



'Innovative Medicines for Malaysia'

Innovating for a Healthier, Economically Vibrant Nation

Industry Fact Book

CONTENTS

3 Transitioning Malaysia to Innovative Health:

A message from the Minister of Health

4 Added Value for Tomorrow:

A message from the President of PhAMA

6 Pharmaceutical Snapshot

8 PhAMA : The Voice of Collaboration

Setting High Ethical Standards, Keeping It Relevant

12 A Vital Force of Health

Benefits to Patients
Monitoring and Patient Safety
Curbing Counterfeits
Continuous Medical Education
Community Centric Moves
Caring for Employees

30 Better Health, Improved Wealth

Increasing Productivity, Reducing Costs
More Jobs, Higher Tax Contributions
Building Research Capabilities
Creating a Clinical Research Culture
Exporting Our Expertise
Developing Malaysia's Pharmaceutical Industry
Emerging Trends

44 Paving The Way for Industry Excellence

By Co-chairs of Policy Committee, PhAMA

46 Appendix



Transitioning Malaysia to Innovative Health

A message from the Minister of Health

The Ministry of Health has always been guided by our vision to provide quality healthcare that is affordable and accessible to all Malaysians. It is with pride that I can say we have made many notable achievements to date, having one of the best healthcare systems in the region. We recognise that the pharmaceutical industry has been an indispensable partner in our quest to manage disease and nurture a progressive nation.

Both multinationals and local companies have played quite distinct yet complementary roles and, together, have ensured that the pharmaceutical needs of the nation are fulfilled. It is heartening to see how some multinationals have taken up the challenge of producing drugs and vaccines for communicable diseases that are endemic to tropical countries; while local companies have gone the extra mile to produce generics that are more affordable to the people. Today, however, as we transition into a high-income economy, as envisaged in the Government's Economic Transformation Programme, there is a need for greater multi-stakeholder collaboration to uplift the industry to the next level.

It is my fervent wish to see more multinationals make the most of the opportunity to partner with local companies in the manufacture of drugs in Malaysia. At the same time, we would like to see more local companies upgrade their R&D and manufacturing infrastructure so as to meet the goals of the Healthcare National Key Economic Area in terms of generics production and nurturing a clinical research environment. These are essential if we are to maximise the potential we have already created in the industry.

On our part, the Ministry will continue to be very supportive of the pharmaceutical industry and will provide the regulatory backbone to ensure further growth and expansion of this vibrant and vital sector in working together for a healthier Malaysia. We believe that with the Government's support, and with greater private investment in the industry, we can guarantee a sustainable quality healthcare system for the country – one that will also help to boost our economy and improve the quality of life for all as we chart our way towards becoming a high income country.


Dato' Seri Liow Tiong Lai

ADDED VALUE FOR TOMORROW:

A message from the President of PhAMA



Malaysia of tomorrow will be more culturally, technically and economically advanced than it is today. We will be a more affluent country, with a population that has heightened awareness of the need to lead a healthy lifestyle in order to preserve their well-being. We will also be an 'older' country, as the number of citizens in the above-65 years bracket grows in relation to the younger age brackets. This will generate greater demand for wellness and therapeutic products both to keep disease at bay and to treat those that surface. Fortunately, our more matured and sophisticated pharmaceutical industry will be able to meet our anticipated healthcare needs.

Many fundamental changes are taking place within the industry which will result in greater self-reliance and capacity to serve the people. While it has traditionally been driven by internal forces of health demands, the Government is further stimulating growth of the industry by providing various incentives and encouraging greater investments by the public and private sectors. The ulterior objective is to move the industry up the value chain by concentrating on the principal drivers of research and development, and manufacturing.

MULTINATIONALS ARE BEING ENCOURAGED TO PARTNER WITH LOCAL COMPANIES AND TO OUTSOURCE THE MANUFACTURING OF PHARMACEUTICAL PRODUCTS TO THEM. AT THE SAME TIME, LOCAL COMPANIES ARE UPGRADING THEIR MANUFACTURING CAPABILITIES, SPURRED BY ALLOWANCES FOR THE SETTING UP OF PRODUCTION FACILITIES AND THE IMPORT OF ESSENTIAL RAW MATERIALS, EQUIPMENT AND MACHINERY.

These new production centres will no longer churn out only low-value vitamins and over the counter drugs but also higher grade generics to provide for the needs of Malaysians as well as the international market.

Various trends in the international market are set to positively influence the growth of Malaysia's generics sector. An interesting development is that of high-value biogenerics, the production of which requires technically superior knowledge and facilities. As Malaysian companies are already building on the physical and technical infrastructure for pharmaceutical production, the biogenerics sector offers an attractive value proposition because we have the added advantage of being able to source for bioactive compounds from our unrivalled biodiverse natural assets. Equally attractive is the international halal pharmaceutical products market, which offers Malaysian companies the opportunity to capitalise on local expertise in halal production and the global halal marketing network that the country has established.

At the same time, to continue to attract multinationals and to promote a stronger research-based industry, we will need an enhanced framework supported by regulations to protect intellectual property rights.

Given local and international developments, the future is very exciting for the pharmaceutical industry. However, in order to realise the industry's own ambitions, as well as those of the Government, there is a need for greater collaboration and cooperation between the various stakeholders involved in healthcare.

PhAMA has over the years already encouraged such multi-stakeholder engagement, and is very eager to be able to play our part now as the industry makes its timely transition into a more advanced, value-driven space. Our members have always striven to meet the healthcare needs of the country; now we eagerly take on the challenge of also energising the national economic engine.

Ewe Kheng Huat
President of PhAMA

PHARMACEUTICAL SNAPSHOT

Both multinational and local companies recognise the potential for further growth of the pharmaceutical industry in Malaysia.



Both **multinational** and **local companies** recognise the **potential** for further growth of the **pharmaceutical industry in Malaysia.**

Malaysia has an effective pharmaceutical industry which has contributed to the nation having one of the best World Health Organisation (WHO) report cards in the region. Broadly speaking, the industry comprises two parallel streams – local companies that focus primarily on traditional medicine, vitamins, supplements, over the counter (OTC) drugs and generics; and multinationals, which have been responsible for bringing to Malaysia hundreds of internationally tested and accepted drugs whose safety, efficacy and quality have been proven, backed by very strong research and development capabilities.

Both streams are regulated by the Drug Control Authority (DCA) under the Ministry of Health and, together, have helped to manage a number of potentially devastating diseases. While the local companies are involved in the entire value chain from R&D to the marketing and sales of therapeutic products, regulatory and other factors have meant that only about 13% of the multinationals operating in Malaysia have set up local manufacturing operations, while a further 7% have manufacturing arrangements with local companies.¹ This means that some 80% of multinationals are constrained to the import and marketing of life-saving drugs.

¹ PhAMA Pharmaceutical Industry Survey, 2010

Drugs developed by multinationals typically have patents valid for a certain number of years, following which local companies are able to manufacture generics and market them at more affordable prices to hospitals, clinics and pharmacies. While this represents a growing source of income for the local sector, more than two-thirds of Malaysian pharmaceuticals still focus on traditional medicine, based on the country's rich natural resources and knowledge of indigenous communities on their healing properties. Consequently, Malaysia still relies quite heavily on imports to fulfil the need for drugs to treat contemporary diseases such as high cholesterol, diabetes, cardiovascular ailments and cancer. As much as 70% of local demand for pharmaceuticals is imported.

At the same time, as a result of high quality standards, Malaysia is one of the few countries in the region that have been accepted into the Pharmaceutical Inspection Co-operation Scheme (PICS). This has opened the global market for local manufacturers to export vitamins and supplements, OTC and generic drugs. The halal drugs market in particular represents a potentially lucrative source of income to local manufacturers, with a number of Middle Eastern countries already importing products made in Malaysia and others showing keen interest to follow suit.

Both multinational and local companies recognise the potential for further growth of the pharmaceutical industry in Malaysia. They are encouraged by the Government's intention to enhance healthcare services in the country under the Economic Transformation Programme (ETP), targeting it as one of the 12 National Key Economic Areas. Industry players have always done their best within existing frameworks to provide for Malaysians and are now excited at the prospects of not only fulfilling the healthcare needs of the nation but also taking on a greater role in the economic development of the country.



THE VOICE OF COLLABORATION

Both multinational and local companies recognise the potential for further growth of the pharmaceutical industry in Malaysia.



The Pharmaceutical Association of Malaysia (PhAMA) serves to build relationships between pharmaceutical companies and other stakeholders of the healthcare sector, namely consumers, healthcare providers, hospital and clinic administrators, the media, regulators and the Government. Our ultimate aim is to ensure access to quality healthcare and healthcare products for all Malaysians. Registered in 1972, our members currently comprise 42 local and multinational companies.

