

Internship Training

At

ZS ASSOCIATES INDIA PRIVATE LIMITED

**COMPARATIVE ANALYSIS OF EUROPEAN AND ASIA PACIFIC HEALTHCARE
SYSTEMS**

by

NIDHI KHATURA

PG/13/040

Under the guidance of

MS. KIRTI UDAYAI

Post Graduate Diploma in Hospital and Health Management

2013-15



**International Institute of Health Management Research
New Delhi**

Completion of Dissertation from respective organization

The certificate is awarded to

NIDHI KHATURA

In recognition of having successfully completed her

Internship in the department of

Knowledge Management

And has successfully completed her Project on


Comparative Analysis of European and Asia Pacific Healthcare System

30th April 2015

ZS Associates India Private Limited

He/She comes across as a committed, sincere & diligent person, who
has a strong drive & zeal for learning

We wish him/her all the best for future endeavors


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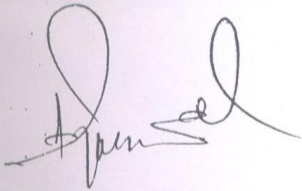
TO WHOMSOEVER IT MAY CONCERN

This is to certify that NIDHI KHATURA student of Post Graduate Diploma in Hospital and Health Management (PGDHM) from International Institute of Health Management Research, New Delhi has undergone internship training at ZS Associates India Private Limited from 9th February 2015 to 24th April 2015.

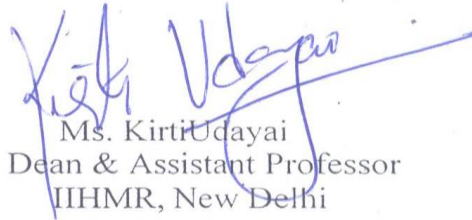
The Candidate has successfully carried out the study designated to her during internship training and her approach to the study has been sincere, scientific and analytical.

The Internship is in fulfillment of the course requirements.

I wish her all success in all his future endeavors.



Dr. A.K. Agarwal
Dean, Academics and Student Affairs
IIHMR, New Delhi



Ms. Kirti Udayai
Assistant Dean & Assistant Professor
IIHMR, New Delhi

Certificate Of Approval

The following dissertation titled "**COMPARATIVE ANALYSIS OF EUROPEAN UNION AND ASIA PACIFIC HEALTHCARE SYSTEMS**" at "**ZS ASSOCIATES INDIA PRIVATE LIMITED**" is hereby approved as a certified study in management carried out and presented in a manner satisfactorily to warrant its acceptance as a prerequisite for the award of **Post Graduate Diploma in Health and Hospital Management** for which it has been submitted. It is understood that by this approval the undersigned do not necessarily endorse or approve any statement made, opinion expressed or conclusion drawn therein but approve the dissertation only for the purpose it is submitted.

Dissertation Examination Committee for evaluation of dissertation.

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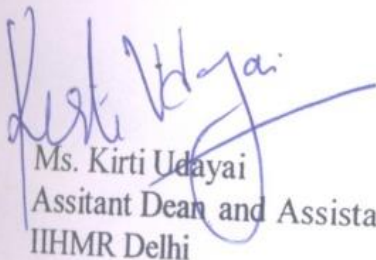
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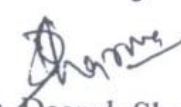


Certificate from Dissertation Advisory Committee

This is to certify that Ms. Nidhi Khatura, a graduate student of the **Post- Graduate Diploma in Health and Hospital Management** has worked under our guidance and supervision. He/ She is submitting this dissertation titled “ Comparative Analysis Of European And Asia Pacific Healthcare Systems” at “ZS Associate India Private Limited” in partial fulfillment of the requirements for the award of the **Post- Graduate Diploma in Health and Hospital Management**.

This dissertation has the requisite standard and to the best of our knowledge no part of it has been reproduced from any other dissertation, monograph, report or book.


Ms. Kirti Udayai
Assitant Dean and Assistant Professor
IIHMR Delhi

 
Ms. Sherin Alex and Mr. Deepak Sharma
Knowledge Management Consultant
ZS Associates India Private Limited

**INTERNATIONAL INSTITUTE OF HEALTH MANAGEMENT RESEARCH,
NEW DELHI**

CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled **Comparative Analysis of European and Asia Pacific Healthcare Systems** and submitted by **Nidhi Khatura** Enrollment No. **PG/13/040** under the supervision of **Ms. Kirti Udayai** for award of Postgraduate Diploma in Hospital and Health Management of the Institute carried out during the period from 9th February 2015 to 24th April 2015 embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other Institute or other similar institution of higher learning.



Signature

FEEDBACK FORM

Name of the Student: Nidhi Khatura

Dissertation Organisation: ZS Associates India Pvt. Ltd.

Area of Dissertation: A Comparative analysis of European Union and Asia Pacific Healthcare System

Attendance: Regular

Objectives achieved: Successfully executed the cross country analysis of 24 healthcare systems

Deliverables: Country score cards (PowerPoint format) detailing the Regulatory process, Pricing and Reimbursement mechanism and Distribution & Marketing model across the target countries

Strengths: Dedicated, high on motivation, effective communication skills and positive attitude. Has shown good learning curve and was quick to adopt to the project requirements and build her expertise in secondary research. Nidhi has shown good understanding of the pharma space. She took feedback very constructively and managed to work on it which was visible in her work. She has good MS PowerPoint skills and was able to present information in a concise way.

Suggestions for Improvement: Nidhi must try to improve on her daily work plan and should list down the work priorities. At times, it felt like that she was stuck with research and spent more time than required on some research pieces. But that is okay as she is still very new to the corporate work life and we are sure she would use this experience to improve her task management skills.

Signature of the Officer-in-Charge/ Organisation Mentor (Dissertation)

Date: 23/04/2014

Place: GURGAON

INTRODUCTION

The following report provides critical understanding of the existing healthcare systems of the listed countries of Europe as well as Asia Pacific region. The study aims to comprehend the essential facts regarding the existing healthcare system and bring forward a comparative analysis among the twenty four countries.

Through this study an attempt has been made to understand the healthcare system based on the healthcare needs and demands (through the means of demographic data, health indices and the macroeconomic parameters), the organization of the healthcare and the resources available and their utilization.

Apart from the basic outline of the above listed components of the healthcare system, the report majorly revolve around understanding the pharmaceutical system as a part of the healthcare system in the respective countries. This include an overview of present pharmaceutical market, the pricing, reimbursement as well as the intellectual property regime existing across various countries, the distribution system and the recent trends or reforms in the healthcare and the pharmaceutical system .

The report presents the comparative analysis of these countries on the basis of the above listed parameters and highlights the strengths, weaknesses and the best practices existing in the systems which offer new opportunities for the countries to secure substantial improvements in their healthcare systems. It also extends a help for the new pharmaceutical companies to understand the various entry and exit barriers while trying to explore the healthcare and pharmaceutical industry.

The countries included in the study are:

European Region: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Hungary, Norway, Slovakia,

Asia Pacific Region: Australia, India, Vietnam, Hongkong, Philippines, Indonesia, Malaysia.

REVIEW OF LITERATURE

Health care systems stem from specific political, historical, cultural and socio-economic traditions. As a result, the organizational arrangements for health care differ considerably between different countries as well as its Member States.

The Healthcare System

The framework used to describe and compare the healthcare system has the following components:

I. The needs and the demands

Each system attempts to meet the population's need for health and health care. A complex issue is to what extent the demand for health care appropriately reflects the actual population health need and to what extent it is met by health care service provision and utilization. Population health needs can translate into "justified" demand and appropriate use of health services, but some health care need might be neglected due to lack of demand and utilization. Thus, a particular challenge for health care systems is to move closer to the identification of the real need for health care, satisfying justified demand and promoting demand where appropriate.

Health cannot be measured directly. Therefore to measure the health status it is pre requisite to measure the need and the demand prevailing in the society and interpret them to analyse the gap which would directly reflect the health status of the society.

Useful indicators for measuring the healthcare needs and demands are as follow:

1. Demographic indicators

Demographic characteristics of a country provide an overview of its population size, composition, distribution and changes therein. These indicators for a country as well as

its states help in identifying areas that need policy and programmed interventions, setting near and far-term goals, and deciding priorities, besides understanding them in an integrated structure.

1.1. Population size

Population size is the actual number of individual in a population

1.2. Population growth Rate

Population growth is the increase in the number of individuals in a population. Population growth (annual %) is the exponential rate of growth of midyear population from year $t-1$ to t , expressed as a percentage.

1.3. Population above 65 years

Number of individual of age 65 and above as a percentage of the total population.

Societal aging may affect economic growth and many other issues, including the sustainability of families, the ability of states and communities to provide resources for older citizens, and international relations.

An increase in ageing population has been seen as a development for a nation because of the increase in the life expectancy due to better availability of healthcare. It is also seen as an opportunity because as the ageing population will increase the needs and demands for the healthcare also rises.

2. Macroeconomic indicators

Macroeconomic indicators provide the economic statistic of a country. These indicators provide insight into the economic performance of a particular country or region, and

therefore can have a significant impact on the healthcare of a country Source: alpari.com, "Macroeconomic Indicators"

The various macroeconomic indicators applied for the comparison under the study are discussed below:

2.1. GDP

The value of all final goods and services produced in a country in one year.

GDP can be measured by adding up all of an economy's incomes- wages, interest, profits, and rents- or expenditures- consumption, investment, government purchases, and net exports (exports minus imports). Both results should be the same because one person's expenditure is always another person's income, so the sum of all incomes must equal the sum of all expenditures.

2.2. GDP per capita

GDP per capita is the Gross Domestic product divided by midyear population

2.3. Total health expenditure (as percentage of GDP)

Percentage of total general expenditure spent on health.

- Health expenditures are broadly defined as activities performed either by institutions or individuals through the application of medical, paramedical, and/or nursing knowledge and technology, the primary purpose of which is to promote, restore, or maintain health.
- Health spending measures the consumption of health services and goods, including outpatient care, hospital care, long-term care, pharmaceuticals and other medical goods, prevention and public health services, and administration.

