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Research Article

BUSINESS MODEL BASED PRICING STRATEGY FOR PHARMA PRODUCTS IN SOUTHEAST ASIAN REGION

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ABSTRACT

Purpose To study pharmaceutical product procurement and pricing system in Southeast Asian countries and challenges, factors influencing and industry practices of the pricing.

Methodology Study was carried out based on secondary data published in various journals, domain knowledge of the author and industry experts' inputs on the various business models and pricing practices.

Findings Factors influencing pharmaceutical products pricing in markets under study including the government policy, distribution practices, selling expenses and industry practices.

Research implications This article provides generic observations of product pricing in the context of prevailing regulatory and business environment. Individual strategies differ based on country, company, business model product and market strategy. Further study can be taken up to decide a product pricing model for individual model

Practical implications Provides basic reference for healthcare system, pharma product procurement practices and pricing strategies for industry and academia.

Social implications Helps Industry and regulatory authorities in rationalising the generic drugs prices and increase the access to affordable medication which will address unmet needs of patients

Originality It is an original study carried out to understand and review on how industry is arriving at a business model based pricing for pharma products in Southeast Asian countries.

Key words: Southeast Asia pharmaceutical market; Pricing strategies; Pricing models for pharmaceutical products; Procurement of pharmaceuticals

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Introduction

The term Southeast Asia was first used to define "War Theatre" during the Second World War.¹ As such, unlike some other regional descriptions, it is not a term with long or resonant history. Southeast Asia is a regional intergovernmental organization of 10 countries across Southeast Asia and its member

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countries are Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Burma, Philippines, Singapore, Thailand, and Vietnam. Southeast Asia was initially formed by the leaders of Indonesia, Philippines, Singapore, Thailand, and Malaysia following the signing of the Southeast Asia declaration on August 8, 1967. Later remaining countries joined. Southeast Asia also adopted a written constitution known as the Southeast Asia charter in 2007. This charter established the Southeast Asia group as a legal entity creating permanent representation for its members at its secretariat in Jakarta, Indonesia and committed member heads of state to twice-yearly meetings.

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Among the 10 Southeast Asian countries for the consideration of generic market, five countries are taken into study to estimate the pharmaceutical pricing nature. There is a larger scope for the growth of pharmaceutical market in those five countries. Indonesia is the largest pharmaceutical markets in the South-East Asian region followed by Thailand, Philippines, Vietnam, and Malaysia. Pharmaceutical companies in Southeast Asia are viewed as secondary to traditional markets due to their lower purchasing power and overall health system maturity². Demographic and economic indicators are illustrated in Table 1. PESTEL analysis of all 5

countries illustrated in Table 2 indicates that these countries have enormous potential yet pose lot of challenges.

Table 1. Demographic and economic indicators of select countries in Southeast Asia³ Country GDP Per HDI(2015) Capital Population GDP(2016) (2015)(Statistic capita Source: UNDP Times 2015) (2016) 257.563.815 3.511\$ 0.684 895.677.000.000 Jakarta Indonesia Thailand 67,842,669 437,344,000,000 5,697\$ 0.722 Bangkok Philippines 100,699,395 369,188,000,000 3.568\$ 0.668 Manila Vietnam 2.370\$ 0.638 93 447 601 187 848 000 000 Hanoi Malaysia 30,116,502 367,712,000,000 13,123\$ 0.773 Kuala Lumpur

Country	Political	Economical	Social	Technological	Ecological	Legal
Malaysia	1.NSC bill give more power to authorities to tackle violent extremism 2. Increasingly progressive government policy aimed at attracting international investment	Per capita health expenditure is very high when compared with other countries in Southeast Asia	1.The demand of traditional halal medicines has been increasing extensively 2.An attractive location for medical tourism	The commencement of first medical device clinical trial for automatic peritoneal dialysis device takes place which is a major reform	Malaysia faces problem of deforestation, soil erosion, pollution of inland and marine waters	Lax patent law remains conspicuously below international standards Strict government drug pricing policy heavily biased towards local drug
Indonesia	1.Trying to reduce bureaucratic red tape 2.Political infighting due to vested interest and nationalistic sentiment 3. No comprehensive reimbursement coverage, nor private insurance schemes	1. Per capita health expenditure is very low 2. Expenditure on health is not increasing rapidly when compared with other countries in Southeast Asia	1.Low purchasing power of the large sector of population 2. Demographic profile is relatively young and senior citizens account for 5% of total population	Biopharma wants to share its vaccine technology with the country	Indonesia is especially prone to the onslaught of natural disasters	producers 1. Biased regulatory system favors local drugs 2. Taxes on raw materials lowered as a part of trade agreements
Thailand	Risk of further deepening of the political division and the country and leads to Myanmar's style authoritarianism	1. High per capita expenditure compared with some countries in Southeast Asia 2. Decreasing healthcare expenditure since 2010	Fast growing population with a presently low level of drug consumption 2.Majority of population in the age of 25-60	1.Contract manufacturing is viewed as an enormous opportunity 2. The local industry has learned and improved greatly in the last 5 years with respect to the GMP standards	Increased burden of air pollution due to various uncontrolled factors in the country	1.Law of patents relates to intellectual protection of new drugs 2.Drug act 1967 sets out a regulatory regime for the supervision of drug production
Philippines	Security risks will continue to deter investment and economic development 2. Government failed to revise its discriminating pricing policy and price caps	Low per capita expenditure suggesting majority chunk of population cannot afford to buy medicines 2. Health Expenditure has been increasing at a CAGR of 8% over the past few years. It shows the country's concern towards the health	A large and growing population coupled with low per capita levels of drug consumption 2.A high younger population compared to other age groups 3. Family planning legislations could keep a control on population in years to come	Centre of excellence for clinical trials has been set up in the country 2. Dengue test kit. innovated by local people that could diagnose in dengue in an hour	Natural Disasters such as floods coupled with inadequate infrastructure reduce mobility across regions	1.Legislation allowing faster entry of generic products into the mark 2.Four major laws affecting are: a. Generic Drugs act of 1988 b. Local government code of 1991 c. National Health Insurance act of 1995 Universally accessible cheaper and quality medicines act of 2008
Vietnam	The upcoming leadership is unlikely to make dramatic changes in the country's policies	1.Very low per capita health expenditure 2. High import rate which is increasing year by year	Preference to opt for traditional medicines A good chunk of people take the advice of unlicensed pharmacists instead of doctor's prescription	1. Opening of cyclotron 30 Mev acceleration center at military hospital 108 for diagnosing and treating cancer 2. Electronic insurance records are available from 2010 to book appointments and seek health and pharmaceutical information	Land degradation, afforestation, and increasing air pollution	1.Membership in WTO resulted in minor improvement to the country's intellectual property regime 2.Vietnam has local clinical trial requirements for newly developed pharmaceuticals