Because PhAMA represents all the major research-based pharmaceutical companies in the country, we are often seen as the 'voice' of the industry. We take up concerns of our members with the relevant parties and organise dialogue sessions for better understanding and cooperation across the sub-sectors. The management and activities of PhAMA are overseen by the Board of Directors, consisting of the President, 10 elected members and one co-opted member, all of whom are chief executives of member companies.



<p>We have several committees dedicated to improving the service provided to our members and the community, and to enhancing the level of professionalism of pharmaceutical representatives in general.</p>	
<p>The Policy & PR Committee advises the Board on government policies that impact the industry; and prepares position papers on issues affecting the industry</p>	<p>The Regulatory Affairs Committee represents the common regulatory interests of members; and promotes an optimum regulatory environment that facilitates the registration and marketing of pharmaceuticals</p>
<p>The Consumer Healthcare Committee represents the interests of the OTC medicines industry; and advocates liberalisation of direct-to-consumer advertising for selected Group C medicines</p>	<p>The HR & Training Committee responsible for sharing of best practices in human resources management; and upgrading skills and knowledge of the industry's HR</p>
<p>The Ethics & Marketing Practices Committee develops and enforces the PhAMA Code of Conduct for prescription products; and adjudicates on ethics case complaints</p>	

We are affiliated to the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), which represents manufacturers and marketers of ethical (or prescriptive) products; and the World Self-Medication Industry (WSMI), comprising manufacturers and marketers of over-the-counter pharmaceuticals. Both bodies are non-governmental organisations affiliated to the World Health Organisation. Through them, we are able to keep our own members abreast of developments and best practices in the global industry.

We also provide our input on matters relevant to the industry via government bodies and working groups such as Pemandu and the Ministry of Health. In addition, PhAMA has close working ties with the ASEAN Pharmaceutical Industry Association, the EU-Malaysia Chamber of Commerce and Industry (EUMCCI), Malaysian International Chamber of Commerce and Industry (MICCI) and the American Chamber of Commerce (AMCHAM).

VISION AND MISSION

OUR VISION

is to be an organisation **working together** with key stakeholders for **better health and quality of life**.



OUR MISSION

is to provide access to **innovative medicines** for better health and **improved quality of life** for all in Malaysia by:

- Promoting timely access to quality and innovative medicines
- Encouraging research and development of pharmaceutical products in Malaysia
- Forming strategic health partnership with key stakeholders for the advancement of public health
- Empowering consumers for safe and responsible self-medication
- Promoting industry values and contributing to the nation
- Upgrading the skills and knowledge of industry's human resources
- Ensuring the ethical promotion of medicines in compliance with local laws and a set of marketing practices

Setting High Ethical Standards, Keeping It Relevant



We have formulated a code of ethics which is shared with our members via various programmes and activities. The PhAMA Code of Pharmaceutical Marketing Practices (the Code) was first drawn up and adopted by our members in 1978. In order to keep it relevant, the Code is constantly reviewed by the association and has been amended several times to enhance its clarity as well as to keep up with evolving international standards. The Code is now in its 18th edition, incorporating the latest amendments in 2010.

While promoting compliance with existing and relevant legislation governing the pharmaceutical industry, the Code further provides clear guidelines on the dissemination of accurate, fair and objective information to the medical and allied professions so that physicians and clinicians are able to make rational and informed prescribing decisions.

PhAMA also strongly advocates non-member companies in the industry to observe the Code to ensure products

are marketed on their inherent merit, based on their proven efficacy, as this is fair and just not only to the manufacturer but also to the patient who will eventually be treated by the medication. The Code contains provisions for channelling complaints to the association and how these are to be dealt with. Our Ethics Committee deliberates on every case and makes a decision which is communicated to the complainant as well as to the company alleged to be in breach, which could be a non-PhAMA member. The negative publicity generated within healthcare circles serves to deter all pharmaceutical players from any form of unethical behaviour.

Aside from this Code, many PhAMA member companies have their own code of ethics to govern their marketing and sales practices as well as interactions with healthcare professionals.





Malaysians get to benefit from such cost and time-intensive research, as all leading multinational pharmaceuticals have a presence here and bring into the country their best, most efficacious drugs.



A VITAL FORCE OF HEALTH

- Benefits to Patients
- Monitoring and Patient Safety
- Curbing Counterfeits

- Continuous Medical Education
- Community Centric Moves
- Caring for Employees

A VITAL FORCE OF HEALTH

Both multinational and local companies recognise the potential for further growth of the pharmaceutical industry in Malaysia.

Over the decades, Malaysia's health profile has changed drastically. From an undeveloped country plagued by communicable diseases, it finds itself now having to grapple with a different set of lifestyle and age-related ailments more common to developed nations. Throughout, pharmaceuticals have played a significant role in contributing to a healthier population.

From the mid-20th century, pharmaceuticals have helped to reduce the number of fatalities from prevalent diseases through preventative measures as well as the treatment of patients. The Government's BCG vaccination programme, for example, greatly reduced the incidence of tuberculosis (TB) which, following the Second World War, caused the highest mortality rate among all diseases in the country. As a result of vigilance and up-to-date treatments, Malaysia at present has a relatively low TB rate, at 109 per 100,000, as opposed to 160 and 201 per 100,000 in the region and world, respectively.²

Typhoid and cholera were contained through better sanitation/hygiene and treatment while malaria was largely curbed via mosquito control and drug intervention. Although much less common today, these diseases do still surface periodically and a number of multinational pharmaceutical companies are channelling millions of dollars into research to develop more effective treatments, even if these diseases are

not common in the West. Since 2001, GlaxoSmithKline has been working to develop a vaccine and new drugs to treat malarial infections; while AstraZeneca entered into a collaboration with Medicines for Malaria Venture (MMV) in 2010 to identify novel drugs for the treatment of the disease. In Malaysia itself, multinationals are working alongside the Institute for Medical Research (IMR) to develop pioneering treatments and potential cures for various tropical diseases. Where drugs are too expensive for patients to afford, MNCs have stepped in to provide free, or greatly discounted, treatment. Novartis, for example, provides a cancer drug and a treatment for eye degeneration to Malaysians who cannot afford them via a patient assistance programme in collaboration with the Ministry of Health.

Malaysia has also been able to significantly increase the health and well-being of children via a comprehensive vaccination programme, contributing to a very low infant mortality rate of six in 1,000 (in 2009), against regional and global rates of 21 and 60 out of 1,000 respectively. Focus on maternal health, meanwhile, has reduced the maternal mortality rate during childbirth to 31 per 100,000 live births as compared to 51 and 260 per 100,000 live births at the regional and global levels. At the same time, life expectancies of men and women have increased, averaging 77.6 for women and 72.9 for men, according to 2010 statistics by the United Nations (see Figure 1).

² WHO Malaysia Profile, 2009

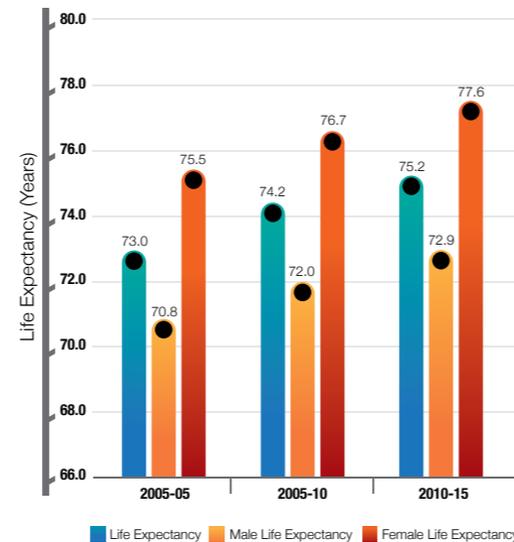


Figure 1 : Life Expectancy of Malaysians
Source: United Nations, 2010

Benefits to Patients

The increase in life expectancy brought about by better healthcare services, combined with economic progress in Malaysia, has led to a growing incidence of age-related ailments such as cardiovascular disease, cancer, arthritis, cataracts, osteoporosis and Alzheimer's, as well as lifestyle diseases including hypertension (high blood pressure) and diabetes. According to government statistics, from 1996 to 2006, the country saw a 43% increase in the number of Malaysians with hypertension and an 88% increase in the number of diabetic patients.³

Fortunately for Malaysia, these are the very same diseases that are prevalent in the West, where pharmaceutical companies have for years been spending billions of dollars (or its equivalent) on research to find effective prophylactics and cures. In the US, for example, it cost on average US\$1.3 billion (RM3.9 billion) to develop a drug in 2005, while the industry spent an estimated US\$67.4 billion (RM202.4 billion) in 2010 on research and development.⁴ No less than 20.5% of domestic sales is channelled right back into R&D among American pharmaceuticals, a figure that far outstrips R&D vis-à-vis sales for any other industry in the country. What's more, the entire process of bringing a new drug to market is laborious and takes between 13-15 years.