- It is the sum. Total expenditure on health is the sum of general government health expenditure and private health expenditure in a given year, calculated in national currency units in current prices.

2.4. Public health expenditure (as percentage of total health expenditure)

The diversity of healthcare systems across countries is explicitly reflected in the degree of public health expenditure. Public health expenditures contain social security spending, taxing to private and public sectors, and foreign resources like loans and subventions.

Public Health expenditure (as percentage of total health expenditure) determines public share of healthcare spending out of the total healthcare spending of a nation.

2.5. Private Health expenditure (as percentage of total Health expenditure)

Privately funded part of total health expenditure. Private sources of funds include out-of-pocket payments (both over-the-counter and cost-sharing), private insurance programmes, charities and occupational health care.

2.6. Out of pocket expenditure (as percentage of private health expenditure)

Household out-of-pocket expenditure comprise cost-sharing, self-medication and other expenditure paid directly by private households, irrespective of whether the contact with the healthcare system was established on referral or on the patient's own initiative.

3. Health indicators

Health indicators are summary measures that are designed to describe particular aspects of health or health system performance.

3.1. Life expectancy

Life expectancy at birth reflects the overall mortality level of a population. It summarizes the mortality pattern that prevails across all age groups - children and adolescents, adults and the elderly.

It is defined as the Average number of years that a newborn is expected to live if current mortality rates continue to apply.

It can be further identified separately for males and females.

LE is an a worldwide indicator and is also regarded as an overall indicator of Global Health

3.2. IMR

Infant mortality rate is the number of infants dying before reaching one year of age, per 1,000 live births in a given year.

This age group is particularly vulnerable, so high rates can indicate limited resources for antenatal and post natal care, vaccinations and medical care of a specialist nature. This could highlights a country is poorer in terms of healthcare, where there are high level of IMR. Although distorted, it does reflect a country's levels of development.

This rate is often used as an indicator to measure the health and well-being of a nation, because factors affecting the health of entire populations can also impact the mortality rate of infants.

4. Organization and Financing of Healthcare

A good health system delivers quality services to all people, when and where they need them. The exact configuration of services varies from country to country, but in all cases

requires a robust mechanism; a well established policy formulation body, decision making body, implementing authorities, a well-trained and adequately paid workforce; reliable information on which to base decisions and policies; well maintained facilities and logistics to deliver quality medicines and technologies.

A good understanding of the organization of the system is critical for analyzing it.

5. Healthcare Resources and their Utilization

Two main avenues important for improving the healthcare of a nation are : availability of the resources and their effective utilization. There needs to be equilibrium between the availability of the resources and their utilization. An analysis of the distribution and availability of the resources as well their utilization can picturize the present status of the healthcare as well as can also identify the gaps in the system.

6. The Pharmaceutical System

Pharmaceutical care is a necessary element of healthcare. According to the definition of Hepler & Strand (1989)¹, pharmaceutical care is the responsible provision of medicine therapy for the purpose of a definite outcome that improves a patient's quality of life.

Pharmaceutical care is based on a relationship between the patient and the healthcare providers who accept responsibility for the patient.

The understanding of the pharmaceutical system calls for the apprehension of the pharmaceutical care practices across various countries based on the market structure, the regulatory or approval processes, the pricing and the reimbursement regime, the marketing and distribution practices as well as the important recent reforms or trends.

A. The Pharmaceutical Market

Defining a pharmaceutical market structure would involve elucidating various components of the particular market. These include a description of the market share of branded versus the generic drugs, prescription versus the OTC (over the counter drugs), the pharmaceutical market value in terms of total sales/revenue or expenditure on pharmaceuticals.

B. The Approval process or the regulatory regime

After passing through the clinical trials, the pharmaceutical product, in order to gain a market permit, requires an approval. The drug approval process of the countries is highly regulated.

In general, the effective regulation of medicines requires a variety of functions including evaluating safety and efficacy data from clinical trials and licensing and inspecting manufacturing facilities and distribution channels. Other tasks include, monitoring drug adverse reactions for investigational and marketed drugs and controlling drug promotion and advertising.

In some countries all the functions related to drug regulation, are handled by a single agency, while in other, states or provincial government have some regulatory authority.

Countries also employ various methods/ principles while granting the market authorization

C. The Pricing Regime

The pharmaceutical pricing refers to determining the selling price of the drugs at various stages.

The pricing policies of a country can determine the availability and utilization of medicines by its population, which in turn can lead to an effect on their health.

Pharmaceutical prices are, to considerable extent, driven by supply and demand, but the nature of the product means that the pharmaceutical market does not always follow the same rules as other markets.

The government employs various price control measures to regulate the pharmaceutical prices.

The various pricing strategies employed are Statutory pricing, Price negotiations, Free pricing. The other commonly used pricing strategies are:

- *International price comparison* (or external reference pricing): The practice of using the price(s) of a medicinal product in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country.
- *Profit controls* (or rate of return regulation³): Describes a profit framework which is negotiated periodically between the Department of Health and the pharmaceutical industry (Pharmaceutical Price Regulation Scheme, PPRS)
- *Internal reference pricing*: Commonly employed as a means to regulate out-of-patent drug prices. Describes the practice of setting the price to be paid by public payers by comparing prices of equivalent or similar products in a chemical, pharmacological or therapeutic group. The 'reference price' applies to all pharmaceuticals within the corresponding group of products.

D. The Reimbursement Regime

Once a regulatory agency has determined the clinical benefit and safety of a product and pricing has been confirmed (if necessary), a drug manufacturer will typically

submit it for evaluation by a payer of some sort. Payers may be private insurance plans, governments (through the provision of benefits plans to insured populations or specialized entities like [Cancer Care Ontario](#), which funds in-hospital oncology drugs) or health care organizations such as hospitals. Each country has its own policies and legislations on reimbursement

E. The Intellectual Property Regime

Intellectual property rights (IPR) have been defined as ideas, inventions, and creative expressions based on which there is a public willingness to bestow the status of property. IPR provide certain exclusive rights to the inventors or creators of that property, in order to enable them to reap commercial benefits from their creative efforts or reputation. There are several types of intellectual property protection like patent, copyright, trademark, etc. Patent is a recognition for an invention, which satisfies the criteria of global novelty, non-obviousness, and industrial application. IPR is prerequisite for better identification, planning, commercialization, rendering, and thereby protection of invention or creativity. Each industry should evolve its own IPR policies, management style, strategies, and so on depending on its area of specialty. Pharmaceutical industry currently has an evolving IPR strategy requiring a better focus and approach in the coming era.

To keep a check over a country's IP practices relating to pharmaceuticals, a USTR (United State Trade Representative) and comes up with the PhRMA (Pharmaceutical research and Manufacturers of America) Special 301 report annually. The PhRMA lists the countries, on the basis of their IP environment, under the following three categories:

- *Priority Foreign Country*: It is a status reserved by those nations that are the most egregious violators of the IP rights and have most negative impact on the competitiveness
- *Priority Watch List*: countries with limited anti-counterfeiting enforcement efforts, discriminatory market access barriers resulting from the lack of legislative and regulatory transparency and advance consultation are included in this category
- *Watch List*: The PhRMA submission identifies countries which should be included on the Special 301 Watch List in as those countries whose specific issues of IP protection and enforcement concern will require continued or enhanced monitoring by USTR.

This classification is in accordance with WHO Agreement on Trade related Aspects of Intellectual Property.

F. The Marketing/ Distribution practices

In recent years there has been significant focus on the distribution system prevailing in the country. The pattern of the distribution of pharmaceuticals is a critical factor while analyzing the entire pharmaceutical system as a whole. There exists a significant diversity pertaining to the operational framework of the distribution system, along with the entities including wholesalers, retailers, pharmacies.

The understanding in this regard involve outlining the organization of the distribution system including the key trends in market structure of wholesaling and retailing, the distribution of pharmacies, and various existing practices.

METHODOLOGY

The study is solely based on Secondary Research.

The secondary data collection comprised a comprehensive literature search , review and its analysis. The data sources employed for the study can be broadly divided into two classes:

- i. Secondary Data Sources (Publically available sources)

The essential information has been gathered from various authentic public data sources such as government websites, sources for global data (such as WHO Reports/ World Data Bank, OECD Data Bank), company reports, and organizations websites.

ii. Subscribe/ Paid Data Source

These are the data sources which are employed by various organizations, one can get subscription for the reports from various companies.

One such Data source employed for the data collection is ***Data Monitor (DM)***.

Data Monitor- DM is an international company providing market intelligence, data analysis, and opinion via a worldwide network of in-house analysts. Its website claims to have over 6,000 clients, which it helps make strategic and operational decisions.

The reports called “***Business Monitor International***” Reports have also been utilized from the Data Monitor in order to collect substantial information and carry out a comprehensive analysis

Business Monitor International - BMI provides proprietary data, analysis, ratings, rankings and forecasts covering 195 countries and 24 industry sectors. A data and intelligence tool assessing global, regional, country and company developments and trends.

The countries under the study have been compared as per the following framework. The parameters listed, have been defined under the Literature section.

I	Healthcare needs and Demands	Demographic indicators	Population size, Population above 65 years, population
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			growth rate
		Macro economic indicators	GDP, GDP, Growth rate, GDP per capita, Health expenditures,
		Healthcare indicators	IMR, LE,
		Healthcare resources	Workforce, Hospitals
II	Health care Financing and Organization system		
III	Pharmaceutical system	Pharmaceutical market	
		Drug Approval process	
		Pricing regime	
		Reimbursement Regime	
		Intellectual property	
		Marketing/ Distribution	
		Recent reforms/ Trends	

FINDINGS AND ANALYSIS

The following section provides the values or the trend for each parameter for the countries under study.

A common criterion has been employed to compare the countries i.e the countries have been graded, wherever possible, on the substantiality / Attractiveness / conduciveness/ of each of the parameter. The connotation of each of these terms has been addressed separately.