Research Methodology

The entire research is done using secondary data from the published articles, journals, tender documents, websites and business analytical reports available on the internet. Author also approached some industry experts to understand some of the complexities and models whenever required. This research seeks to describe the current status of pricing approach in the Southeast Asian countries. The authors did not formulate any hypothesis and used secondary data during this research.

Healthcare Overview of Southeast Asian countries

Indonesia

Indonesia's healthcare system is decentralized and organized on a number of levels including provincial, district and sub district. Each sub-district is served by at least one healthcare centre, run by a doctor and a few sub centers usually by nurses. Most of the centers have mobile service units. The Ministry of Health retains central control of the provisional healthcare, while also determining the National Health Policy and supervising National Health Programs.

A public healthcare programme for the poor Jamkesmas was started in the year 2008 replacing the previous Askeskin programme. According to Indonesia's statistics as of 2015, 68% of the population was covered by various health insurance schemes such as Jamkesmas for those on low incomes, Badan Penyelenggara Jaminan Sosial (BPJS) and schemes established by the private health insurance.⁴

Healthcare indicators

Table 3: Healthcare indicators of Indonesia Life expectancy at birth Male Female Female Maternal mortality rate per 100000 live births Total expenditure on health as % of GDP Private expenditure on health as % of total health expenditure Government expenditure on health as % of total health expenditure 39.6

Medical Procurement system

Ever since January 2014, Indonesia has implemented below mentioned two important reforms in pharmaceutical sector in an attempt to improve medicine procurement system

Formularium Nasional (FORNAS)

The new national formulary of medicine containing list of molecules aims to support cost-effective and rational use of medicines

E-Catalogue

E-catalogue is a transparent system that allows centrally negotiated prices for four respective regions to be made available online. The system allows anyone to view these prices through their website. The e-catalogue implementation has been well appreciated due to its transparency.⁶

Thailand

Healthcare system in Thailand is an entrepreneurialin nature and works with the assistance of public and private providers'. Public health facilities were rapidly expanded nationwide since 1961 when Thailand launched its first five-year national economic and social development plan. Private hospitals also play a key role in health services; however, they are mostly in urban areas. Health policies for continuous improvements of economic growth and for promoting government during the "cold war" period are major drivers for expansion of public health facilities nationwide.⁷

Healthcare financing in Thailand has a long history of evolution of nearly half a decade until Thailand reached the universal healthcare coverage in 2002. It started from user fee exemption and changed to out of–pocket payment to pre-payment system. Various forms of prepayment systems were introduced and tested in Thailand. These implementations led to huge differences in terms of contribution, public subsidy, benefits and quality of services.

The ultimate goal of the Universal Health Coverage (UHC) implementation is to cover all population. In the past decade, the national UHC coverage of Thai citizens in Thailand has increased dramatically from 71% in FY2001 to 92.47% in FY2002 while implementing the UHC policy, and to 99.84% in FY 2014. This coverage did not include stateless group living in Thailand, Thai citizens living aboard, and other foreigners. The number of Thai citizens who were eligible to enroll to the universal coverage scheme (UCS) but did not enroll in FY2014 were 105,184 people (0.16% of all population). However, the eligible non-registered group was to access health services at any health facility registered to the UCS when they needed. They were also allowed to register to the UCS and select their respective contracting unit near their home. The main government health insurance schemes, i.e., Civil Servant Medical Bene? t Scheme (CSMBS), Social Security Scheme (SSS), and the Universal Coverage Scheme (UCS), coverage of

every scheme in the past decade have increased. A proportion of each government schemes in FY2014 was 73.80% of the UCS, 16.73% of the SSS, 7.11% of the CSMBS, and the rest were other small government schemes such as local administration offices and non-enrolled group.

Healthcare Indicators

Table 4: Healthcare indicators of Thailar	าd⁵
Life expectancy at birth	
Male	71
Female	79
Maternal mortality rate per 100000 live Births	21
Total expenditure on health as % of GDP	3.4
Private expenditure on health as % of total health expenditure	20.5
Government expenditure on health as % of total health	
expenditure	79.5

Procurement of Medicines

Hospitals are supposed to purchase according to a 3-year procurement plan that they must develop. However, in reality many hospitals purchase as per their annual needs. If the amount of procurement was 100,000 Bahats or more, then a tendering process was undertaken and a procurement committee formed. Thus, many hospitals procure lesser amount of medicines frequently 1 week. For some drugs, hospital in a province or region underwent pooled procurement. In the case of 1 region, 4 provinces group together to purchase 100 items, each province undertaking actual procurement of some of the items after having conducted the procurement process together. Drugs are supplied directly from supplier to the facility.⁸

Philippines

Eight years ago, the National Health Insurance program paid only eight of every 100 people's health expenses. Patients could not avail insurance benefits because of availability of only few accredited health facilities and doctors in the community. In 2007, only 4 in every 10 Barangay as had health stations. Thus, Philippines lagged behind other countries in achieving health-related UN Millennium development goals, especially those related to maternal and child mortality. A universal healthcare program was then crafted to ensure that the poor receive health insurance and access healthcare from the best possible public health facilities and welltrained health workers. The passage of the Sin Tax reform law has ensured that the government has enough resources to fund its healthcare agendas.