Malaysians get to benefit from such cost and time-intensive research, as all leading multinational pharmaceuticals have a presence here and bring into the country their best, most efficacious drugs. This quest to keep improving on existing drugs means that pharmaceutical companies constantly add new

production lines for the different diseases, and an increasing number of drugs are being manufactured that are more effective and target-specific than their predecessors. Advances in scientific knowledge - and particularly greater understanding of the molecular or genetic basis of disease - keep fuelling the pharmaceutical machinery, ensuring that more and better drugs are released which serve humanity the world over.

Multinational pharmaceutical companies closely monitor health trends in the country and bring to market drugs that are most relevant to Malaysia's needs. Between 2005 and 2009, PhAMA members introduced a total of 369 new ethical products in Malaysia, the top three being antineoplastics (drugs that inhibit the growth and spread of cancer cells), vaccines and drugs that treat diabetes (see Figure 2).



Drugs Classification	Ethical Products Total
Oncology/Cancer	34
Vaccines	30
Diabetes/Anti-Diabetic	22
Eyecare	13
Antibiotics	18
Antidepressants	16
Vitamins	3
Antivirals	15
Anti-Hypertensive	14
Antacids	8
Drugs Acting on the Central Nervous System	12
Nasal Decongestants	11
Analgesics	8
Cough & Cold Medication	8
Cholesterol Regulators	8
Orthopaedic Related	7
Mood Stabilisers	10
Hormones	10
Others	122
TOTAL	369

Figure 2 : Number of Ethical Products Launched in 2005-2009
Source: PhAMA Survey, IMS 2010

In terms of sales, the top three therapeutic areas drugs between 2006 and 2009 all catered to non-communicable diseases such as cardiovascular ailments, diabetes and cancer, which are leading health concerns in the country.

However, as our health demographic continues to evolve, multinational pharmaceutical companies are bringing in a different set of new drugs to manage emerging priority diseases. Of the 101 new products that 15 multinationals are planning to launch in Malaysia over the next five years, 16 will target cancer, which is expected to become more prevalent as the life expectancy of the local population continues to increase (see Figure 3).

Second on the list are drugs for neurological diseases, namely disorders of the brain, spinal cord and nerves throughout the body. These include strokes, meningitis, brain tumours, Huntington's disease, muscular dystrophy, spina bifida and degenerative diseases such as Parkinson's and Alzheimer's. Neurological diseases are expected to become the second leading cause of morbidity and mortality after heart disease in Malaysia in the next 10 years.⁵ To combat these debilitating diseases, leading multinational pharmaceutical organisations are to launch 15 innovative products in the next five years.

The country will also benefit from 12 new drugs to treat cardiovascular disease, and eight for diabetes. Cardiovascular disease is currently the leading cause of mortality in government hospitals, contributing to 16.4% of all deaths; while WHO expects the incidence of diabetes to almost triple from 942,000 patients diagnosed in 2000 to 2.5 million patients by 2030.⁶

Drugs Classification	Number of Products
Oncology/ Cancer	16
Neurology/ CNS	15
Cardiovascular	12
Diabetes/ Anti-diabetics	8
Hematology (blood)	6
Hypertension	4
Anti-asthma/ COPD products/ Respiratory System	4
Immunology	4
Other therapeutic products	4
Urology	3
Fertility	3
Vaccines	3
Endocrine including growth hormones	2
Anti-inflammatory/anti-rheumatic products/pain	2
Allergy	2
Anti-obesity	2
Musculo	2
Anti-epileptic	1
Digestive system e.g. gastro pro-kinetics	1
Diagnostic Agents	1
Anti-hepatitis B	1
Critical care	1
Anaesthesia	1
Anti-smoking	1
Women's Health	1
Infectious Disease	1
TOTAL	101

Figure 3 : Drug Launches of 15 MNCs in Malaysia
From 2010-2015
Source: PhAMA Survey, 2010 & IMS, 2010

Neurological diseases are expected to become the **second leading cause** of morbidity and mortality after heart disease in Malaysia in the next 10 years.



⁵ National Response to Neurological Diseases in Malaysia: Planning for the Future. The Southeast Asian Journal of Tropical Medicine and Public Health. <http://www.ncbi.nlm.nih.gov/pubmed/17121309> (retrieved 8 October 2010)

⁶ World Health Organisation: Prevalence Data http://www.who.int/diabetes/facts/world_figures/en/index6.html. (retrieved 3 August 2010)

Monitoring & Patient Safety

The ultimate objectives of the pharmaceutical industry are to save lives and improve the general well-being of people around the world. Hence, the safety of drugs is of utmost concern to manufacturing companies. Before any drug is released into the market, it has to go through a pre-clinical lab test to make sure it is safe to be administered to patients. Following this, extensive clinical trials are conducted, which generally take six to seven years. These trials are so rigorous and safety standards set so high that, out of six drugs that enter this process in the US only one is submitted to the Food and Drug Administration (FDA) for approval.⁷

In Malaysia, the Drug Control Authority (DCA) under the Ministry of Health keeps a check on all pharmaceutical manufacturers and suppliers, ensuring prescription as well as over the counter products satisfy stringent quality safety and efficacy requirements. Drugs are also subject to regular post-marketing surveillance and testing, while DCA inspectors conduct random checks on manufacturing facilities and processes to ensure they comply fully with the Code of Good Manufacturing Practice, based on the Pharmaceutical Inspection Co-operation (PIC) Code.

Curbing Counterfeits

There is a real problem of counterfeit and unregistered pharmaceutical products in Malaysia, which poses a serious threat to consumers as there is no control over their chemical compositions. According to a 2008 report by healthcare market research company Espicom, counterfeit drugs make up an estimated 5% of the local pharmaceutical market. To curb the sales of fake drugs, the Government in 2005 introduced a Meditag system which helps consumers and pharmacists recognise the genuine products. In order to tackle the root of the problem, however, there is a need for greater enforcement and deterrent penalties for those dealing in the illegal trade of counterfeits. On our part, the pharmaceutical industry fully supports all efforts made by the Government in its on-going battle against counterfeit manufacturers. We are committed to working together with the authorities to increase public awareness through dialogues, patient education, public forums, medical health seminars and media campaigns.

⁷ Pharmaceutical Industry Profile 2011

Continuous Medical Education

To keep healthcare professionals updated on developments in the pharmaceutical industry, PhAMA members have taken it upon themselves to provide targeted education and training to thousands of general practitioners, specialist doctors, pharmacists, nurses, lab technicians and others on a regular basis. The number of continuing medical education (CME) activities organised has been increasing over the years, from 952 in 2007 to 1,596 in 2009, with correspondingly bigger budget allocations. Just in the three years from 2007 to 2009, pharmaceutical companies more than doubled their investment in CME programmes, from RM48,300,000 to RM101,768,000. Details of the CME programmes held in 2009 are given in figures 4 and 5.

In addition, every year, the industry supports a number of regional and international medical conferences in Malaysia, at which key opinion leaders (KOLs) share with their global counterparts the latest developments in medical science. These events not only fulfil the primary purpose of knowledge-sharing across borders but also serve to establish Malaysia as a leading healthcare provider in Asia.

HC Professionals Covered	Total No. HC Professionals
General Practitioners	2,812
Specialist Doctors	1,570
Pharmacists	1,191
Other HC Professionals (nurses, lab technicians, etc.)	652
TOTAL	6,225

Figure 4 : Number of Healthcare Professionals Contacted by Pharmaceutical Organisations
Source: PhAMA Survey, 2010

Types of CME Activities	Number of Activities
New product launches	12
New clinical data	12
New indication	10
Continued education	17
Others	52

Figure 5 : Types of Continuing Medical Education (CME) Activities
Source: PhAMA Survey, 2010



Community Centric Moves

Pharmaceutical companies are at the forefront of Corporate Social Responsibility (CSR) endeavours throughout the world, and their contributions to Malaysia are indicative of their commitment to raising the quality of life of people everywhere.



PhAMA and our members regularly carry out public health campaigns to create greater awareness of the benefits of a healthy lifestyle, and what this entails. By inspiring behavioural change for the better, not only are pharmaceutical companies creating a healthier, more productive nation but are also saving the Government and its people from unnecessary healthcare costs, easing the load on the healthcare system.