I. Need and demand for healthcare

The size, age and sex structure of the population served is the most basic determinant of health care demand

1. Demographic Indicators

i. *Population size*

Europe

Country	Population
Austria	8,479,823
Belgium	11,182,817
Czech Republic	10,514,272
Denmark	5,614,932
Finland	5,438,972
France	65,939,866
Germany	80,651,873
Greece	11,027,549
Hungary	9,893,899
Ireland	4,597,558
Netherlands	16,804,432
Norway	5,080,166
Slovak Republic	5,413,393
Spain	46,617,825
Sweden	9,600,379
United Kingdom	64,106,779
Table 1: Population in EU (2013) Source: World Data Bank	

Asia Pacific

Country	Population
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Australia	23,129,300
Hong Kong	7,187,500
India	1,252,139,596
Indonesia	249,865,631
Malaysia	29,716,965
Philippines	98,393,574
Thailand	67,010,502
Table 2: Population in Asia Pacific (2013) Source: World Data Bank	

EU Member State populations under study, range from 4.5 million, as the lowest in Ireland to 80 million, being the highest in Germany.

Among the countries of Asia Pacific, India has been observed as the most populous nation with the population size being 1.2 million.

ii. Population Growth Rate

Europe

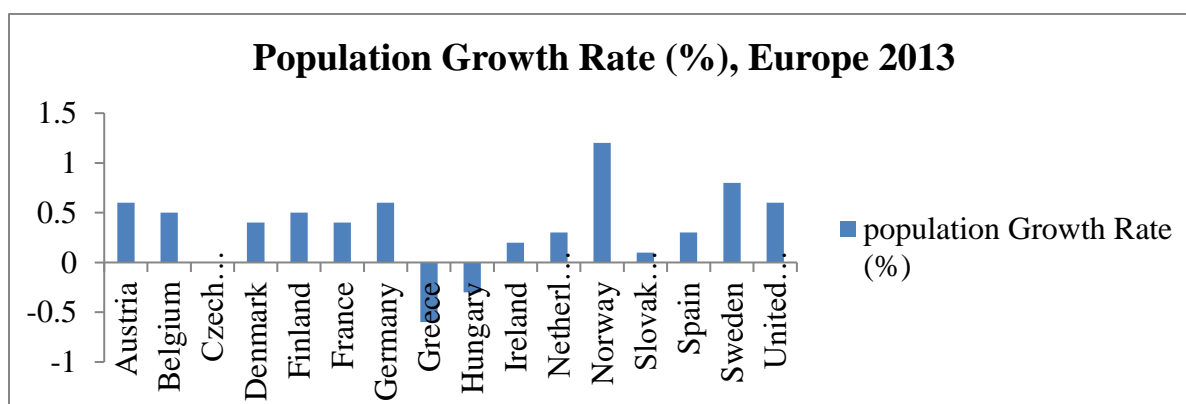


Fig 1: Population Growth Rate in EU, 2013

Source: Plotted through World Data Bank data

Asia Pacific

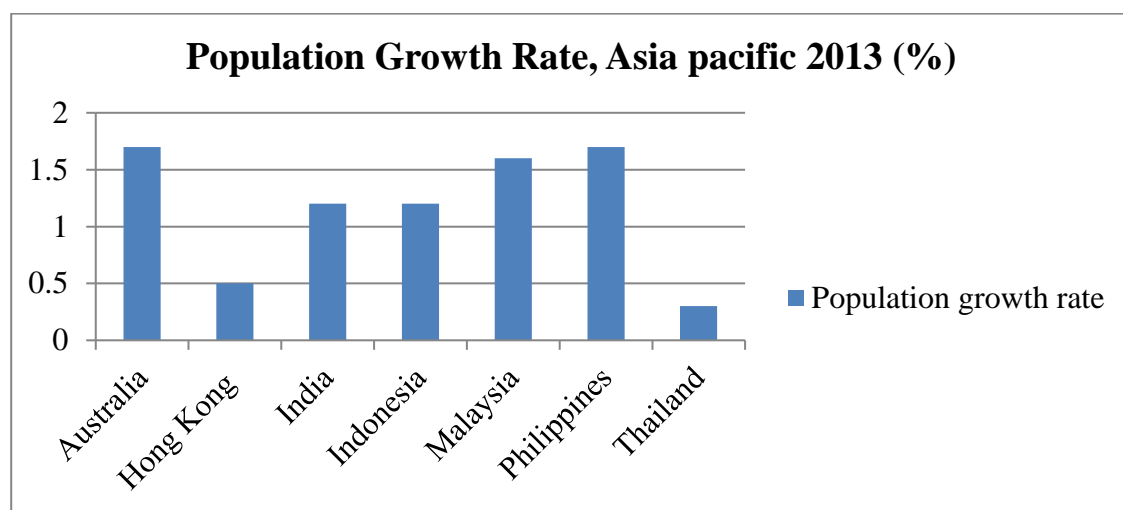


Fig2: Population Growth Rate (annual) in Asia pacific countries, 2013

Sources: Plotted from World data Bank data

Parameter {Population Growth Rate (2013) (%)}	Grading	Countries	
		EU	A-PAC
Low growth Rate	O or lesser	Greece, Hungary, Spain, Czech Republic	Nil
	0.1 to 0.5%	Belgium, Denmark, Finland, France, Germany, Ireland, Netherlands, Slovak Republic	Thailand, Hong Kong
Moderate Growth rate	0.6 to 1%	Austria, Sweden and United Kingdom	Nil
High Growth Rate	More than 1%	Norway	Australia, India, Malaysia, Philippines, Indonesia

Fig2: Population Grading, in Europe and Asia pacific countries, 2013

Sources: Created from World data Bank data

ii. *Population above 65 years*

Europe

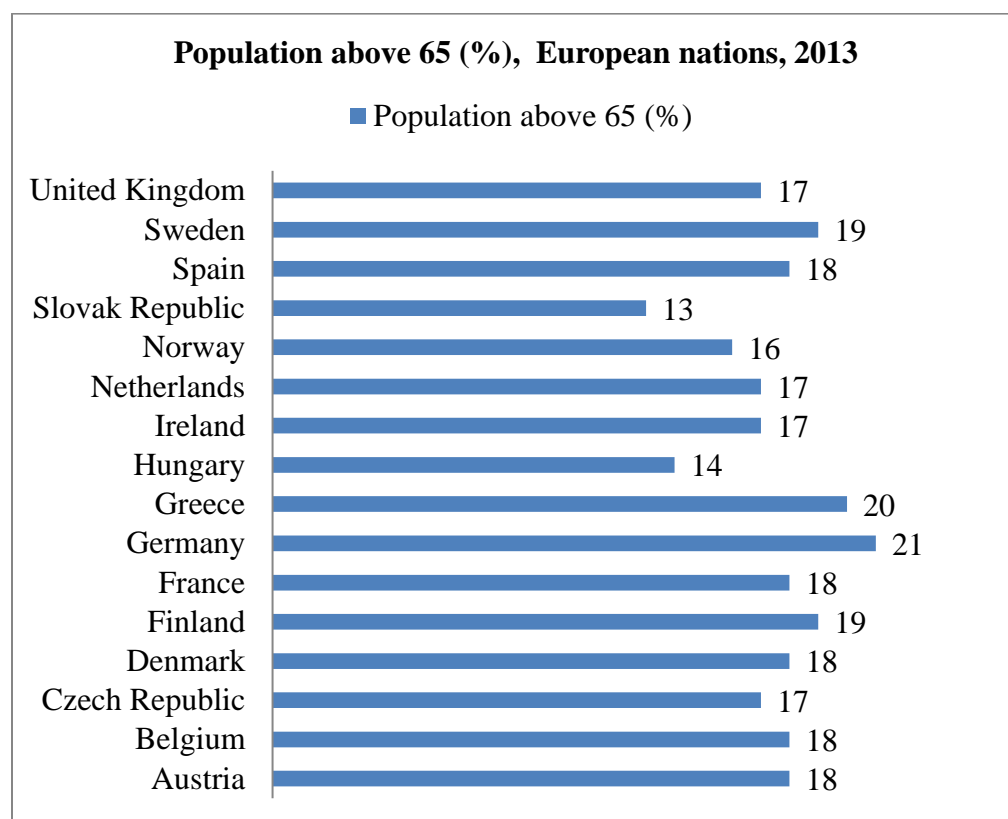
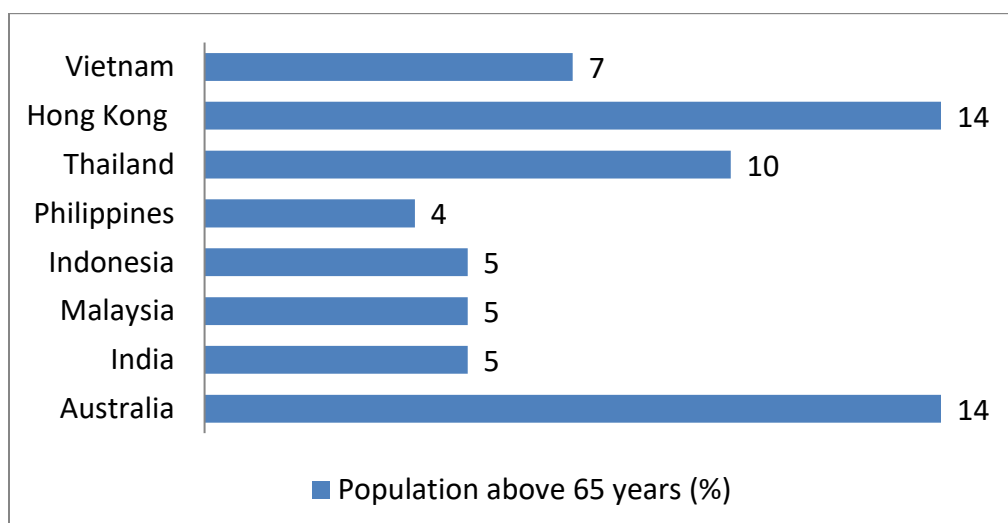


Fig2: Population above 65 years (%) in Asia pacific countries, 2013

Sources: Created from World data Bank data

Asia Pacific



Parameter Grading {Population above 65 years, (2013) (%)}	Description	Countries	
		EU	A-PAC
Substantial	Above 15%	Ireland, Netherlands, Norway, Spain, Sweden, UK, Greece, Germany, Austria, Belgium, Denmark, Finland, France, Hungary	
Moderate	11% to 15%	Nil	Hong Kong
Low	Below 15%	Nil	India, Malaysia, Indonesia, Philippines, Vietnam, Thailand

The type of health care demanded alters with increasing age, partly because the elderly tend to need health care more frequently as they develop more chronic, mainly cardiovascular and respiratory diseases. The incidence of cancer also rises with age.