President Benig no Aqua III signed the Republic Act 10606, or the National Health Insurance Act of 2013

on June 19. The act mandates compulsory National Health Insurance in all provinces, cities and municipalities. In January 2006, the government launched medical tourism programme with the aim of making the country a regional healthcare center. The country is trying to emulate India, Malaysia and Thailand each of which has a medical tourism industry worth 1Bn \$ a year.

Health status has improved dramatically in Philippines over the last forty years: infant mortality has dropped by two thirds; the prevalence of communicable diseases has fallen and life expectancy has increased to over 70 years. However, considerable inequities in healthcare access and outcomes between socio-economic groups remain.⁹

A major driver of inequity is the high cost of accessing and using healthcare services. Philippines has had a national health insurance agency – Phil Health – since 1995 and incrementally increased population coverage, but the limited breadth and depth of coverage has resulted in high-levels of out of pocket payments. In July 2010, a major reform effort aimed at achieving 'universal coverage' was launched, which focused on increasing the number of poor families enrolled in Phil Health, providing a more comprehensive benefits package and reducing or eliminating co-payments.

Attracting and retaining staff in under-served areas is key challenge. Philippines is a major exporter of health workers, yet some rural and poor areas still face critical shortages. Inefficiency in service delivery persists as patient referral system and gate keeping do not work well.

Successive reform efforts in financing, service delivery and regulation have attempted to tackle these and other inefficiencies and inequalities in the health system. But implementation has been challenged by the decentralized environment and the presence of a large private sector, often creating fragmentation and variation in the quality of services across the country.

Healthcare Indicators

Table 5: Healthcare indicators of Philippines⁵ Life expectancy at birth Male 65 Female 72 Maternal mortality rate per 100000 live Births 114 Total expenditure on health as % of GDP 3.2 Private expenditure on health as % of total health expenditure 3.3 Government expenditure on health as % of total health expenditure expenditure 69.2

Procurement system

Medicines must be registered with the BFAD prior to marketing which issues them with a certificate of product registration. Medicines are commonly sold as Individual units. Government procurement of medicines in Philippines is subject to the Government Procurement Reform act (RA 9184/2003:GPR Act) which stipulates the procedures and methods to be used in the public procurement. All procurements are supposed to be based on competitive bidding except in cases of emergency. Alternative methods came in to force in the procurement, limited source bidding and direct procurement methods are set as alternative methods. When these two procurement methods fail then negotiated procurement comes into effect. The Act also initiated a central electronic system for advertising tenders. The system is popularly known as PHILGEPS. 10

Central DOH procurement

Since 1992 the procurement of medicines was largely the responsibility of local government units. DOH retained hospitals and some CHDS performed their own public bidding. The DOH, through the Central Office Bids and Awards Committee, undertakes limited central procurement for vertical programs e.g. Tuberculosis and Vitamin A supplementation

Vietnam

The government of Vietnam is clearly committed to universal coverage and has approved a number of important laws relating to health financing and health insurance. In addition to some good healthcare indicators, there are impressive achievements to Vietnam's health financing system, namely a population coverage rate of 60% continuous commitment to state subsidized premium payments and developments in the payment systems.

Vietnam has a mixed delivery system, with the public-sector dominant in the provision of hospital care services. Like a lot of countries, Vietnam has a public system that is based on a pyramid model with four levels. The private sector appears to have grown in recent years, with drug vendors and general practitioner clinics being the largest groups of registered private providers but the private hospital sector is highly undeveloped. There are around 170

private hospitals on a total of 2,150 hospitals and they represent 6% of the number of total hospital beds in Vietnam. These private hospitals are principally located in major cities. Vietnam has in total 21 hospital beds per 1,000 populations. ¹¹ The healthcare administration in Vietnam is organized in a three-level system. The territory level is the ministry of health-the main National authority in the health sector which formulates and executes health policy and programs in the country. At provincial level, there are 63 provincial health bureaus which follow MOH policies but are in fact organic parts of the provincial local governments under the Provincial People's Committees (PPCS). The primary level or basic health network-includes district healthcare centers, commune health stations and village health workers.

Healthcare Indicators

Table 6: Healthcare indicators of Vietna				
Life expectancy at birth				
Male	71			
Female	80			
Maternal mortality rate per 100000 live births	59			
Total expenditure on health as % of GDP	4.9			
Private expenditure on health as % of total health expenditure	42.6			
Government expenditure on health as % of total health				
expenditure	57.4			

Procurement of Medicines

There are two ways of conducting public drug procurement in Vietnam: (i) tenders by individual state owned hospitals and (ii) centralized tenders. Currently, centralized tenders are only conducted at the provincial level, where the provincial Department of Health (DOH) is responsible for organizing the tenders and choosing the winning bids. All hospitals under a provincial DOH are required to use the tender results from the DOH to purchase drugs used in their establishments. Individual state-owned hospitals under the Ministry of Health (MOH) organize tenders and choose winning bids by themselves. However, according to the defined roadmap, centralized drug tenders will be held at the national level starting in 2016 and the MOH, not the DOH, will be responsible for organizing them. There are still no detailed guidelines for centralized tenders at the national level.12

As of Jan 1, 2009, in line with the WTO's commitments, foreign investors have been allowed to establish a wholly owned foreign company to import or export pharmaceutical products and sell their imported products to local licensed

distributors. In order to import pharmaceutical products, foreign organizations have to depend on local distributors. In order to procure medicines centralized tender process is the most important part of the pharmaceutical and medical device market. In its most basic form the tender process is a government-organized and run bidding and procurement mechanism that is designed to select drug and device products that are characterized by an optimal balance between high quality on the one end and low pricing on the other. In total, it comprises more than 90% of the drug and medical device market.