The CSR commitment of pharmaceutical companies goes beyond educating and empowering local communities with the knowledge to better manage their health, however. It also encompasses uplifting general standards of living, providing aid to communities that need it, promoting access to better education, preserving the environment, and enhancing their own workplace for greater employee satisfaction. Some of the CSR programmes are highlighted in Figure 6.

Types of CSR Activities	Number of Activities
Disease awareness campaigns	13
Community Programmes	12
Social education	9
Patient group support	9
Environment	7
Others	1
Total	51

Figure 6 : Types of CSR Activities
Source: PhAMA Survey, 2010

Community Centric Moves

► Disease Awareness Campaigns

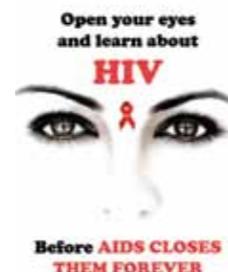
Given the nature of their core business, it is only natural for pharmaceutical companies to focus their CSR efforts on helping the public better understand diseases – in particular how to avoid them and manage them. Some of the programmes target caregivers, providing them with essential information and support to best look after afflicted patients.

In 2010, **Abbott Laboratories Malaysia** collaborated with the Arthritis Foundation Malaysia, Malaysian Society of Rheumatology, MOH, Ministry of Human Resources and Ministry of Women, Family and Community Development to launch an awareness campaign on rheumatoid arthritis in women. On an on-going basis, the company also runs a We KARE programme to educate HIV/AIDS patients and their families on effective treatment and management of the disease.

Another pharmaceutical that lends its expertise to the management of HIV/AIDS is **Merck Sharp & Dohme (MSD)**. Since 2005, it has been promoting the It Begins With You campaign together with the Malaysian Society for HIV Medicine and the Malaysia AIDS Council to raise awareness of HIV/AIDS issues and the need for support and understanding for people living with HIV/AIDS.

Bayer HealthCare Malaysia focuses on haemophilia care. It organised the first Asia Pacific Haemophilia Camp, in Malaysia, in 2009 and has built on this awareness initiative by launching a global online lifestyle magazine for teens and young adults with haemophilia, Frankly.net, in 2010; and engaging in a more intense awareness drive in 2011.

Eisai has taken on the role of an educator on Alzheimer's Disease (AD). In 2010, the company conducted 12 public forums across the nation in collaboration with government hospitals and NGOs such as the Alzheimer's Disease Foundation Malaysia (ADFM) to help the public to recognise the signs and symptoms of AD. Screenings were also conducted, as a result of which a number of high-risk patients were detected and sent for further evaluation and treatment. **Eisai** also organised six caregiver workshops across the nation, conducted by volunteer doctors. These offered a platform for the caregivers to form a network and to share experiences.



In collaboration with vaccine world leader **Sanofi Pasteur**, MOH Malaysia is involved in the region in advancing the development of a novel vaccine for the prevention of dengue disease in children and adults. A broad clinical study program with the vaccine looking into sero-prevalence, acute febrile episodes and dengue infection, safety, immunogenicity, and ultimately efficacy. Clinical trials have already started since the middle of 2010 involving 300 volunteers. States involved are Kuala Lumpur, Penang, Perak, Negeri Sembilan, and Sarawak. A dengue vaccine is the ultimate next step in the prevention of dengue fever and with this vaccine Sanofi Pasteur is committed to prepare the future in controlling this disease in Malaysia.



GSK's Consumer Healthcare division, meanwhile, regularly conducts awareness campaigns to improve the well-being of Malaysians. In 2010, it ran an Oral Health Awareness Campaign on the importance of good oral health. This programme was set up in partnership with the Malaysia Dental Association and supported by the Ministry of Health.

Merck Serono launched an International Thyroid Awareness Week to draw worldwide attention to the symptoms and cure for thyroid disorders. The campaign was brought to Malaysia in 2009 and is to become an annual event here.

Since 2006, **Pfizer** has been running the Pfizer Malaysia MenCare – Male Support for Breast Cancer Screening in Women. The programme advocates greater male support for breast cancer screening via training of service providers, public awareness campaigns and education. A book of testimonials from MenCare participants comprising breast cancer survivors and their husbands, titled His Story, Her Story, was launched in 2008 and has been translated into Bahasa Melayu, Chinese and Tamil to complement the Ministry of Women, Family and Community Development's Mammogram Subsidy Programme. The book is given for free by **Pfizer** and the National Council of Women's Organisations (NCWO).

Sun Pharmaceutical regularly organises public health forums to provide free healthcare screening and disease-prevention education to the public. Sun is the secretariat for Medical Outreach Malaysia, an NGO set up by a group of dedicated doctors to provide free healthcare services to the rural community; and Health Awareness Association, another NGO set up by medical practitioners to provide free healthcare services and disease prevention education to the community throughout Malaysia.

Community Centric Moves

► Community Programmes

Pharmaceutical companies have a tradition of reaching out to the underprivileged and communities with limited resources to help raise their living standards in various ways.

Baxter, for example, believes in Making a Meaningful Difference and runs a CSR programme that extends support to underprivileged communities wherever it operates. **Eisai** visits AD daycare centres, old folk's homes, orphanages and homes for the disabled to bring some fun and laughter into the lives of the underprivileged. The company also takes part in fundraising activities in conjunction with NGOs such as ADFM and Lion's Club in aid of homes and AD centres. **MSD** takes underprivileged children on exciting excursions, in addition to donating to the homes.

GlaxoSmithKline focuses on children with special needs. In early 2009, it adopted a home for special children, the Pusat Penjagaan Kanak Kanak Cacat Taman Megah. Personnel spend some meaningful time with the children here, assisting them to develop their linguistic and motor response skills. To help the home meet its daily requirements, GSK conducts fundraising exercises and has to date channelled over RM150,000 towards the home. GSK also supports the Special Children Society of Ampang.

Pfizer is committed to making healthcare services accessible to everyone, and in August 1999 launched its Pfizer Care-A-Van (CAV). This initiative takes volunteer medical professionals, nurses and Pfizer employees to underprivileged communities throughout Malaysia, where they provide medical screening to those who would normally not have access to such facilities.

A number of companies, such as **Boehringer Ingelheim Malaysia**, **GlaxoSmithKline** and **Sanofi Malaysia** have CSR programmes targeting orang asli communities.

Astra Zeneca has responded to the need for better disaster response. In 2006, it contributed towards the establishment of the British Red Cross disaster response centre in Kuala Lumpur with US\$700,000 in funds, which it topped up with an additional donation of US\$440,000 in 2009.



Community Centric Moves

► Professional & Social Education

Pharmaceutical companies are playing their part to increase the level of professionalism in healthcare in the country via the transfer of knowledge and technology. They are also supporting the Government's objective of nurturing a knowledge-driven society by providing educational opportunities to those who cannot afford it.

Abbott Laboratories Malaysia has been partnering with the Malaysia Society of Rheumatology and Ministry of Health (MOH) to develop Malaysia as a centre of excellence in ultrasonography. For the period 2010-2011, it has committed to providing 10 major rheumatology hospitals with portable musculoskeletal ultrasound equipment and to training the personnel to operate the cutting edge machinery. At the same time, nurses will be guided so as to be able to monitor patients and counsel them to ensure they adhere to their treatment schedules. The pharmaceutical company has also set up a peer-to-peer training programme for physicians from around the globe to share the most up-to-date scientific findings and practice-based insights.

Targeting youth, GSK co-funds the Chevening Scholarship for Malaysians wishing to study in the UK along with the British High Commission.

► Environment

As responsible corporate citizens, pharmaceutical companies are conscious of the need to reduce our carbon footprint and have embarked on various green initiatives themselves via also promoting greater awareness of environmental issues among the public, particularly youth.

Bayer is a partner to the United Nations Environment Programme (UNEP) that aims at nurturing a generation of young environmental leaders. The Bayer Young Environmental Envoy (BYEE) programme runs nationwide from February to November every year involving about 10 Malaysian students who are selected to attend a five-day eco-camp in the country. The two most outstanding performers are then sent on a week-long study tour in Germany, where they get to meet delegates from different parts of the world to exchange ideas and experiences.

MSD is also a keen advocate of eco-consciousness and encourages its employees to adopt a green lifestyle by:

- Providing shopping bags for staff to use in a bid to reduce the use of plastic
- Providing recycling bins for trash from the office and home
- Discontinuing the use of bottled water and non-reusable cutlery in styrofoam, plastic and paper at in-house company events



Community Centric Moves

► Patient Assistance Programmes

Multinational pharmaceutical companies are making efforts to ensure their products are accessible to the greatest number of people who need them. Often, new treatments are too expensive for certain communities. Where this is the case, it is not unusual for the manufacturing company to step in and provide the treatment at a discounted rate, or at no cost at all, to the needy.