A substantial percentage of over 60 population reflects the presence of a strong healthcare system. Also, such geographies are good opportunity for the pharmaceutical market

II. Macroeconomic Indicators

i. GDP

Europe

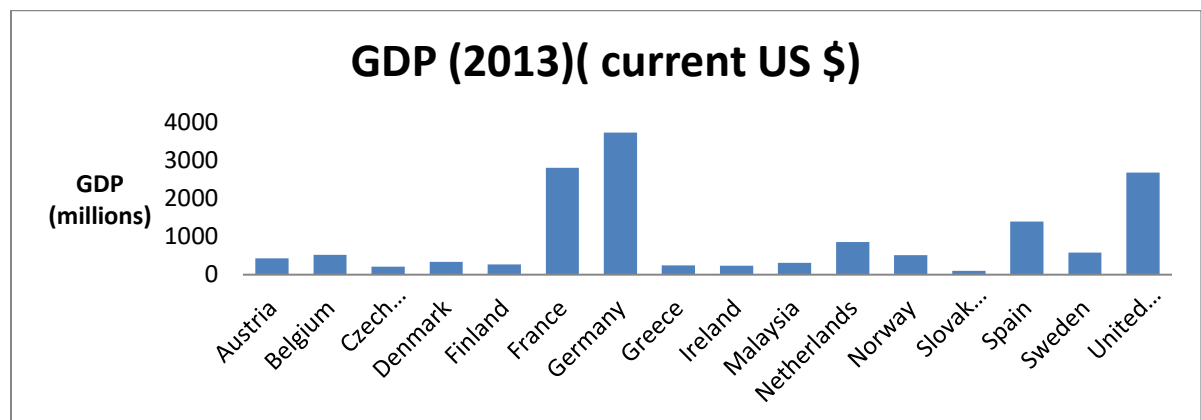


Fig3: Gross Domestic Product, 2013 of European countries, in current US\$
Source: Plotted from data of World Data Bank

Asia Pacific

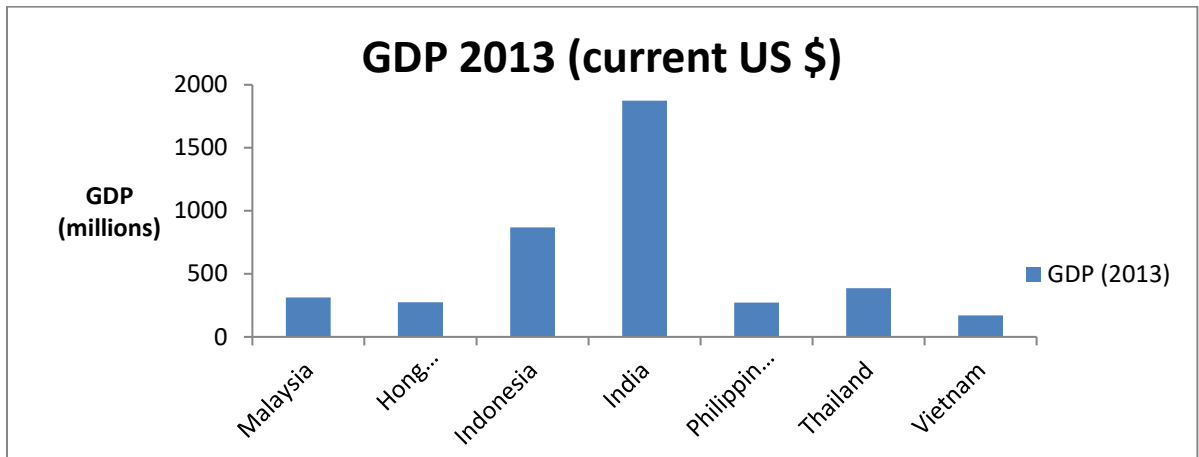


Fig3: Gross Domestic Product, 2013 of Asia Pacific countries, in current US\$
Source: Plotted from data of World Data Bank

ii. GDP Growth Rate

Europe

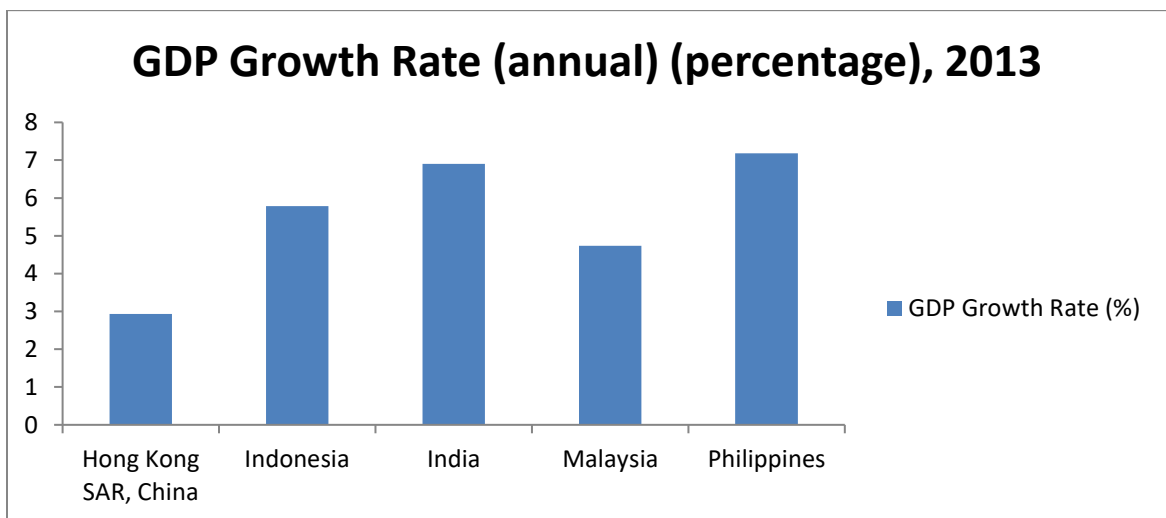


Fig3: GDP Growth Rate, 2013 of European countries, in current US\$

Source: Plotted from data of World Data Bank

Asia Pacific

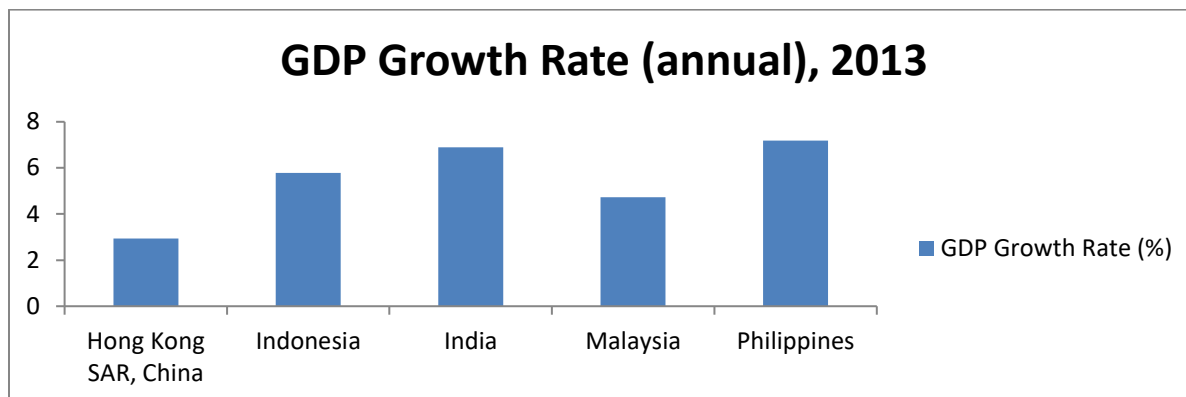


Fig: GDP Growth Rate, 2013 of Asia Pacific countries, in current US\$

Source: Plotted from data of World Data Bank

iii. Healthcare Expenditure

Europe

Country	Healthcare Expenditure			
	Total Health expenditure (as % of GDP)	Public Health expenditure (as % of total Health expenditure)	Private Health expenditure (as % of total health expenditure)	Private Health expenditure (as % of private Health expenditure)
Austria	11	75.7	24.3	65.2
Belgium	11.2	75.8	24.2	82.3
Czech Republic	7.2	83.3	16.9	94.1
Denmark	10.6	85.4	14.6	87.4
Finland	9.4	75.3	24.7	75
France	11.7	77.5	22.5	32.9
Germany	11.3	76.8	23.2	55.6
Greece	9.8	69.5	30.5	86.6
Hungary	8	63.6	36.4	75.5
Ireland	8.9	67.7	32.3	52.1
Netherlands	12.9	79.8	20.2	41.7
Norway	9.6	85.5	14.5	95.9
Slovak Republic	8.2	70	30	73.9
Spain	8.9	70.4	29.6	77.1
Sweden	9.7	81.5	18.5	88.1
UK	9.1	83.5	16.5	56.4

Table: Health Expenditure of European countries, 2013 Source: Plotted, World Data Bank

Asia Pacific

Country	Health Expenditure			
	Total Health expenditure (as % of GDP)	Public Health expenditure (as % of total Health expenditure)	Private Health expenditure (as % of total health expenditure)	Out of Pocket Health expenditure (as % of private Health expenditure)
Hong Kong				
India	4	1.3	98.7	85.9
Indonesia	3.1	1.2	98.8	75.1
Malaysia	4	2.2	97.8	79.9
Philippines	4.4	1.4	98.6	82.9
Thailand	4.6	3.7	96.3	56.7
Vietnam	6	2.5	97.5	85

Table: Health Expenditure of APAC countries, 2013 Source: Plotted, World Data Bank

The health expenditure on health is an indicator of the seriousness of the population about its people's health. It can be clearly seen that European spending on healthcare as a percentage of GDP is far better than that of Asia pacific nations. The expenditure on health by the APAC countries is even lesser than the least nation's spending in Europe.