Malaysia

Malaysia has made great gain in life expectancy for its people. Between 1970 and 2008, the life expectancy in women increased from 65.6 to 76.4 years, while for men the increase was from 61.6 to 71.6 years. Current life expectancy is more than that of uppermiddle income countries, but below high-income countries. Malaysia is undergoing an epidemiological transition with the causes of mortality shifting from communicable to non-communicable diseases. Most deaths in Malaysia are from non-communicable diseases, with diseases of the circulatory system. Malaysia needs better mortality data since some deaths are not medically certified.¹³

Malaysia's health system is mainly financed through general taxation and revenue collected by the Federal government while the private sector is financed through private health insurance and out-of-pocket payment systems from the consumers. Health expenditure remains below the average for upper middle-income countries. Health expenditure has remained predominantly public spending at 55% of total health expenditure. Malaysia faces the challenge of rising public expectations and increasing health expenditure, as do most middle and upper income countries, prompting the government to consider options for future sustainable financing. The government set out ambitious goals for the health system in its 'Vision for Health'. Through this vision, Malaysia is all set to be a nation of healthy individuals, families and communities through a health system that is equitable, affordable, efficient, technologically appropriate, and environmentally adaptable and consumer friendly.

Healthcare Indicators

Table 7: Healthcare indicators of Malays	ia⁵
Life expectancy at birth	
Male	72
Female	64
Maternal mortality rate per 100000 live births	41
Total expenditure on health as % of GDP	3
Private expenditure on health as % of total health expenditure	44.8
Government expenditure on health as % of total health	
expenditure	55.2

Procurement of Medicines

100% online procurement system is available in Malaysia. Most of the medicines are generally procured through open tendering process. Sometimes procurement takes place through competitive tendering. On time, renewal of contract, pharmacy home delivery systems are very much prevalent in Malaysia. 14

Pharma market dynamics of select countries in Southeast Asia

Pharmaceutical market dynamics, growth, channels of business etc., are shown in Table 8.

Table 8: Ph			_	ics of	select
countries in	Southe	ast As	ia		
Parameters	Indonesia	Thailand	Philippines	Vietnam	Malaysia
Pharmaceutical	5.79	4.465	3.17	4.219	2.015
sales(2015)USD Bn					
2016(f)USD Bn	5.98	4.548	3.285	4.608	2.048
2017(f)USD Bn	6.410	4.832	3.401	5.057	2.323
2018(f)USD Bn	7.420	5.119	3.593	5.640	2.606
Per capita pharma					
expenditure (2015)	22.47	65.814	31.47	45.148	66.9
Prescription Drugs					
Sales(USD Bn)	3.534	3.568	2.232	3.108	1.48
OTC Drugs Sales	2.109	0.893	0.8559	0.9262	0.60
Generic Drugs					
Sales	2.394	2.2325	1.3948	2.184	0.68
Patented Drugs					
Sales	1.158	1.3395	0.8559	0.9262	0.80
Imports(USD Mn)	457.41	1919.95	951	2742.35	1430.65
Exports(USD Mn)	532.68	370.595	634	143.446	221.65
Source: Business Monito	r Internationa	al 2016			

Pharmaceutical Sector overview of Southeast Asian countries Indonesia

The growth of the Indonesian pharmaceutical market will be supported by the government's quest for better healthcare provision and the industry's desire to capitalize on these healthcare initiatives and raising inflation. Compared to its other Asia Pacific neighbors, Indonesia's market is small, especially in terms of per capita spending. The Robust expenditure growth along with rapid growth of population will continue to provide substantial income to companies operating in the country. OTC

products are regarded as "preventive" medicines. Therefore, these are popular in Indonesia given the low purchasing power and limited availability of prescription drugs. However, the roll-out of JKN programme could further increase the contribution of prescription drugs especially generic ones when all Indonesians are covered in 2019. Healthcare expenditure and pharma market dynamics is illustrated on Table 9 and Figure 1.

Table 9: F	Pharn	naceu	ıtical	and	Healtl	ncare	fore
casts of In	done	sia					
Parameters	2014	2015	2016 (f)	2017 (f)	2018 (f)	2019(f)	2020(f)
Pharmaceutical							

sales(USD Bn)	5.930	5.790	5.980	6.410	7.420	8.750	9.720
Pharmaceutical sales % of GDP	0.67	0.66	0.66	0.65	0.64	0.63	0.62
Pharmaceutical sales % of health							
expenditure	23.5	23.7	23.9	24.0	24.2	24.3	24.5
Health spending (USD Bn)	25.290	24.490	25.080	26.660	30.700	35.990	39.760

Source: Business Monitor International 2016



Fig. 1: Spending on pharmaceuticals vs. healthcare spending in Indonesia

Thailand

In 2015 Thailand's Pharmaceutical market reached to 4.465Bn\$ making a return to positive growth. Over the 2015-2020 forecast period the pharmaceutical market of Thailand is expected to be at 5% CAGR. The higher value of imported drugs over domestically produced medicines will remain a feature of the Thai Pharmaceutical market over the forecasting period, despite the sizeable counterfeit activity in the country, government preference for generic and domestically produced drugs and the Healthcare economics requirements imposed on patented drugs. During the same period, the imports are expected to grow faster.