In 2001, **Novartis** launched a comprehensive patient assistance programme (PAP) for a drug it had developed that treats leukaemia as well as gastro-intestinal tumours. The program known as Glivec International Patient Assistance Program has some 33,000 patients in more than 80 countries have received leukaemia medication at significantly reduced or no cost. In 2002, GIPAP reached Malaysian shores. In collaboration with the Ministry of Health, the Malaysia Patient Assistance Program (MYPAP) was launched – the first time ever such a programme had been initiated by any government in this region. As a result, 51 physicians in 35 treatment centres nationwide have helped about 1,300 cancer patients to get access to medication. Currently, 921 patients continue to receive medication through GIPAP/MYPAP. **Novartis** has contributed an estimated RM233 million worth of medication for this programme, and is expected to contribute an additional RM766 million of the drug to take the programme through to year 2020.

Bayer HealthCare Malaysia, meanwhile, assists patients with liver cancer via NexPAP, a patient assistance programme established in partnership with the Malaysian Liver Foundation in September 2009. The programme offers Sorafenib, a leading liver cancer treatment, to patients who have already undergone two months' treatment with the oral targeted therapy and are financially unable to continue with the medication. More than 54 patients have benefitted from this programme and are enjoying a better quality of life as a result.

In 2010, **Novartis** embarked on its second patient assistance programme in Malaysia, this time for a treatment targeted at age related macular degeneration of the eyes, which can lead to blindness. The medication is administered as an injection. Patients require three doses on a monthly basis. Although available in Malaysia since 2007, **Novartis** decided to make the medication available to a larger number of patients via government and teaching hospitals, under a patient assistance programme. The multinational has so far contributed about RM1.2 million worth of this sight-saving treatment to Malaysian patients who can't afford it.



Since 2004, every year **Pfizer** channels RM200,000 to the National Heart Institute (IJN) Foundation to help financially constrained adult patients pay for their surgery, hospitalisation and medicines for a period of two months following surgery. To date more than 80 individual have benefited from the programme and given a new lease of life with more than RM1million contribution from Pfizer for this purpose alone.

Bayer HealthCare runs a second patient assistance programme in Malaysia, for a drug that treats multiple sclerosis (MS) - interferon beta. The PAP, carried out in partnership with the social welfare departments of government hospitals, offers free interferon beta to MS patients who have been prescribed the drug by their doctor. This programme is complemented by patient care consultant services that give MS patients the benefit of close and personal patient follow-ups, periodic home visits, counselling and guidance on the administration of therapy, among others, by a trained MS nurse.



Caring For Employees

Employees are among the most important assets in any organisation, and are invaluable in research-intensive companies. In the pharmaceutical industry, specialist knowledge and a high level of technical skills are required of research scientists to successfully develop new and more effective drugs.



Pharmaceutical companies therefore place the utmost importance on attracting and retaining the best talents with attractive salary packages and numerous incentives that enhance job satisfaction. As these companies are in the business of promoting health and well-being, they only naturally encourage their employees to adopt a healthy lifestyle too. Health screenings, health talks and a healthy work-life balance are a regular part of the work environment among PhAMA member companies.

Safety at work is also accorded top priority in the industry, and statistics compiled by the Social Security Organisation (PERKESO) under the Ministry of Human Resources⁹ indicate that only 43 accidents occurred in the drugs/medicines manufacturing sector in 2007. This represents one of the lowest incident rates among all industrial sectors in Malaysia, and testifies to the commitment of pharmaceutical companies to providing a healthy and safe workplace for their employees which in turn ensures the smooth provision of healthcare access to the larger population.

⁹ PERKESO Statistic Report 2008, <http://www.perkeso.gov.my/en/yearly-report.html> (retrieved 3 August 2010)





While the pharmaceutical industry in Malaysia has primarily served the social role of ensuring safe, efficient and quality healthcare for the people, it has grown organically over the years to become one of the fastest-expanding industries in the Malaysian economy.



BETTER HEALTH, IMPROVED

WEALTH

- Increasing Productivity, Reducing Costs
- More Jobs, Higher Tax Contributions
- Building Research Capabilities
- Creating a Clinical Research Culture

- Exporting Our Expertise
- Developing Malaysia's Pharmaceutical Industry
- Emerging Trends

BETTER HEALTH, IMPROVED WEALTH

In 2010, the Malaysian pharmaceutical industry was estimated to be worth RM5 billion for prescription and OTC medicines.

While the pharmaceutical industry in Malaysia has primarily served the social role of ensuring safe, efficient and quality healthcare for the people, it has grown organically over the years to become one of the fastest-expanding industries in the Malaysian economy. During the five-year period from 2006-2010, it delivered a stronger performance in terms of profit and growth than larger, more traditional economic sectors such as automotive, agriculture and electronics.⁹

Although not quite recession-proof, the pharmaceutical sector in Malaysia performed much better than most other industries during the global meltdown in 2009, growing at 5.6% (as compared to 10.7% in 2008). In terms of sales of pharmaceutical products, the pharmacy sector registered an impressive double-digit growth rate of 13.3% in 2009, followed by the private hospital sector which grew 8.5% year-on-year, and the clinic and government sectors which grew at less than 5%.

In 2010, the Malaysian pharmaceutical industry was estimated to be worth RM5 billion for prescription and OTC medicines. According to industry analyst IMS, the industry is expected to experience a compounded annual growth rate (CAGR) of 9.5% for the period 2009-2014, by the end of which it should be worth RM5.4 billion.



Healthcare in general has been identified by the Government as one of **12 National Key Economic Areas** that will help achieve its Economic Transformation Programme.

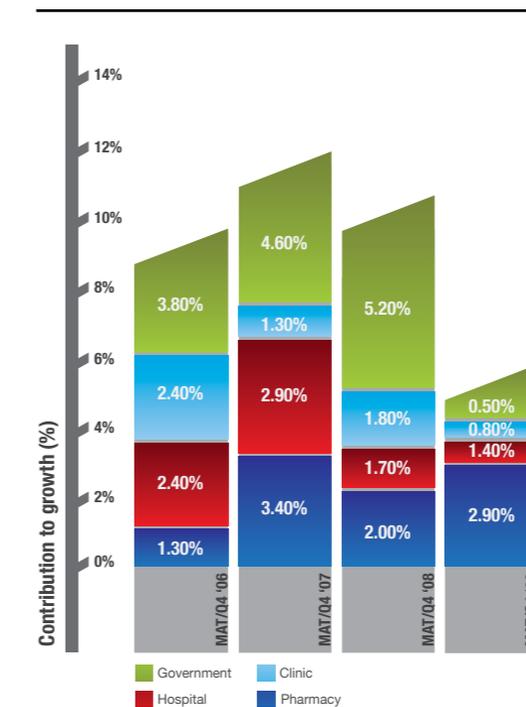


Figure 7 : Contribution of Different Sectors to Malaysia's Pharmaceutical Market Growth Rate
Source: IMS Health, 2010

Sales Channels

Malaysia's pharmaceutical industry has four major distribution outlets, namely the Government, pharmacies, clinics and private hospitals. In 2009, the share of these four markets was:

Government	38%
Pharmacies	23%
Clinics	22%
Private hospitals	17%

Healthcare in general has been identified by the Government as one of 12 National Key Economic Areas that will help achieve its Economic Transformation Programme. The pharmaceutical industry in particular is one of four sectors within healthcare that have been targeted to increase the nation's gross national income (GNI). The aim is for the industry to increase its GNI contribution by 22%, delivering a total of RM16.6 billion by 2020. The government has identified 9 Entry Points Projects to drive this GNI contribution.

⁹ Economic Transformation Programme, A Roadmap for Malaysia

Increasing Productivity, Reducing Costs

Malaysians get to benefit from such cost and time-intensive research, as all leading **multinational pharmaceuticals** have a presence here and bring into the country their best, **most efficacious drugs.**

Among the industry's most significant contributions to the country's economic development is increasing productivity across the board by ensuring a healthy and vibrant workforce. Better treatments and wellness therapies mean that employees are less likely to fall ill, and even when they do, the time taken to recover is faster. In addition, those with chronic ailments can better manage their health. As a result, the major recipients of medical bills – namely individuals, insurance companies and the Government – save on hospitalisation, treatment and medication costs.

The Pharmaceutical Research and Manufacturers of America (US PhRMA) reports that patients with congestive heart failure, hypertension, diabetes or dyslipidemia (lipid disorders including high cholesterol) have lower healthcare bills if they adhere to their medication regimes. Those with congestive heart failure are able to save US\$7,823 (RM23,958) in their annual

healthcare spend by taking their medicines regularly, while those with hypertension saved US\$3,908 (RM11,968), and diabetics and dyslipidemia patients saved US\$3,756 (RM11,502) and US\$1,258 (RM3,853) respectively.



