



Shire Malaysia Sdn. Bhd.

SUMMIT COMPANY (MALAYSIA) SDN BHD  
Summit Company (Malaysia) Sdn. Bhd.

Sun Pharmaceutical Sdn. Bhd.



Takeda Malaysia Sdn. Bhd.



Zuellig Pharma Sdn. Bhd.

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