The innovative pharmaceutical industry is gravely concerned about recent actions of the Royal Thai Government that have seriously undermined patent protection in the Kingdom of Thailand. The Thai FDA does not have a formal patent linkage system to prevent the regulatory approval of copy versions of

pharmaceuticals that are still covered by patent. In recent years, there has been a marked increase in the number of copy products receiving Thai FDA approval while the original product is still under patent. This imposes a significant cost on PHRMA member companies. ¹⁶ Healthcare expenditure and pharma market dynamics is illustrated on Table 10 and figure 2.

Table 10: Pharmaceutical and Healthcare forecasts of Thailand									
Indicator	2014	2015	2016(f)	2017(f)	2018(f)	2019(f)	2020(f)		
Pharmaceutical sales(USD Bn)	4.480	4.465	4.548	4.832	5.119	5.445	5.786		
Pharmaceutical sales % of GDP	1.11	1.13	1.15	1.14	1.13	1.12	1.11		
Pharmaceutical sales % of Health Expenditure	25.3	24.9	24.6	24.2	24.0	23.7	23.5		
Health Spending (USD Bn)	17.712	17.940	18.524	19.933	21.365	22.968	24.637		

Source: Business Monitor International 2016



Fig.2: Spending on pharmaceuticals vs. Healthcare spending in Thailand

Philippines

In 2015 Philippine's Pharmaceutical market reached to 3.17 Bn \$, a positive growth. When compared with patent market, the generic drug market is growing rapidly. Due to the bad governance in Philippines, pharmaceutical markets are enjoying profits to a huge extent. Philippines will see stable economic growth due to healthy investment activities and private consumption. Due to the mandating of National Health Insurance for all citizens in Philippines the health infrastructure is expected to grow extensively. Prescription medicines will continue to account for majority of the market with a share of 71%. Foreign companies account for the majority of sales in all therapeutic categories, a part from hospital solutions. Philippines is not a major exporter apart from the herbal medicines. The exports and imports balance is unlikely to change hugely due to the concentration of local markets. Raw materials were imported for the pharmaceutical products in a greater extent. 10 Philippines is planning to cut some of its tariffs for pharmaceutical products and lower those on raw material imports. This move should be popular with the local drug makers, as it will result in lower production costs, though the local sector may also face stiff competition. Healthcare expenditure and pharma market dynamics is illustrated on Table 11 and Figure 3.

Table 11: I casts of Ph			utical	and I	Health	ncare	fore-
Indicator	2014		2016 (f)	2017 (f)	2018 (f)	2019 (f)	2020(f)
Pharmaceutical				(//			
sales(USD Bn)	3.282	3.328	3.285	3.401	3.593	3.800	4.037
Pharmaceutical sales % of GDP	1 15	1 11	1.06	1 01	0.96	0.92	0.88
Pharmaceutical	1.10	1.11	1.00	1.01	0.90	0.92	0.00
sales %of Health							

20.2

193

19.659

18.7

21.634

Health Spending (USD Bn) 12.735 13.900 14.724 16.086 17.825 Source: Business Monitor International 2016



Fig.3: Spending on pharmaceuticals vs. health-care spending in Philippines

Vietnam

Expenditure

With the growing conception on healthcare and medical need of Vietnamese people, the revenue of the medicine industry keeps increasing. The average revenue growth during the period of 2009-2013 reached 18.8% per annual. This growth is opposed to other economic sectors during the current economic crisis period of 2008-2013. This is mainly because pharmaceutical products are essential and irreplaceable items.¹⁷

Generally speaking, the pharmaceutical market is still characterized by imported drugs. Domestic producers mostly focus on generic medicines while their export is relatively weak. Consumption of pharmaceuticals produced by domestic companies only stood at 1.9% Vietnam's GDP in 2015. Some of the challenges the Vietnam pharmaceutical market faces are the poor regulatory and intellectual property standards which allegedly added to hold back foreign investment in the country. Although foreign products are likely to dominate in the near future, domestic companies are expected to start investing in research and development (R&D) activities to build up infrastructure facilities that

meet international standards. The pharmaceutical industry in Vietnam faces barriers on price and policy. The high price is caused by the fact that Vietnam's pharmaceutical industry has to import raw materials while the other countries produce many of the key components themselves. Imports account for 65% of the total sales in the pharmaceutical sector where as exports are 3%. Export revenue is gradually increasing as export revenues have increased over the Years. Healthcare expenditure and pharma market dynamics is illustrated on Table 12 and Figure 4.

Table 12: casts of V			eutical	and	nealth	care	fore-
Indicator	2014	2015	2016 (f)	2017 (f)	2018 (f)	2019 (f)	2020 (f)
Pharmaceutical							
sales (USD Bn)	3.808	4.219	4.608	5.057	5.640	6.375	7.167
Pharmaceutical							
sales % of GDP	2.05	2.18	2.29	2.33	2.35	2.36	2.37
Pharmaceutical							
sales % of Health	า						
Expenditure	34.1	35.5	36.8	37.9	38.8	39.5	40.0
Health Spending							
(USD Bn)	11.159	11.875	12.513	13.332	14.524	16.127	17.911
Source: Business M	onitor Int	ernational	2016				



Fig.4: Spending on pharmaceuticals vs. healthcare spending in Philippines

Malaysia

Malaysia has an effective pharmaceutical industry which has contributed to the nation having one of the best World Health Organization (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 constrained multinationals to set up to only 20% the market. About 13% of the multinationals operating in Malaysia have set up local manufacturing operations, while a further 7% have manufacturing arrangements with local companies. Thus these multinationals are constrained to the import and market life-saving drugs.