More Jobs, Higher Tax Contribution

In a more direct fashion, the pharmaceutical industry supports the economy by providing highly rewarding employment opportunities to Malaysians. Though the pharmaceutical industry was also impacted by the recent economic downturn, it remains a lively job market, providing income to tens of thousands of Malaysians and leading to an increase in income tax contribution to the Government.

A PhAMA survey of 20 member companies showed that, in 2009, they employed an average of 191 staff (or a total of 3,820 staff) and paid an average of RM146.8 million in taxes. Of these companies, 15 were multinationals, offering their employees competitive salaries and attractive benefits, including the opportunity to advance professionally within their respective organisations. The branching out of pharmaceutical companies beyond central Peninsular Malaysia also means they are creating excellent job opportunities for suitably qualified Malaysians in semi-urban and rural areas, and helping to grow local economies all over the country.

For each direct job in the pharmaceutical industry, approximately three indirect jobs are supported in sectors such as professional services (eg finance, accounting, management and legal services); wholesale trade (eg raw materials), building services, food and retail, hospitals and clinics.¹⁰ Hence, just the 20 companies surveyed would have supported an additional 11,460 indirect jobs, providing a total of about 15,280 industry and industry-related employment opportunities. PhAMA itself has more than twice the

¹⁰Manufacturing FDI jobs: factor of 3

number of respondents of this survey, indicating a total industry-related job creation of more than 30,000 employment opportunities.

Pharmaceutical companies also utilise the services of various support industries such as travel, advertising/

media and printing, and contribute to the growth of these. In 2009, the 20 PhAMA members surveyed provided about RM162 million worth of custom to these industries.

Location Within MY	Number of Activities
Total	191
Central Peninsular of MY	130
Northern Peninsular of MY	20
Southern Peninsular of MY	18
East MY	15
East Coast Peninsular of MY	7

Figure 8 : Average Number of Employees per Pharmaceutical Organisation, 2009
Source: PhAMA Survey, 2010

Economic Contribution	Amount (RM million)
Travel Industry (ie airlines, hotels)	94.0
Printing Industry	48.8
Advertising/Media Industry	18.7
Others	0.5
Total	162.0

Figure 9 : Economic Contribution of 20 PhAMA members in 2009
Source: PhAMA Survey, 2010

A PhAMA survey of 20 member companies showed that, in 2009, they employed an average of 191 staff (or a total of 3,820 staff) and **paid an average of RM146.8 million in taxes.**

Building Research Capabilities



Being a heavily research and technology based industry that relies on innovation to create new drugs or improve the efficacy of existing ones, the pharmaceutical industry contributes significantly to the growth of a value-add economy fuelled by a technically skilled workforce in Malaysia. This supports the Government's vision, under the Economic Transformation Programme, of transitioning the country into the high-income bracket.

All multinational pharmaceutical companies are backed by very strong R&D traditions, as reflected in their ranking in the top most innovative pharmaceutical companies in the country. Some of these leaders in innovation are sharing their knowledge and expertise with local counterparts. Pfizer provides medical and academic partnership (MAP) grants and awards to support medical innovation in a wide range of disciplines, while GlaxoSmithKline and a number of other organisations provide internships to scientists interested in pursuing pharmaceutical research.



Ranking of Top Innovative PhAMA Members 2010

Rank	Innovative Organisations
1	PFIZER
2	GLAXOSMITHKLINE
3	MERCK SHARP&DOHME
4	SANOFI-AVENTIS
5	ASTRAZENECA
6	NOVARTIS
7	ELI LILLY
8	ABBOTT PHARMA
9	JANSSEN-CILAG
10	B.INGELHEIM
11	BAYER SCHERING
12	MERCK SERONO
13	SERVIER
14	SANOFI-PASTEUR

Figure 10 : Top Innovative Pharmaceutical Manufacturers in Malaysia
Source: IMS Health, 2010

Meanwhile, Novartis has signed agreements to expand its biodiversity research in Malaysia by partnering with the Sarawak Biodiversity Centre (SBC) and the Malaysian Biotechnology Corporation (BioTechCorp). At the same time, it will enable SBC scientists to further their research by undertaking internships at the Novartis Institute for Biomedical Research in Basel, Switzerland.¹¹ While enhancing local knowledge and research capabilities, this partnership will also better position the country as a biotechnology hub, supplementing the draw of our natural resources with confidence in the availability of a world-class research infrastructure to support the discovery and innovative use of bio-products.



¹¹Novartis Teams Up With Malaysia in Bioactive Compounds Research, Malaysian National News Agency, <http://www.bernama.com/bernama/v5/newsbusiness.php?id=455866> (retrieved 6 October 2010)

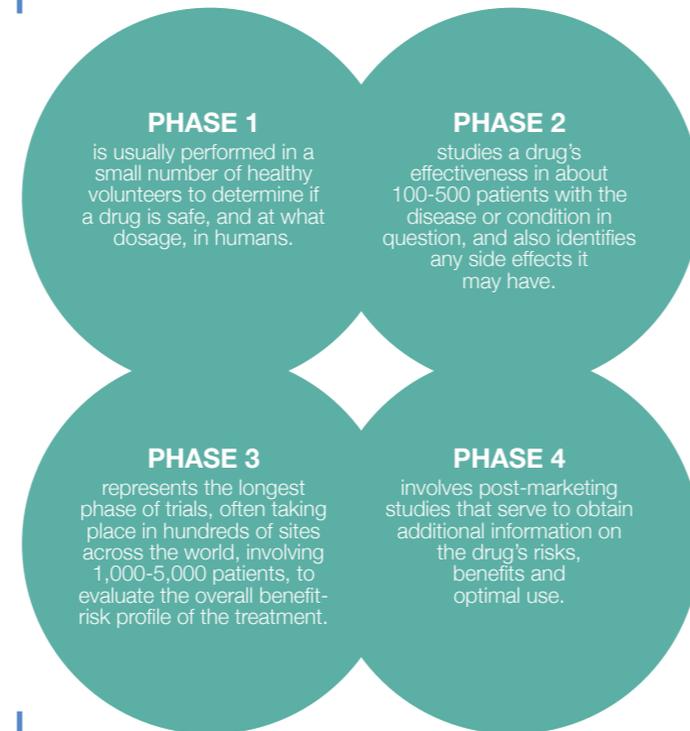
Creating a Clinical Research Culture

Clinical research is essential to test the efficacy of new drugs before they are launched into the market. This component of the upstream **pharmaceutical industry** is so important, it accounts for six to seven years of the total of about 15 years that it takes **to bring to market a new drug**.

Since 2007, multinational PhAMA members representing 26 companies have initiated a total of 160 trials in Malaysia, focusing primarily on cardiovascular diseases and cancer treatments. Of these, more than 100 Phase 3 trials are 'compassionate trials' in which the medication has been given in a compassionate manner to patients who require the relevant treatment and does not form part of a large scale, rigorous clinical trial process.

It is acknowledged, however, that more can be done to promote a more vibrant clinical research environment in the country, and the pharmaceutical industry is working with the Association of Clinical Research Professionals (ACRP) and Malaysia's Clinical Research Centre (CRC) to ensure the country has an adequate number of trained clinical research professionals.

Clinical trials are made up of four phases:



In 2011, CRC conducted a soft launch and membership drive for the Malaysian Chapter of ACRP. PhAMA itself is very supportive of the Government's intention – under the Economic Transformation Programme – to develop Malaysia as a clinical research centre in the region, and to increase the number of trials conducted from approximately 150 currently to at least 1,000 by the year 2020. The association has produced a White Paper outlining various gaps that exist in the current clinical trial ecosystem and how these can be addressed. It is the belief of the industry that there is vast potential for this niche sector to grow, both for the economic benefit to the country as well as to provide early access to the latest treatments to Malaysian patients.

Total yearly expenditure on clinical trials for key member companies alone have increased to 27% and the number of trials conducted also increased to 15% respectively in 2010.

Nonetheless, more efforts should also be spent in raising the Human Intellectual Capital, for example, with local investigators where more involvement, engagement and enhancing their scientific expertise to be on par with international standards. This will not only draws more investment of clinical trials to the country but also acts as an invaluable sustainability measure to balance and grow the said ecosystem.