III. Health Indicators

Health status indices are commonly employed to determine the level of health care need.

Available international data on health status indices often are associated with life expectancy and rates of infant mortality.

Europe

Country	Healthcare Indicators	
	Infant Mortality Rate	Life Expectancy
Austria	3	81
Belgium	4	80
Czech Republic	3	78
Denmark	3	80
Finland	2	81
France	4	82

Germany	3	81
Greece	4	81
Hungary	5	75
Ireland	3	81
Netherlands	3	81
Norway	2	81
Slovak Republic	6	76
Spain	4	82
Sweden	2	82
United Kingdom	4	81

Table: Health Indicators of European countries, 2013 Source: Plotted, World Data Bank

Asia Pacific

Country	Health Expenditure	
	Infant Mortality rate	Life expectancy (years)
Australia		82
Hong Kong	41.4	84
India	24.5	66
Indonesia	7.2	71
Malaysia	23.5	75
Philippines	11.3	69
Thailand	19	74
Vietnam	41.4	76

Table: Health Expenditure of APAC countries, 2013 Source: Plotted, World Data Bank

Life expectancy at birth provides a composite indication of health status, varying by 4.0 years for females and 5.3 for males within the European Union. There are differences in rankings between females and males in all Member States. Life expectancy at birth has substantially increased in all countries of the EU during recent decades. Higher life expectancy in the southern European countries is sometimes attributed to the Mediterranean diet consumed by their populations.

The life expectancy of countries of Asian regions lies majorly below 80 years, except in Hong Kong which reflects a good Life expectancy. The rest of the nations exhibit a value

lower than that of European nations. A wide diversity has been observed even within Asia Pacific with values ranging from 66 years in India to 84 years in Hong Kong

II. Healthcare Finance and Organization

Europe

Although EU countries have each developed their own funding mechanisms, similar objectives and common historical developments have resulted in systems which have much in common. All systems rely on a mixture of funding sources, but the majority of funds are state-controlled, whether directly or indirectly. Only a small proportion comes from direct fee-for-services.

State regulation in the Member States provides for **universal health insurance** or **service coverage** (Denmark, Finland, Greece⁵, Italy, Portugal, Sweden, United Kingdom) or **nearly universal coverage** (99 and 99.5% of the population in Austria, Belgium, France, Luxembourg, Spain, and 92.2% of the population in Germany) for health care through compulsory schemes. In Ireland, universal coverage for primary care only applies to low income groups. In the Netherlands, compulsory health insurance covers only 60% of the population. The rest of the population are usually covered by voluntary private or public insurance (Belgium, France, Germany, Luxembourg, and the Netherlands.)

Health care in the EU systems is either financed through general taxation or by contributions to health insurance funds. There are three predominant systems of health care finance in the European Union.

- The first is public finance by general taxation (often referred to as the Beveridge⁶ model).

- Secondly, there is public finance based on compulsory social insurance (the Bismarck⁷ model).
- Thirdly, there is private finance based on voluntary insurance, which covers only a small minority of EU citizens entirely, but which also operates on top of social insurance as a supplementary form of funding health care.

Countries	Predominant system of finance	Main supplementary system of finance
Finland, Greece, Ireland, Sweden, Spain, United Kingdom	public: taxation	private voluntary insurance, direct payments
Denmark	public: taxation	direct payments
Austria, Belgium, France, Germany	public: compulsory social insurance	private voluntary insurance, direct payments, public taxation
Norway	mixed compulsory social insurance and private voluntary insurance	public taxation, direct and private voluntary insurance payments

Asia

With the exception of Thailand, most health care systems of Asia provide very limited financial risk protection. The role of public prepaid schemes such as tax and social health insurance is minimal, and out-of-pocket payment is a major source of financing. The large informal sector is a major challenge to the extension of population coverage in many low-income countries of Asia, which must seek the optimal mix of tax subsidy and health insurance for universal coverage.

Countries	Predominant system of finance	Main supplementary system of finance
Malaysia	public: taxation	Public revenue
India	public: taxation Pvt.: Direct payment	Voluntary Pvt. Health insurance, compulsory social health insurance (very low coverage)
Indonesia	Direct payment	Community financing
Thailand	Taxation – Direct tax	SHI

Philippines	Direct payment	
Vietnam	Direct payment	

III. Healthcare Resources and their utilization

The allocation of health care resources differs considerably between the health care systems of the countries as does utilization by the population they serve. Each health service is complex in this regard.

Resources and facilities range from large multi specialty hospitals to single room public facilities in the Asia Pacific region and from large hospitals, single room clinics from specialist surgeons to chiropodists in Europe. To make a comparative analysis feasible, the major resources and facilities have been identified as hospitals, hospital beds, Healthcare workforce (Doctors and nurses)

Europe

Country	Doctors	Doctors per 1000 population	Nurses per 1000	Hospitals	Hospital beds
Austria	40,912	486	797	310	63,951
Belgium	41,979	378	1415	363	72,147
Czech Republic	38,983	371	879	357	73,592
Denmark	19,056	340	1540	69	19,609
Finland	14,369	270	960	380	31,989
France	214558	338	930	4171	418836
Germany	451,280	560	1138	2017	668861
Greece	65973	610	330	337	35000
Hungary	33769	341	642	167	71343
Ireland	17278	270	1220	176	20,477
Netherlands	49242	291	844	129	79052
Norway	18414	361	1251	74	168178
Slovak Republic	16233	330	600	111	34,629
Spain	184996	396	528	738	149454
Sweden	37,262	387	1100	73	26010
United Kingdom	174698	277	947	na	189545

Table: Healthcare Resources, European countries, 2013 Source: Plotted, All Global 2013

Asia pacific

Country	Health care resources and Work Force					
	Doctors	Doctors (per 1000)	GPs	Nurses	Hospitals	Hospital Beds
Australia						
Hong Kong	13,203			45,846		
India	786626				12760	576793
Indonesia		0.3		0.9		
Malaysia		0.9		2.45		
Philippines			10,773			
Thailand		0.65		1.524		
Vietnam		0.65				

Table: Health Expenditure of European countries, 2013 Source: Plotted, World Data Bank

Although, There is a lack of availability of reliable and recent comparable data on health care input factors and utilisation rates, the blurr picture also reflects that there is a mismatch between the resource vailability as well as utilization between Asian and European countries.

IV. Pharmaceutical System

i. Pharmaceutical Market

The understanding of the pharmaceutical market is critical for understanding the system as a whole. This is because it constitutes a major contribution to the country's economy as well as adds to the health of its nation.

The Following table highlights the various components of the prevailing market of the country's under the study.

Country	Market value (US\$ billion)	Prescription drug sales (as % of total sales)		OTC sales as % of total sales
		Patented drug sales as % of total sales.	Generic drug sales as % of total sales	
Austria	6.05	67.5	12.6	19.9
Belgium	7.70	78.7	10.6	10.7
Czech Republic	3.66	48.9	33.7	7.4
Denmark	3.58	-	-	-
Finland	3.393	69.1	18.8	12.1
France	3.17	66.5	16.5	17
Germany	52.82	65.8	22.5	11.7
Greece	7.45	68.2	23.3	8.5
Hungary	2.53	49.3	34	16.7
Ireland	2.77	88		12
Netherlands	8.04	23.2	63.7	13.1
Norway	3.363			
Slovak Republic	2.20	40.3	41.6	12.1
Spain	31.79	82.9	10.3	6.8
Sweden	5.70	75.6	15.1	9.3
United Kingdom	36.15	59.5	24.8	15.7

Asia Pacific

Country	Market value	Prescription drug sales (as % of total sales)		OTC sales as % of total sales
		Patented drug sales as % of total sales.	Generic drug sales as % of total sales	
Australia	23.4	67.5	12.6	19.9
Hong Kong	1.33	57	24.8	15.7
India	15.4	8.7	75.9	14.4

Indonesia	6.123	19.3	41	39.7
Malaysia	2.11	40.3	52.7	27
Philippines	3.5	28	32.7	29.3
Thailand	4.69	30.1	50.3	19.6
Vietnam	3.30	22.3	51.2	26.4

ii. Approval Process

Europe

There are four procedures by which a marketing authorization in EU can be obtained. These are summarized below. Most European countries use any or some of the following procedures.

National procedure	<ul style="list-style-type: none"> • This procedure is used whenever a company wants to commercialize a product in only one EU Member State. • The National procedure is specific to each country. That is, each country within the EU has its own procedures for authorizing a marketing application for a new drug • A national market authorization is valid for five years • Time required for application approval is 210 days
Centralized Procedure	<ul style="list-style-type: none"> • The centralized procedure is a Europe wide authorization procedure, conducted by EMA's Committee for Human Medicinal Products (CHMP), an organism containing representatives of all Member states, EEA members, patient organizations and health professionals. • When a sponsor applies for drug approval through the Centralized Procedure, two member states are first selected, a rapporteur and a co-rapporteur. These two member states will be responsible for the creation of an evaluation report that will be assessed by the CHMP • Products authorized through the centralized procedure are granted marketing authorizations that cover all EU member states

Mutual Recognition Procedure	<ul style="list-style-type: none"> • This procedure requires the drug to already be approved in a member state. • This procedure is based on the principle that a Marketing authorization and evaluation in one Member States (the so-called concerned Member States) ought to recognize the competent authorities of the other member states, that is, if a Member State concedes a national MA to a drug, other Member States can recognize the evaluation conducted by it and grant a MA for the drug themselves
Decentralized Procedure	<ul style="list-style-type: none"> • The decentralized procedure works in a similar way as the mutual recognition one, except here the medicinal product in question has not yet received a marketing authorization in any Member State at the time of application. • Like the MRP, a reference member state is chosen, which will evaluate the MAA. • The remaining member states then proceed to give their opinion on the evaluation. • If all concerned member states agree on the evaluation by the reference member state, the drug will be approved and allowed for sale in those countries(14). If a member state disagrees, the Co-ordination Group for Mutual Recognition and Decentralized Procedures will, like in the MRP, play a referee role

Most of the EU countries obtain market authorization through any or some of the above listed procedure. The concerned authorities for each of the country are listed below:

Country	Approval Process	Approving Authority
Austria	Centralized, National, MCP	Austrian Federal Office for safety in Healthcare
Belgium	Centralized, National, MCP	Federal Agency for Medicine and Healthcare
Czech Republic	Any of the four	State Institute of Drug Control

Denmark	Any of the four	Danish health and Medicine Authority
Finland	Any of the four	Finish Medicine Agency
France	Any of the four	National Drug Regulatory Body
Germany	Any of the four	Federal institute for drugs and medicinal devices
Greece	National procedure (lengthy) or EU procedures	National Pharmaceutical organization (EOF)
Hungary	National Procedure	National institute for Pharmacy
Ireland	Any of the three procedures	Health Product Regulatory Authority
Netherland	National, Centralized and MCP	Medicine evaluation Board
Norway	Centralized or MRP (EEA)	Norwegian Medicine Agency
Slovak Republic	National ,centralized, the MRP	Medicine Evaluation Board
Spain	Any of the four	Spanish Medicine and Health Product Agency
Sweden	Centralized procedure or MRP	Medical product Agency
UK	Any of the four	Medicines and Healthcare products Regulatory Agenc

Asia Pacific

There is no common procedure for drug approval across the Asia pacific countries. Each country has its own regulatory procedure. The following table highlights the approval procedure employed as well as the concerned authority.