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.¹⁸

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 fulfill the need for drugs to treat contemporary diseases such as high cholesterol, diabetes, cardiovascular ailments and cancer. Healthcare expenditure and pharma market dynamics is illustrated on Table 13 and figure 5.

Table 13: Pharmaceutical and Healthcare for	e-
casts of Malaysia	

Indicator	2014	2015	2016 (f)	2017 (f)	2018 (f)	2019 (f)	2020 (f)
Pharmaceutical sales(USD Bn)	2.206	2.015	2.048	2.323	2.606	2.883	3.167
Pharmaceutical sales % of GDP	0.67	0.70	0.71	0.72	0.73	0.75	0.76
Pharmaceutical sales %of health	1						
expenditure	16.9	17.2	17.4	17.6	17.7	17.8	17.8
Health spending (USD Bn)	13.022	11.727	11.772	13.228	14.734	16.232	17.789

Source: Business Monitor International 2016

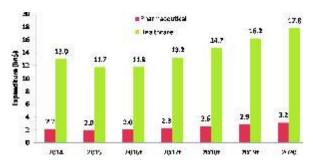


Fig. 5: Spending on pharmaceuticals vs. healthcare spending in Malaysia

Economic characteristics of Pharmaceuticals in Southeast Asian countries

The level of competition among different pharmaceutical product categories is important in understanding medicine-pricing strategies. The products fall into three main categories as illustrated in figure 6.

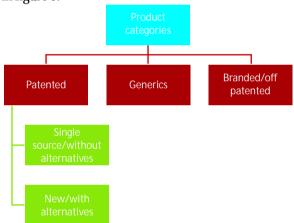


Fig. 6: Illustration of product categories

Patented drugs

This group can be further categorized into

- Patented, innovative, essential medicines where no alternative medicine or intervention can provide the same therapeutic outcome sometimes referred to as single source medicines
- New medicines protected by patents, but for which alternative therapies are available (such as Tamiflu for the treatment of influenza)

The distinction between the two types is important because it reflects the degree of market power held by the seller and the price elasticity of demand. Demand for single source medicines that are considered essential is likely to be inelastic and combined with patent protection; the seller is in a strong position compared to situations where therapies are available.²¹

Generic drugs

Generic or multi-source medicines are not under patent protection and can be produced using the same compounds found in the originator product using the same or a different process. Multi-source pharmaceutical products are pharmaceutically equivalent products that may or may not be therapeutically equivalent. The generic products may not be therapeutically equivalent due to a possibility of change in the process of manufacturing. Under special circumstances, such as a public healthcare emergency, countries are allowed to manufacture patented medicines under the compulsory licenses that are granted by World Trade Organization's (WTO) agreement on trade-related aspects of intellectual property rights.

In general, the absence of patent protection lowers the barrier to entry into the market since it reduces the costing of R&D. Reduced R&D costs enable multiple companies to enter the market resulting in a huge competition. However, the expiry of patents does not mean that barriers to market entry disappear. Buyers may always not be aware of the availability of low priced generic medicines, they may have persuaded by promotional efforts not to change brands, or they may view the generic product as inferior or poor quality.

Branded Off Patented drugs

A complicating issue in the generic market is when well-known branded medicines go off patent and the originator company produces generic versions of its own products and retains the brand name that are recognizable through extensive marketing campaigns. Apparently, when the brand name generic has a larger share of the generic market, the brand name medicine will be more expensive. In addition, a higher market share held by the brand name generic will result in high generic medicine prices among all companies. The market entry of brand name generic medicines, if combined with a large market share for the manufacturer will prevent prices falling to levels reached with more diverse competition. Therefore, by entering both brand and generic segments, large companies can exercise considerable market power.19

Government Intervention in Pricing

Government intervention in pricing is a controversial topic because market economists feel strongly that the market should be left to its own devices.¹⁹

Price controls on the Manufacturer

These price controls usually take the form of governments restricting medicine prices to the cost of production plus a profit margin. However, accurate cost information from the manufacturer is difficult to obtain.

Reference pricing and Brand Premiums

The reference pricing does not necessarily become the market price for all the medicines in the same therapeutic class but rather a benchmark price. Manufacturers can set higher price than the reference pricing but in doing so they need to compete against equivalent, lower priced medicines. Branded premiums are often used in conjunction with reference pricing. They are used when the third party comes into scene during the co-payment.

Fixed Margins

These margins are a fixed percentage of the wholesale price. Problems include the tendency for pharmacists to negotiate rebates and other discounts directly with the wholesalers that do not get passed on the consumer. In some countries these discounts are illegal.

Capitation systems

The pharmacist is reimbursed with a fixed sum based on the number of patients per year or a fixed fee per prescription. The system's goal is to keep pharmacists from benefiting from either the price or volume of units dispensed.

Eliminating Tariffs and Taxes

The sizeable price increase can occur through the out of supply chain in the form of tariffs and taxes. Though taxation increases revenue in low income countries it leads a negative effect in the Health systems.

Factors influencing Pharmaceutical Prices and Total costs

Multiple factors influence the pharmaceutical prices and total costs. Some of these factors are depicted in the figure 7.



Fig. 7: Factors affecting pharmaceutical prices and total costs

Competition

Competition enforcement plays an important role in preserving and promoting competition to stimulate innovation and reduce prices in pharmaceutical markets. Entry by generic drug companies does not only reduce prices of existing medicines, it also stimulates originator companies to innovate and develop new drugs. The pharmaceutical industry features a number of characteristics that are worthwhile bearing in mind when assessing the conducts of pharmaceutical companies.