Clinic Trials	Phase I	Phase II	Phase III	Phase IV
No of clinical trials in cardiovascular	0	3	20	13
No of clinical trials in oncology	0	4	13	14
No of clinical trials in Others (Endocrine)	0	7	11	2
No of clinical trials in vaccines	0	3	8	3
No of clinical trials in CNS	0	0	8	3
No of clinical trials in Others (Respiratory)	0	1	6	3
No of clinical trials in Infectious Disease	0	0	3	4
No of clinical trials in HIV	0	1	3	1
No of clinical trials in Others (Diabetes Mellitus)	0	0	5	0
No of clinical trials in Pain Management	0	0	1	3
No of clinical trials in Others (Inflammation)	0	0	4	0
No of clinical trials in Others (Urology)	0	0	3	0
No of clinical trials in Others (Women's health)	0	0	0	2
No of clinical trials in Others (Men's health)	0	0	1	1
No of clinical trials in Others (Nephrology/ kidney)	0	0	2	0
No of clinical trials in Others (Fertility)	0	0	0	1
No of clinical trials in digestive system	0	0	0	1
No of clinical trials in Others (Psychiatry)	0	1	0	0
No of clinical trials in Others (Not specified)	0	0	0	1
Total Number of Clinical Trials	0	20	88	52

Figure 11 : Number of Clinical Trials Performed in Malaysia since 2007
Source: PhAMA Survey, 2010

Exporting our Expertise

Malaysia has an advantage over other pharmaceutical manufacturing countries in the region by having attained global recognition for the quality of our products. In January 2002, the pharmaceutical industry was granted admission to the Pharmaceutical Inspection Co-operation Scheme (PICS), which has stringent requirements on manufacturing processes and systems as embodied by the Good Manufacturing Practices. According to the Malaysian Industrial Development Authority (MIDA), a total of 242 pharmaceutical premises with Good Manufacturing Practices certification have registered with the DCA. These certified premises produce vitamins, supplements and OTC and generic drugs, all of which can potentially be channelled towards the export market.

Currently, Malaysian pharmaceutical companies are exporting generic and OTC drugs to countries in Latin America, Asia-Pacific, the Middle East and Africa. They are also starting to venture into PICS markets such as the European Union, Australia and Canada. Meanwhile, vitamins manufactured in Malaysia are being exported to Singapore, Vietnam, Brunei, Hong Kong, Taiwan, India, Japan, Germany and certain countries in Africa and Central America.

The total export value of drugs from Malaysia stood at US\$131 million (RM399 million) in 2004 and has been growing at a CAGR of 5.4% from 2006 till 2013, according to Frost & Sullivan.

Developing Malaysia's Pharmaceutical Industry

As much as the pharmaceuticals industry has already developed, all indications point to further progress in tandem with a growing population and an increasingly ageing population that will have more disposable income to spend on improving their health and quality of life. Coupled with the Government's clearly outlined strategies to boost medical tourism in the country, create a thriving clinical trial ecosystem, and promote the export of generic drugs, there is every reason to deliver a positive prognosis on the pharmaceutical industry. Some of the more pertinent factors that will see to accelerated growth are highlighted below.

Targeting Growth in Production

The Malaysian Government provides Pioneer Status and Investments Tax Allowance incentives for local manufacture of pharmaceuticals and related products, including intravenous dialysis solutions, vaccines and medicaments. As the patents for a number of blockbuster drugs are to expire over the next 10 years, Malaysian pharmaceutical companies have the opportunity to focus more intently on generic production, which holds the potential of generating RM435 billion in exports.¹²

¹²The Economic Transformation Programme, Chapter 16

Growth-Friendly Intellectual Property Laws

Malaysia's intellectual property laws make it attractive for international pharmaceutical companies to operate in Malaysia. As a member of the WTO, Malaysia abides by the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), which is the most comprehensive international agreement on intellectual property to date. Moreover, as the Government seeks to grow knowledge-intensive industries to move the country to a high-income level, there will be greater focus on protecting the intellectual property of all research-based companies – both foreign and local. As it stands, all manufacturers – foreign and local – are protected by the Intellectual Property Corporation of Malaysia (MyIPO), while foreign companies are also covered by the Patent Cooperation Treaty (PCT), which protects their products for up to a year of having filed a patent in another PCT country, following which a local patent has to be filed. It is also acknowledged that enforcement of intellectual property rights in Malaysia is taken seriously, to engender a high level of confidence among multinationals who are marketing drugs that have billions of dollars of research behind their production.

Natural Haven for Clinical Research

Malaysia has a natural advantage over many other countries as a centre for clinical research given our multiracial composition, relatively low research costs, good infrastructure and the availability of trial participants. At present, however, the country ranks 6th after Japan, China, South Korea, Taiwan and Singapore in terms of clinical research.¹³ Between the years 2003-2009, the annual growth rate in clinical trials was 7-8% and only 100 clinical trials were conducted in the country in 2009.

As part of the initiatives under the healthcare NKEA, the Government aims for Malaysia to be a clinical trial hub in Asia by increasing the number of trials conducted per year to 1,000 by year 2020. A new corporatised entity, Clinical Research Malaysia (CRM) has been formed to support growth of this niche sector, which will receive a boost in the form of RM38 million in start-up investment. The objective is to draw RM4.3 billion from clinical research to the country's gross national income by year 2020.



Greater Health Spend

Malaysia continues to progress, and the national income grows, Malaysians will be able to spend more on their general health and well-being. The total expenditure on health (TEH) in Malaysia over the 11-year period from 1997 to 2008 more than quadrupled from RM8.21 billion to RM35.15 billion. By 2008, the TEH represented 4.78% of the country's Gross Domestic Product. The overall per capita health spend more than tripled from RM381 in 1997 to RM1,268 in 2008. Demand for pharmaceutical products will necessarily increase in tandem with healthcare spend.

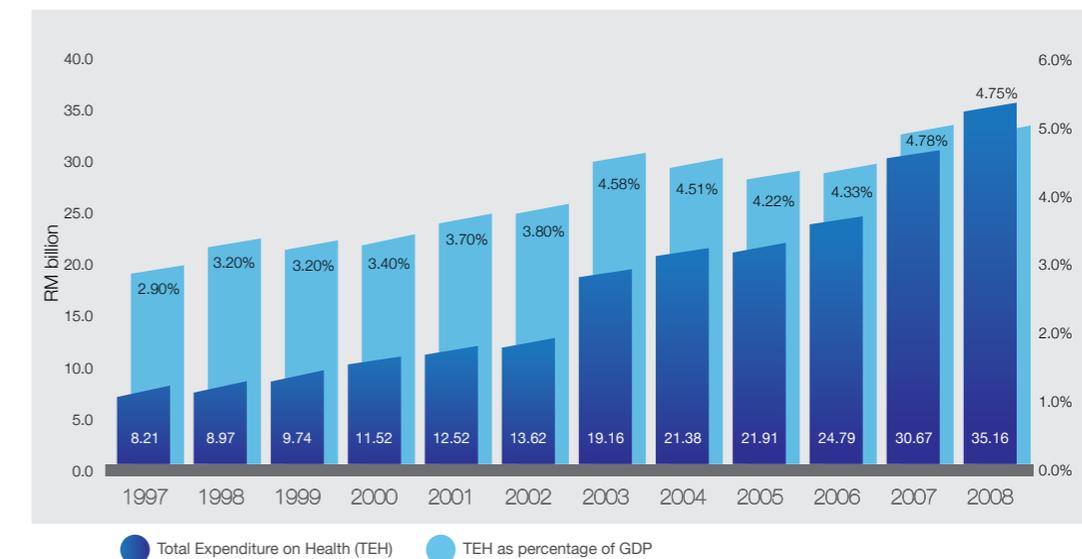


Figure 12 Total Expenditure on Health in Malaysia from 1997-2008
Source: IMS Health, 2010

¹³The Malay Mail, Malaysia to Position Itself as Region's Clinical Trial Destination, 2 June 2010, <http://www.mmail.com.my/content/38477-malaysia-position-itself-regions-clinical-trial-destination> (retrieved 3 August 2010)

Exploding Healthcare Needs

Malaysia's population is growing at roughly 1.8% a year, and is projected to reach 31 million by 2014 from 28.5 million in mid-2011. As the population increases, the number of potential patients will follow suit. What's more, the 65+ age group is expected to grow the fastest, at 4.4% on average per year. Along with an ageing population, there will be an increase in lifestyle diseases such as diabetes, cardiovascular disease and cancer, leading to greater demand for quality healthcare.