Country	Approving Authority	Approval Procedure
Malaysia	Drug Control Authority (DCA)	<ul style="list-style-type: none"> • Three staged Process: <ul style="list-style-type: none"> ➤ Preliminary Screening ➤ Laboratory Testing ➤ Dossier evaluation
Thailand	Thai Food and Drug Administration	<ul style="list-style-type: none"> • Drug Approval is a combination of two separate stepped processes: <ul style="list-style-type: none"> ➤ Market Authorization

		<p>➤ Drug Registration</p> <ul style="list-style-type: none"> A drug is first granted a conditional Approval for two year for its safety monitoring fulfilling which it qualifies for unconditional approval.
Vietnam	Drug Administration Vietnam	<ul style="list-style-type: none"> The process involve pre submission preparation, manufacture sign on dossier, submission of dossier, Dossier evaluation.
Hong Kong	Pharmacy and Poisons Board	The process relies reviewing the application on the basis of safety, efficacy and quality.
Indonesia	National Agency for Drug and Food Control	<p>Two stepped procedure:</p> <ul style="list-style-type: none"> Pre registration <ul style="list-style-type: none"> Screening of drug registration Determination of registration category and evaluation path Registration <ul style="list-style-type: none"> Issuance of head of agency submission letter Drug registration application and dossier submission Dossier evaluation
India	Central Drug Standard Control Organization (CDSCO)	<ul style="list-style-type: none"> Submission of application to Investigation New drug (IND) Examination and review by New Drug Division Recommendations from Drug Controller General of India (DCGI) Licensing by CDSCO and DGCI
Australia	Therapeutic goods Administration	<ul style="list-style-type: none"> Submission of application to TGA Premarket evaluation, quality, safety and efficacy. Price assessment and inclusion in PBS
Phillipines	Food and Drug Administration	<ul style="list-style-type: none"> Issue of LTO (License to Operate) by FDA Registration of Drug by the Center for Drug Regulation and Research

iii. Pricing

Each country has its own regulation for setting up the prices of the pharmaceutical.

The following table highlights the details of pricing process employed by various countries. Each of the strategy has been explained in detail in the literature:

EUROPE

Country	Pricing Technique	Pricing Authority
Austria	<ul style="list-style-type: none">• External Price referencing	Federal ministry of Health and Pricing Committee
Belgium	<ul style="list-style-type: none">• No price control• Free pricing	Commission for the Prices of Medicine Product
Czech Republic	<ul style="list-style-type: none">• Maximum pricing through reference of average of the three lowest of 21 EU countries• Maximum distribution margin	State Institute Of Drug Control
Denmark	<ul style="list-style-type: none">• Free Pricing	Danish Medicine Agency
Finland	<ul style="list-style-type: none">• Reference pricing	Pharmaceutical Pricing Board
France	<ul style="list-style-type: none">• Non reimbursable drugs, freely priced• Prices of Reimbursable medicines are set through negotiations	Economic Committee On Healthcare Product (CEPS)

Germany	<ul style="list-style-type: none"> • Reference pricing for therapeutic and generic substitutes • Maximum pricing by the manufacturer, for drugs with no additional benefits. • For drugs with additional benefits, prices are set through negotiations 	GKV-SV: National Association of statutory Health Insurance Fund
Greece	<ul style="list-style-type: none"> • Pricing is based on average of the three lowest prices in EU 	Pricing Committee, Greece
Hungary	<ul style="list-style-type: none"> • No price control for non reimbursable products • For reimbursable medicine: <ul style="list-style-type: none"> ○ Reference pricing, price volume agreements for non generics ○ Price cuts for generic (30% lower for first generic version with a further 10% decrease in subsequent versions) 	The National Insurance Fund Administration
Ireland	<ul style="list-style-type: none"> • External Reference pricing (prices of the 9 EU countries) • Strict cost saving price cut regulations (70% reduction on patent expiry, for product with existing patents- a 60% reduction to the wholesaler, further 50% reduction after 12 months) 	Health service executive (HSE)
Netherlands	<ul style="list-style-type: none"> • Maximum retail price • External Reference pricing in 4 EU countries (Germany, France, Belgium and the UK) 	Ministry of Health, Welfare and Sports

Norway	<ul style="list-style-type: none"> • Maximum price send through External Price referencing • Stepped price model for generics (prices are reduced through stepwise predetermined rates) 	Norwegian Medicine Agency
Slovak Republic	<ul style="list-style-type: none"> • OTC and reimbursable pharmaceuticals are freely priced, although manufacturers and importers may submit their pricing proposals. • External Reference Pricing is employed , reference from two lowest in the EU 	Slovakian Ministry of Health
Spain	<ul style="list-style-type: none"> • Three pricing techniques involved: <ul style="list-style-type: none"> ○ External referencing ○ Internal referencing ○ Cost plus referencing • For non reimbursable medicines, free pricing is used 	Inter Ministerial Commission Of Medicinal Prices and National Committee On Rational Use Of Drugs
Sweden	<ul style="list-style-type: none"> • No explicit pricing criteria • Inpatient products are subjected to free or market based pricing 	Dental and Pharmaceutical pricing Agency
United Kingdom	<ul style="list-style-type: none"> ▪ Non reimbursable drugs are freely priced at manufacturer's level. ▪ Pricing of reimbursable drugs is dependent on the category to which it belong, are set by negotiations and profit control 	Medicines and Healthcare products Regulatory Agency (MHRA)

Asia Pacific

Thailand	<ul style="list-style-type: none"> • No price control • Allows free competition 	
Vietnam	<ul style="list-style-type: none"> • Prices of drugs purchased by 	Drug Price Management

	govt. are highly regulated <ul style="list-style-type: none"> • Essential drugs, contracted through tenders are unregulated • Prices of the Drugs sold to open market are proposed by the companies but regulated by the govt. 	division
Hong Kong	<ul style="list-style-type: none"> • No strict government control , prices unregulated 	Ministry of Health
Indonesia	<ul style="list-style-type: none"> • No pricing regulation in private sector • Public sector regulations include: <ul style="list-style-type: none"> ○ Max margin on generics- 50% • Patented products are set by the companies 	
India	<ul style="list-style-type: none"> • Prices controlled by capping industry profits • Maximum allowable post manufacturing expenses (MAPE) • The Maximum Retail Price (MRP) of formulations are worked out 	National Pharmaceutical Pricing Authority
Phillipines	<ul style="list-style-type: none"> • Very strict pricing regulations <ul style="list-style-type: none"> ○ Four pricing stages • Medicines are generally much expensive as compared to other neighbouring countries. 	
Malaysia	<ul style="list-style-type: none"> • In Public sector, the prices of the drugs listed in the essential drug list are regulated by the ministry. • Private sector pricing is free in theory, however, practically many times, are guided by the prices on essential drug list of the public sector. 	Ministry of Health

Summary of the pricing practices across various countries

Pricing techniques	<u>Free Pricing</u>	<u>External Referencing</u>	<u>Internal Referencing</u>	<u>Cost plus</u>	<u>Negotiations</u>	<u>Profit capping</u>	<u>Others</u>
Countries (Europe)	UK (non reimbursable drugs), Sweden (inpatient drugs), Spain (Out patient drugs), Slovak (reimbursable drugs), Austria, Belgium, Hungary (for non reimbursable), France (non reimburse drugs)	Spain, Slovak (non reimbursable drugs), Norway, Netherlands, Czech republic, Ireland, Hungary, Greece	Spain, Germany (for therapeutic and generic substitutes)	Spain	France (reimbursable), Germany (drugs with no additional benefits)		Norway (stepped price method for generics), Netherlands, Ireland (strict cost saving method). Hungary (for reimbursable)
Countries (APAC)	Malaysia, Indonesia (pvt. sector medicines), Thailand, Vietnam,					India, Indonesia (public sector medicines)	Philippines

iv. Reimbursement

Europe

Country	Reimbursement Practices	
Austria	<ul style="list-style-type: none"> Statutory health insurance covers 98% Strict inclusion criteria 	
Belgium	<ul style="list-style-type: none"> Reimbursement Based on therapeutic value 	
Czech Republic	<ul style="list-style-type: none"> Indication based Medicines for hospital use Prescription medicines 	
Denmark	<ul style="list-style-type: none"> Indication based Rates depends upon patients accumulated expenses 	Reimbursement committee, Danish health and medicine agency
Finland	<ul style="list-style-type: none"> Three level, based on therapeutic use and cost of medicine 	Social Insurance Institution
France	<ul style="list-style-type: none"> Reimbursed through mandatory health insurance. Either through Retail pharmacies or Hospital drugs Based on therapeutic value 	Done by UNMAC, Based on SMR rating granted by HAS
Germany	<ul style="list-style-type: none"> Runs a negative list for non reimbursable medicine Reimbursement is based on therapeutic value as well as patient's age 	Cost benefit analysis by GBA Federal Joint Committee
Greece	<ul style="list-style-type: none"> All Medical products that require prescription are reimbursed Reimbursement is based on disease severity as well as socio economic status 	
Hungary	<ul style="list-style-type: none"> Two types- Normative (for all indications), Indication based Reimbursement level is Based on the severity of the disease 	
Ireland	<ul style="list-style-type: none"> Easy inclusion on list, no or very low copayment 100% reimbursement for severe disease Other models based on health economics 	Health service executive
Netherlands	<ul style="list-style-type: none"> Divided in two levels: <ul style="list-style-type: none"> those bought at pharmacies – (reimbursed based on substitutability/ therapeutic comparability)and those administered at hospital 	