The choice of which drug is consumed by a patient to treat a particular condition is largely made by the treating physician. Pharmacists cannot substitute a different branded drug within the same therapeutic category without the physician's permission. Pharmacists can, however, substitute generic equivalents of branded drugs—indeed, they are often mandated to do so. For most patients, the costs of consuming prescription drugs are also shared with insurance plans. Insurers and Pharmacy Benefit Managers ("PBMs") can influence drug choice through the co-payments they charge their members. It is within this context that competition between drug manufacturers occurs.²⁰

Regulatory system of the country

Drug regulation is an essential part of any country's National Pharmaceuticals policy. Drug regulation needs to flow from a legislative framework that provides the legal basis for a specialized government agency to interpret, implement and enforce laws. In some Southeast Asian countries, the local Regulatory system does not allow the parental company to enter into the market directly. The distribution should be owned by the local distributors which influence the cost of drugs.

Patent status /Intellectual Property Rights Intellectual Property Rights (IPRs) have been defined as ideas, inventions and creative expressions on which there is a public willingness to bestow the status of property (IPRs) provide certain exclusive rights to the creators of IP, in order to enable them to reap commercial benefits from their creative efforts or reputation. The purpose of IPR legislation is to protect against unauthorized imitation, copying or

deceptive usage of identifying marks.²¹

Patent protection does not last forever in the pharmaceutical sector, patent expiration leads to big loss for the originator. But during the patent protection period the Originator Company enjoy profits in a huge number. After the expiration of patent rights generic drugs will come into flow. They will be available at lower price since the R&D costs do not exist.

Selling Expenses

Selling expenses will be very low when the company has its own marketing and sales team in the country. These expenses will be very high when the company do not operate its own and depends upon the local distributors in the country. Due to this, the retail price will increase without the involvement of the manufacturer.

Reorder Frequency and the Total cost of Purchases

Pharmaceutical acquisition prices are only one part of the total cost of pharmaceutical purchasing, the other components are the costs associated with holding inventory, the costs of operating, the purchasing system and the extra costs incurred when stock outs occur. Although procurement offices typically concern themselves mainly with the pharmaceutical costs, the other cost components may increase the total cost by 50% or more of the acquisition costs. For each country's situation, total purchasing costs can be minimized by choosing the optimal reorder frequency model. The reorder frequency model may differ from one type or class of drug product to another. The central medical store can purchase most of the items required in annual tender. The health centers and hospitals may order at a frequency of one month. Total cost analysis examines stable and variable costs for potential savings.

Visible and Hidden costs

The costs associated with shortages and poor supply performance are not so obvious, hidden costs associated with poor performance by the supplier or the procurement office include

- Increased acquisition costs due to emergency procurement, such as when a vital medicine is ordered too late or usage exceeds estimates or the supplier fails to deliver on time
- Replacement costs when goods are lost or must be discarded because of poor packaging, improper shipping conditions
- Replacement costs for short shipments, incorrect concentrations of liquid preparations, wrong dosage forms and so on
- Health and economic costs of stock outs resulting from delay or default in delivery

Unit Prices

In some markets even sole source suppliers may offer discount pricing to the public sector that is not necessarily related to purchase volume to establish or maintain market share or to negotiate with international development entities. The type of procurement method used greatly influences competition among potential suppliers. Good procurement practices directly or indirectly influence the degree of competition and the degree of discounting price available to the health system. Components of Price Build-up of pharma products According the WHO/HAI there are six key components which contribute to the price build-up

Manufacturer selling price

of medicines. These are as follows:

The net acquisition cost of the medicine from the manufacturer, reflecting all discounts, rebates or other reductions in price.

Cost, insurance, freight charges (CIF), import tariffs and charges. The cost of importing a finished pharmaceutical product (FPP) or active pharmaceutical ingredient (API) into a country.

Importer margin

It is the margin applied by the importer who procures and receives delivery of imported goods.

Distributor margin

It is the margin applied by wholesalers and subwholesalers to perform the logistical role of storing and subsequently transporting medicine to point of sale.

Retailer margin

It is the margin applied by retailers in the final step of the distribution chain, the point at which medicines are dispensed to patients.

Taxes

The final component of the price build-up that can include both national and regional taxes. ²²

Business Models adopted by Pharma companies in Southeast Asia. An effort is made to elaborate and explain various pricing models in Figure 8.

Distribution Model

- · Supply to distributor at a transfer price
- · Supporting Marketing activity
- · To control on sales and Marketing activity
- Good model for a Non aggressive players

Participation Mod

- · Supply at transfer price with a better gross margin
- Share the cost of sales and marketing
- · Moderate control on the Business activities
- As the Business grows difficult to manage in the long term

Collaboration Mode

- · Good model provided entry barriers for local Manufacturers
- No privileges in Tender pricing
- · Local companies do not get any share in Tender sales
- Registration timeline and guidelines is almost same compare to
- Imported products

 Cost of Manufacturing and maintaining is expensive

Promotion Mode

- Good model when the Manufacturing company is employable in marketing skills
- When the Local distributor do not have any product knowledge this model is essential to follow
- Promotional expense will be borne by the Manufacturer

Fig. 8: Illustration of various business models with respective to the scope and activities

Dynamic pricing model for Southeast Asian countries

After the detailed study and evaluation of the channels of business, business model, pricing structure, considering the local regulations in the select countries, an effort is made to develop a dynamic pricing model as illustrated in figure 9.

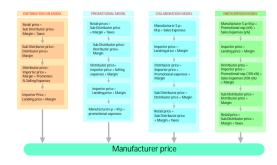


Fig. 9: Illustration of business channels, business models and flow of goods

Limitations of the Study

The current study has its own limitations. The study of pricing strategies and pricing model has been conducted through reference of articles, journals, import data, tenders, books that are published on internet. Author also used the market expertize and contacts to gather information related to the topic. Pricing as a subject is vast and requires lot of resources to have a detailed analysis on this topic. There is lot of scope to further study in depth on each derived model.