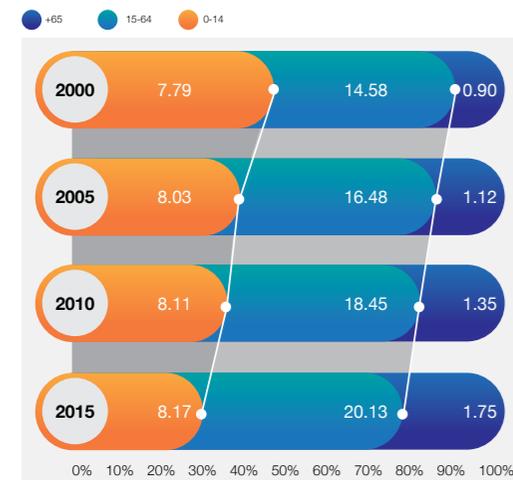


Figure 13. Malaysian Population by Age, Past & Forecast
Source: Economics Intelligence Unit

Heightened Medical Tourism

Medical tourism is burgeoning in Asia, and is projected to be worth at least US\$4 billion (RM12 billion) by 2012. This niche sector is even more profitable for the local economy than normal tourism as medical tourists spend on average double the amount of normal tourists – US\$362 (RM1,093) compared with US\$144 (RM435) per day. Malaysia is emerging as a value-for-money destination for foreign patients as we present world-class health and medical facilities at affordable rates. From 2003-2008 the healthcare travel industry in the country grew at a consistent rate of 38% per annum, but dropped in 2009 due to the global economic crisis.

Medical tourism is another focus area in the healthcare NKEA, and the Government has planned various initiatives to boost the number of foreigners coming to the country for treatment. The objective is to attract higher value customers by offering specialised treatments catering to their needs. The Government is targeting 1.9 million health tourists in 2020, who are expected to contribute RM9.6 billion in revenue to the country.

Emerging Trends

Growing Interest in the Halal Market

Over 20% of the world's population is Muslim and currently account for a halal pharmaceutical market of more than US\$650 billion (RM1,962 billion). As an Islamic country with a sound base in the industry while being a leader in the international halal food trade, Malaysia is well-positioned to make the most of growing global demand for halal-certified pharmaceutical products. The Government is mulling the launch of manufacturing guidelines of halal medicines and industry players will undoubtedly collaborate with the Government in this endeavour.

Tapping the Biologics & Biogenics Sector

Over the last couple of decades, an increasing number of drugs has been made using bioactive compounds from plants and animals. These biologics are superior to chemical drugs in treating cancer, AIDS, Alzheimer's and other life-threatening diseases. However, they are also more challenging to make as no two natural compounds are exactly the same, and all biological compounds are sensitive to the manufacturing environment, such as temperature, light and pollutants. Because they are complex, these drugs are far more expensive than purely chemical therapeutics, hence there is much interest in the production of generics. Given Malaysia's biodiversity, the biogeneric sector represents an as yet untapped potential to advance



the local pharmaceutical industry to the next level. Worldwide, revenues from biologics have been growing at an annual average rate of 20% since 2000 and this demand will likely further accelerate in coming years.¹⁴ According to the Generic Pharmaceutical Association of the US, more than 150 biologic medicines are currently available, and it is expected that nearly half the products approved by FDA by 2012 will be biopharmaceuticals.

¹⁴The Potential American Market for Generic Biological Treatments and the Associated Cost Savings by Robert J. Shapiro with Karan Singh and Megha Mukim, February 2008

Health & Food Supplements

Greater awareness of health issues and the availability of more disposal income has led to an increase in the consumption of health and food supplements. In 2010, the health and food supplements sector in Malaysia was estimated to be worth RM2 billion¹⁵, and all indicators point to continued growth of this sector.

This sector complements the pharmaceutical sector in improving the general health and well-being of Malaysians, and also has significant economic impact on the country's balance of payments. Malaysia exports quite a sizeable volume of health and food supplements to Singapore, Vietnam, Brunei,

Hong Kong, Taiwan, India, Japan, Germany, and destinations in Africa as well as Central America¹⁶. In 2005, the export and import value of products in this sector was almost equal in share, however there is potential for exports to overtake imports in the near future.

¹⁵Malaysia Poised For A Great Leap, Biospectrum Asia Edition: <http://www.biospectrumasia.com/content/100510MYS12627.asp> (retrieved 3 August, 2010)

¹⁶Frost & Sullivan Report, 2008

PAVING THE WAY FOR INDUSTRY EXCELLENCE WITH CONTINUOUS IMPROVEMENT

By Co-chairs of Policy Committee, PhAMA



Angel Choi
Country Manager



Pfizer Malaysia

Malaysia continues to be an attractive market for multinational pharmaceutical companies to invest in, especially now with the ETP initiatives and emphasis on clinical trials and medical tourism. However, in order for MNC investment to be meaningful for the country, the regulatory framework including related regulatory guidelines has to be more supportive of foreign investment. In particular the timelines for regulatory processes could be further improved, for example the time taken for product registration and approval. It would also help if formulary listing process for medicines can be accelerated and streamlined to improve access of medicines for patients. Finally, the initiative to introduce the Pharmacy Bill should be expedited as this will make Malaysia more competitive in the Region. The industry fully supports the Government's initiatives and is committed to engage more proactively with the relevant departments so as to achieve a win-win solution.

Avinash Potnis
Country President



Novartis Malaysia

Although the number of clinical studies being conducted in Malaysia has grown over the years, the rate of growth here is not as high as in other countries in Asia. To prevent this gap from further expanding, and to provide global sponsors compelling reasons to invest and conduct clinical trials in Malaysia, a few critical areas must be reviewed and taken into consideration. For example, regulatory review timelines could be made shorter for new chemical entities (NCEs) that have been tested in Malaysia as part of global studies. Such drugs could also be given priority review in the Blue Book and hospital formulary listing, while patients involved in the trials should be allowed continued access to the NCEs that they have been treated with.

Muru Annamalai
General Manager



Abbott Pharmaceuticals

While intellectual property (IP) laws in Malaysia have been developed to meet higher standards, certain issues such as patent linkage, data exclusivity and patent term restoration are still in their infancy or have yet to be incorporated. These IP functions are essential to attract more innovative drugs to be launched in the country for both physicians and patients to access new, innovative drugs to improve and save lives. This will further support Malaysia's quest to transform into a high income country. Towards this end, it is also important to review IP Rights and include those provisions relating to the pharmaceutical industry and continue to improve and adapt to international standards.



APPENDIX / List of PhAMA Members /

- | | | |
|--|---|--------------------------------|
| 1. Abbott Laboratories (M) Sdn Bhd (Pharmaceutical Division) | 18. IDS Service (M) Sdn Bhd - Pharma Division | 36. Sanofi Aventis (M) Sdn Bhd |
| 2. Antah Pharma Sdn Bhd | 19. IMS Health (M) Sdn Bhd | 37. Schmidt BioMedTech Sdn Bhd |
| 3. AstraZeneca Sdn Bhd | 20. Inova Pharmaceuticals (S'pore) Pte. Ltd. (M'sia Branch) | 38. Servier (M) Sdn Bhd |
| 4. Baxter Healthcare (M) Sdn Bhd | 21. Ipsen Pharma -Intercontinental Operations | 39. Summit Co (M) Sdn Bhd |
| 5. Bayer Co. (M) Sdn Bhd | 22. Janssen-Cilag | 40. Sun Pharmaceutical (M) S/B |
| 6. Blackmores (M) Sdn Bhd | 23. Johnson & Johnson Sdn. Bhd. | 41. United Medica Sdn Bhd |
| 7. Boehringer Ingelheim Div, Diethelm (M) S/B | 24. Leo Pharma M'sia | 42. Zuellig Pharma Sdn Bhd |
| 8. Cambert (M) S/B | 25. Lundbeck Malaysia | |
| 9. Delfi Marketing Sdn Bhd | 26. Merck Sdn Bhd | |
| 10. DKSH Malaysia Sdn Bhd | 27. Merck Sharp & Dohme (I.A) Corp. | |
| 11. Eisai (M) Sdn Bhd | 28. Novartis Corporation (M) S/B | |
| 12. Eli Lilly (M) Sdn Bhd | 29. Novo Nordisk Pharma (M) S/B | |
| 13. Emerging Pharma Sdn. Bhd. | 30. Nycomed | |
| 14. Genzyme Malaysia Sdn. Bhd. | 31. Pfizer (M) Sdn Bhd | |
| 15. GlaxoSmithKline Consumer Healthcare S/B | 32. Pharmaceutical Regulatory Services | |
| 16. GlaxoSmithKline Pharmaceutical S/B | 33. Invida (S'pore) Pte. Ltd. (Malaysian Branch) | |
| 17. Hospira (M) Sdn Bhd (formerly Mayne Pharma (M) Sdn Bhd) | 34. Primabumi Sdn Bhd | |
| | 35. Reckitt Benckiser (M) Sdn Bhd | |

Forming strategic health partnership with key stakeholders for the advancement of public health.

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