	(based on negotiations)	
Norway	<ul style="list-style-type: none"> Based on severity and duration of the disease Also based on health economics and age specific 100% reimbursement for severe, contagious disease 	For generic medicines- NoMA For non generic- National Advisory committee for drug and National Council for healthcare priorities
Slovak Republic	<ul style="list-style-type: none"> Drug administered to inpatients are fully Reimbursed Out patient medicines are fully or partially reimbursed Drugs with limited evidence are not reimbursed 	Slovakian medical chamber
Spain	<ul style="list-style-type: none"> Three levels <ul style="list-style-type: none"> Hospital pharmaceutical (100%) Chronic illness (90%) Prescription only pharmaceuticals (60%) 	Inter ministerial committee and national committee on rational use of drugs.
Sweden	<ul style="list-style-type: none"> Two types of reimbursement <ul style="list-style-type: none"> General (for all medicines) Restrictive (for special conditions) Reimbursement criteria- based on high cost threshold (incremental reduction in patient's copayment with increase in medication cost) 	Dental and Pharmaceutical Benefit agency
United Kingdom	<ul style="list-style-type: none"> HOM are fully reimbursed by the NHS provided that the manufacturer price complies to the reimbursement price In general, almost all OTC and pharmaceuticals prescribed by a private doctor are not reimbursed by the NHS 	The National Institute for Health and Clinical Excellence (NICE)

Asia Pacific

Country	Reimbursement	Reimbursement Authority
Australia	<ul style="list-style-type: none"> Automatic reimbursement under PBS 	
Malaysia	<ul style="list-style-type: none"> MOH Drug formulary-Only in public hospital Medicines purchased from public hospitals are free 	
Thailand	<ul style="list-style-type: none"> Operates national Essential Drug List containing 740 entities. 	

	<ul style="list-style-type: none"> ○ Reimbursement criteria is based on: ○ Safety and efficacy score and cost index ○ Cost effective threshold e.g., QALY Budget impact 	
Vietnam	<ul style="list-style-type: none"> ● Around 800 pharmaceutical products, specified under reimbursement list, qualify for copayment system. ● Social Health insurance members can avail the benefit only if the drug is available at Hospital. ● No reimbursement for drugs purchased from private stores 	
Hong Kong	<ul style="list-style-type: none"> ● Drug formulary 	
Indonesia	<ul style="list-style-type: none"> ● Operates an Essential drug List. <ul style="list-style-type: none"> ○ Public sector EDL Drugs are subsidized ○ Private sector EDL are under strict price control 	
India	<ul style="list-style-type: none"> ● National List of essential Medicines 	MoHFW
Philippines	<ul style="list-style-type: none"> ● Free medicines to the following beneficiaries: <ul style="list-style-type: none"> ○ Children under 5 years ○ Pregnant women ○ Elderly persons ○ Patients who cannot afford ○ Specific medical conditions (Malaria, Tuberculosis, Extended programme for immunization vaccine for children, HIV/AIDS) ● Public Health insurance, social insurance or other sickness funds provides partial medicine coverage for Essential Medicine List. 	

Based on the above reimbursement overview, the reimbursement systems or the copayment criterias for various countries can be broadly categorized as follow

Reimbursement Summary

	Positive list/ negative list	Based on Therapeutic value	Based on cost	Based on dispensing unit (OPD/IPD) or prescription/ OTC	Automatic reimbursement	Any other
Europe	Germany	Belgium, Czech republic, Denmark, Finland, France, Hungary, Norway,	Finland, Ireland, Sweden	Czech Republic, Slovak republic (IPD), Spain, UK (NHS),	Greece	Netherlands (Based on substitutability/ therapeutic comparability), Norway (duration of a disease), Germany (age)
APAC	Malaysia, Vietnam, Hong Kong, Thailand, India	Philippines		Vietnam (HOM)	Australia	Philippines

v. Intellectual Property

The following table highlights the PhRMA and USTR recommendations and placements

PhRMA Status		Priority Foreign Country	Priority Watch List	Watch List
2014	Europe	Nil	The European Union, Hungary	Finland, Greece, Germany, Spain
	Asia Pacific	India	Indonesia, Thailand	Vietnam, Malaysia, Philippines

of the countries according to the existing intellectual property regime of the countries.

The Intellectual Property Regime of Asia pacific is far weaker than Europe. The USTR Submission listed European Union as a whole under the Priority watch list stating its concern on the current practices of European Medical Agency

Marketing and Distribution Practices

Europe

Country	Marketing and Distribution Practices
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USTR Status		Priority Foreign Country	Priority Watch List	Watch List
2014	Europe	Nil	Nil	Finland, Greece
	Asia Pacific	Nil	India, Thailand	Vietnam
Austria		<ul style="list-style-type: none"> Market dominated by the wholesalers 		

	<ul style="list-style-type: none"> • Wholesalers distribute the medicines to the public pharmacies or hospital pharmacies • In outpatient sector, Medicines are generally dispensed by community Pharmacies or branch pharmacies which practice under the supervision of the community pharmacies. • Direct delivery to community pharmacies accounts only 3% • Self dispensing Doctors also allowed dispensing medicine in locations without nearby pharmacies.
Sweden	<ul style="list-style-type: none"> • There are two models of distribution in Sweden <ul style="list-style-type: none"> ○ Single Chain Distribution Pharmaceutical companies distribute the product to the wholesalers who distribute them to the Apoteket (the pharmacy with monopoly) ○ Multi Chain Distributions Pharmaceutical companies distribute their product to the wholesalers who distribute them to the retail pharmacy outlets or chain of independent pharmacies.
Slovakia	<ul style="list-style-type: none"> • Market dominated by wholesalers. • Wholesalers and distributors are represented by the Slovak Association of Pharmaceutical and Healthcare distributors <ul style="list-style-type: none"> ○ Current membership includes 57 manufacturers, 4 distributors and 13 pharmacy chains. • There are around 1800 registered pharmacies in Slovakia, including 54 state owned hospital outlets.
France	<ul style="list-style-type: none"> • A multi channel distribution system is in place • Manufacturers in France can supply the drugs either directly to the pharmacies or to the wholesalers who can supply them to the pharmacies • There are no pharmacy chains in France. Instead individually owned pharmacies operating in groups which makes a basis for their collective purchasing and marketing • France prohibits horizontal and vertical integration of pharmacies, or

	<p>ownership by non pharmacists.</p> <ul style="list-style-type: none"> Each qualified pharmacist can own a maximum of three pharmacy outlets.
Greece	<ul style="list-style-type: none"> The majority of pharmacy sales continue to originate from (full-line) wholesalers Pharmaceutical company supply the products to the wholesalers who supply them to the Pharmacies
Spain	<ul style="list-style-type: none"> The main player in the distribution system are the full line wholesalers The multi channel distribution system operates <ul style="list-style-type: none"> The wholesalers supply to retail pharmacies, hospital pharmacies and the laboratories which can also distribute the products to retail pharmacies and hospital pharmacies
Norway	<ul style="list-style-type: none"> Most of the distribution occurs through the three main wholesalers In addition to these, there is a selection of manufacturers with permission to operate wholesale business for their own products, as well as grocery wholesalers that supply non prescription medicines to LUA 3 outlets. The three major pharmacy chains; Vitus Apotek AS, Alliance Apotek and Apotek 1 are each vertically integrated with wholesalers Norsk Medisinaldepot AS, Alliance Healthcare AS and Apokjeden Distribusjon AS, respectively
Netherlands	<ul style="list-style-type: none"> Around 65% of the pharmacies are owned by pharmacists and 35% by the pharmacy chains, which are themselves primarily owned by pharmaceutical wholesalers The sales of OTC medicines is restricted according to their classification status as pharmacy only, Pharmacy and Drug store and general sales Under certain conditions, the General Practitioners are allowed to dispense the medicines to the customers.
Hungary	<ul style="list-style-type: none"> Both pharmacy units and hospitals are supplied with the major of the drugs they need by the pharmaceutical full line wholesalers.

	<ul style="list-style-type: none"> • Manufactures are allowed to send pharmaceuticals directly to hospitals • Dispensing doctors are allowed in remote areas • Wholesalers supply to Pharmcies, self dispensing doctors, outpatient clinics and departments as well as in patient clinics/hospitals.
Belgium	<ul style="list-style-type: none"> • Wholesalers in Belgium are represented by the National Association of Full line wholesalers • The majority of the drugs are dispensed through independent pharmacies via wholesalers and the reminder through hospital based pharmacies • Independent pharmacies constitute 75- 80% of the total, with the reminder owned by the cooperatives • Retail pharmacies have a monopoly on distribution of prescription and OTC. • Para medicines can be sold in outlets such as pharmacies, health food shops, supermarkets and also by mail orders. • Pharmacy chains in Belgium are represented by Office Pharmacy Cooperative Belgium, which has some 17 members, representing around 600 pharmacies.
Finland	<ul style="list-style-type: none"> • There are two finish wholesalers specialized in distribution, with operations covering whole country. • Wholesalers distribution is based on single channel principle whereby the pharmacy or hospital can purchase a pharmaceutical company's products from one wholesaler • Pharmacies are responsible for the retail distribution of prescription only and self care medicines. • The hospital pharmacies or medical dispensaries run by municipalities or consortia of municipalities often organize the medicien services in the public sector. • Military pharmacy is incharge of medicine supply to the defence force.