Findings/Observations

The findings of the present research depict that pharmaceutical sector growth in Southeast Asiancountries is going with a momentum. Due to applied health insurance benefits, in particular countries, the scope for pharmaceutical sector is humongous. Exports are very low in the Southeast Asian countries when compared to imports. Due to low technological innovation, local industries also do not produce certain medicines. So, the entry into Southeast Asian pharma sector is quite easy. Apart from these characteristics, there are trade restrictions in certain Southeast Asian countries. For instance, in Indonesia imports are very low when compared with exports due import restrictions for locally manufactured drugs. Similarly, Vietnam has also some trade restrictive policies that ensure pharmaceutical product distribution to be owned by the local companies. In Philippines, the trade restrictions are very low. Health systems in Southeast Asia is upgraded in the 21stcentury. Per capita spending on health is very high in Malaysia when compared with other Southeast Asian countries. Malaysian market is growing rapidly when compared with other Southeast Asian markets.

Local companies control over 75% of the Indonesian pharmaceutical market. Universal Health coverage was introduced in Indonesia but it is very limited when compared with other Southeast Asian countries. Raw materials are a problem due to weakening of Rupiah against Dollar. The authorities in Indonesia have been trying to distribute drugs at lower price but lacking of quality in the drugs is a huge drawback.

Philippines is planning to cut some of its tariffs for pharmaceutical products and lower those on raw material imports. This move should be popular with local drug makers, as it will result in lower production costs, though the local sector may also face greater competition due to lower duties. Philippines is trying to follow the footsteps of other Southeast Asian countries as far as the medical tourism is concerned. The prescription of generic products in Malaysian pharma public sector is becoming increasingly popular, indicating a greater willingness to use low cost medicines, but it is the changes in the private sector that remain crucial to market development. The private sector favors patented drugs, as they bring high revenues for healthcare providers, would have also felt the pinch of the economic downturn.

In Malaysia, most of the prescription & OTC medicines are imported from foreign countries. Halal medicines are another area where Malaysia shows growth potential. Government offers to lower healthcare spending which prompted new regulations, will stimulate the generics market. The growth drivers of the Malaysian market comprise of cost containment needs and implementation of the Southeast Asia free trade agreement. The flow of exports is expected to increase, tightening competition and pushing local manufacturers to create competitive advantage. Malaysia's MOH has implemented a generic drug policy in which government hospitals have to prescribe generic drugs when patents for the generic drug expire.

The liberalized environment in Vietnam could cause problems for Vietnam's small drug production sector. Vietnam's regulators faced their greatest challenge with the country's entrance at the WTO at the start of 2007. Foreign enterprises have been given the right to open branches in Vietnam and to import medicines directly although they will still be barred from distributing their products. Vietnam's low per capita health and pharmaceutical expenditure highlights the population's poor access to healthcare for services and low affordability levels for medicines particularly high value drugs. This represents a short-term challenge for pharmaceutical firms, but over the long-term the economic position of Vietnam is going to be strengthened. Vietnam requires firms to conduct domestic clinical trials before marketing approval for all pharmaceuticals that have not been made available in their country of origin for more than five years. From a pharmaceutical firm's perspective, these requirements delay the time to market their and hence the revenue generation will not be up to the

Healthcare spending will be a cost containment target in Thailand. Imports will grow at a CAGR of 7% in the forthcoming days. The political stalemate in Thailand will ultimately hurt economic growth, with the under performance of tourism and export sectors weighing heavily on the economy. On the other hand, the expected longer term economic improvements and the consequent rise in income will have a positive impact on the demand for private health services in the country. US, Germany, Spain, Switzerland, France and UK were major importers in the country. Thailand is one of the expensive country for setting up sales and marketing infrastructure and this could be one of the reason pharma products are sold in high prices comparing to neighboring countries. The heightened intellectual property agreements will be particularly sensitive to Thailand due to its history of compulsory licenses.

CONCLUSION

Companies must embrace strategic product pricings in order to sustain in the globalized world. Price is the best weapon to use in the pharma industry. In order to face stiff competition and to maintain continuous growth, pricing the product is tangled considering all the characteristics which affects them. Business strategies will change from one Industry to another Industry. When it comes to pharmaceutical industry, it should change from country to country. Every company will have its own business strategy to succeed but due to some regulatory issues in some countries, the companies may not implement the same business model globally. Business strategies should not be analogous as there is huge distinction in terms of local regulations. In Indonesia and Vietnam these regulations are very high. So, from the above proposed models Collaboration model accomplish very well for the foreign companies in these countries. This model offers risk mitigation and shared by both the companies proportionately. Companies with tremendous marketing teams can choose Promotion model when the local distributors do not have essential marketing strategies in order to market the product. However, the distribution will be in the hands of Local distributors. Promotion model suits well in Philippines. New Entrants can adopt Distribution model since the financial risk is with the local distributors. The task of the manufacturer is to supply the products according to

the requirement of the distributor. In countries with less trade restrictions like in Malaysia; distribution model plays a key role. The distributor will pay off further risk. Promotional activities also will be looked after by the local distributor. If a pharma company has a deep bondage with the local distributors and is ready to share part of risk, then Participation model is the better option. But the manufacturing company should own a local office to look after the sales and promotional activities. The involvement of distributor is very low in this kind of model. In countries like Thailand where there are lot of complexities, that affects pharmaceutical revenues and hence Participation model is precise. Choosing a right Business model will fetch revenues hugely in the Southeast Asian pharma sector since the growth of Southeast Asian markets are inclining day-by-day above the expectations of the analysts.

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