Denmark	<ul style="list-style-type: none"> • Medicines are dispensed through community or hospital pharmacies. • Denmark has three main wholesalers distributing to private sector. • Pharmaceuticals may also be sold through other types of outlets without pharmacists
Ireland	<ul style="list-style-type: none"> • The wholesale distribution of pharmaceutical is governed by the Medical Products. • The wholesaler function in Ireland is the responsibility of full line wholesalers who are authorized and regulated by the Irish Medicine Board. • Pharmacies order electronically from the wholesalers. • The vast majority of pharmacy business are community or retail, with the remainder classified as hospital pharmacy business.
Czech Republic	<ul style="list-style-type: none"> • The pharmaceutical market itself, originally dominated by domestic and regional generic companies, has been won over by larger multinationals. • Although most major multinational are based at Czech, their manufacturing presence is limited
Germany	<ul style="list-style-type: none"> • Manufacturers in Germany supply to the wholesalers and can also supply directly to the drug stores. • The wholesalers distribute the products to the community pharmacies as well as mail order pharmacies • The wholesalers are represented by the Association of Pharmaceutical wholesaler
United kingdom	<ul style="list-style-type: none"> • The majority of pharmaceuticals are distributed through wholesalers to retail pharmacies, with large pharmacy chains dominating the market. • Direct to pharmacy model permissible

Asia Pacific

Country	Distribution and Marketing Practice
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Australia	<ul style="list-style-type: none"> • Wholesale market dominated by three players. • Local pharmacists own majority of community pharmacies
India	<ul style="list-style-type: none"> ▪ The drug distribution system in India is highly fragmented. Pharmaceutical companies have Clearing and Forwarding Agencies (CFAs) which are responsible for maintaining the stock of the company's products. ▪ Companies may have one to three CFAs in each state and a company may work with 25-35 CFAs in total. ▪ Pharmaceuticals pass through the company's central warehouse to the CFAs, from where they are supplied to distributors and then retailers, or directly to hospitals.
Indonesia	<ul style="list-style-type: none"> • Drugs are distributed from manufacturers to the distributors who distribute them to the pharmacies, drug stores, Plantations, doctors, grocery, pedolers, general stores and hospitals • Manufacturer can also supply to sub distributors and wholesalers directly supply to the hospitals • There is one pharmaceutical company for 11 distributors. • The competition between the distributors are quite high because they have to get orders from one pharmaceutical company and face pressure from other 10.
Hong Kong	<ul style="list-style-type: none"> • Patented and generic drugs are mainly distributed directly to hospitals, clinics or other institutions. • OTC medicines are distributed through well established chain store. • Other important distribution channels for OTC medicines are small

	and medium pharmacies stores and supermarket
Vietnam	<ul style="list-style-type: none"> • Under Vietnamese law, Foreign invested Enterprises are not allowed to distribute pharmaceutical products in Vietnam. Therefore, foreign drug companies generally turn to vietnames distributors to sell their product in Vietnam market.. • Distribution is conducted through two channels: <ul style="list-style-type: none"> ○ Treatment Channel: Represents the bidding and selling that takes place through the hospitals. ○ Commercial channel: represents the bidding and selling that takes place through pharmacies and other commercial entities.
Malaysia	<p>According to the pharmaceutical Association of Malaysia (PhAMA), around 30% of the pharmaceuticals are distributed by pharmacies. A further 26% and 19% are distributed by physicians and government hospitals, respectively.</p> <p>Private hospitals are responsible for a total of 14% of the total pharmaceuticals.</p> <p>Physicians are able to prescribe as well as dispense a drug.</p>
Philippines	<p>Wholesalers and importers are the major distributors.</p> <p>From them, the drugs are supplied to the drug stores (supplying to Independent pharmacies and Chain pharmacies), Hospitals (public and Private), Clinical NGOs and government agencies..</p>
Thailand	<p>The GPO (Government Pharmaceutical Organization), supplies about 1000 products to over 10,000 facilities including public and private hospitals,</p>

	<p>private drug stores including 10 pharmacy shops in Bangkok</p> <p>In addition to GPO there are additional 150 manufacturers in Thailand.</p> <p>Drugs are delivered to hospitals directly from GPOs or other wholesalers whereas community hospitals are responsible for drug distribution to health centers below them.</p>
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Summary of Marketing and Distribution Practices and regulation

Single Channel	Multichannel	Self dispensing doctors	Pharmacy chain permissible	Sales by non pharmacies	Internet pharmacies	Direct supply by manufacturers
Sweden Greece Finland	Sweden France Spain Czech Republic	Austria, Netherlands	Austria, finland, france, germany (under certain conditions), Greece, hungary, Ireland (under certain conditions), Spain, Netherlands	Belgium Denmark	Austria, belgium, finland, france, germany, Greece, hungary, Ireland, Spain, Sweden, Denmark, Slovakia, ireland	Hungary germany
India, philippines		malaysia	Hong kong	Indonesia, Vietnam		

CONCLUSION

SUMMARY ANALYSIS

The following summary matrix compares the entire healthcare system. It also defines the challenges and opportunity for pharmaceutical countries while venturing a new geography.

The parameters have been graded through various colours based on the Conduciveness, attractiveness, substantiality etc. the following key describes the connotations of the color grading.

Color key	Interpretation	Healthcare system	Pharmaceutical market	Approval	Pricing	Reimbursement	IP	Distribution
Blue	Conducive/ Attractive	Funded primarily through public taxation	Higher market value, high growth and potential	All four	Free Pricing, negotiations	Automatic reimbursement, Mandatory Insurance	Non watch list	Direct dispensing. Self dispensing doctors
green	Moderate	Social health insurance, pvt. Voluntary insurance	Moderate potential	Mix model	Mixed model	Category specific , Mixed Model	Watch listed	Dominated by a few Wholesalers
Red	Stringent/ Poor	Direct payment	Low market value, high growth and potential	National procedures (EU/ Non EU)	Tight pricing regulations	Strict inclusion criteria	Priority foreign country/ priority watch list	No regulation in distribution

EUROPEAN AND ASIA PACIFIC COUNTRIES HEALTHCARE SUMMARY MATRIX

	Healthcare system	Pharmaceutical market	Approval	IP	Pricing	Reimbursement	Distribution
Austria	Compulsory social insurance		Centralized, National, MRP	NL	External Price Referencing	Automatic reimbursement	Primarily done by pharmacies
Belgium	Compulsory social insurance		Centralized, National, MCP	NL	Free pricing	Strict inclusion criteria	Mostly dispensed through independent pharmacies
Czech Republic			Any of the four	NL	External Referencing (21 EU countries)	Moderate inclusion criteria	dominated by domestic and regional generic companies,
Denmark			Any of the four	NL	Free Pricing	Based on expenses	Dominated by three main wholesalers
Finland	public: taxation		Any of the four	WL	Reference pricing	Category specific reimbursement rate, moderate to high co payment	Single chain, dominated by two wholesalers
France	Compulsory social insurance		Any of the four	WL	Mix of free pricing and negotiation	Reimbursed through mandatory insurance	Multichain system for distribution
Germany			Any of the four	WL	Mix of reference pricing, negotiations and maximum pricing		Manufacturer and wholesalers dispense directly to pharmacies
Greece	public: taxation		National procedure (lengthy) or EU procedures	WL	External pricing (lowest in EU)	Automatic reimbursement	Manufacturer can supply directly to the hospitals

Hungary			National Procedure	NL	Mix of reference pricing, free pricing and profit regulations	Negative list	Manufactures are allowed to send pharmaceuticals directly to hospitals
Ireland	public: taxation		Any of the three procedures	NL	Internal referencing and strict price cuts	Easy inclusions on list, no or very low co payment	Prior marketing approval not priority
Netherlands			National, Centralized and MRP	NL	Max. retail price and external referencing	Strict inclusion criteria	Pharmacies and self dispensing doctors form a major channel
Norway			Centralized or MRP (EEA)	NL	External Price referencing	Very low co payment	Three chains control the wholesalers and dominate pharmacy outlets
Slovak Republic			National ,centralized, the MRP	NL	Mix of free pricing and external referencing	Category specific reimbursement rate, moderate to high co payment	Dominated by wholesalers
Spain	public: taxation		Any of the four	NL	Mix of free pricing, External referencing ,Internal referencing, Cost plus referencing	Category specific reimbursement rate, moderate to high co payment	Multichannel distribution system
Sweden	public: taxation		Centralized procedure or MRP	NL	Free pricing	Strict inclusion criteria	Single and double channel distribution system
UK			Any of the four	NL	Free pricing, negotiations and profit control	Reimbursed under NHS	Direct to pharmacy model permissible
	ASIA PACIFIC						
Australia			Non EU National		Cost plus,	Automatic	Wholesale

a			Procedure		reference pricing, and weighted average monthly method	reimbursement	market dominated by three players
Hong Kong			Non EU National Procedure	NL	Unregulated	Essential drug list	Patented and generic drugs are mainly distributed directly to hospitals, clinics or other institutions.
India			Non EU National Procedure	PFC	Regulated by capping industry profit	NELM	highly fragmented
Indonesia			Non EU National Procedure	PWL	Private sector unregulated. Others high profit margin	Essential drug list, under strict price control	Drugs are distributed from manufacturers to the distributors who distribute them to the pharmacies, drug stores, Plantations, doctors, grocery, pedol ars, general stores and hospitals
Malaysia			Non EU National Procedure	WL	Free pricing in pvt. Public prices by govt.	Drug formulary	30% of the pharmaceuticals are distributed by pharmacies. A further 26% and 19% are distributed by physicians and government hospitals, respectively.

Philippines			Non EU National Procedure	WL	Very strict regulations	Essential Medicine List, strict inclusion	Wholesalers and importers are the major distributors
Thailand			Non EU National Procedure	PWL	No price control	National essential drug list, strict inclusion	The GPO (Government Pharmaceutical Organization), supplies about 1000 products to over 10,000 facilities
Vietnam			Non EU National Procedure	WL	Highly regulated	Reimbursement list and SHI	Distribution is conducted through two channels