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EMERGING MARKET ACCESS STRATEGY IN THE PHARMACEUTICAL INDUSTRY THE EXAMPLE OF THAILAND

Présenté

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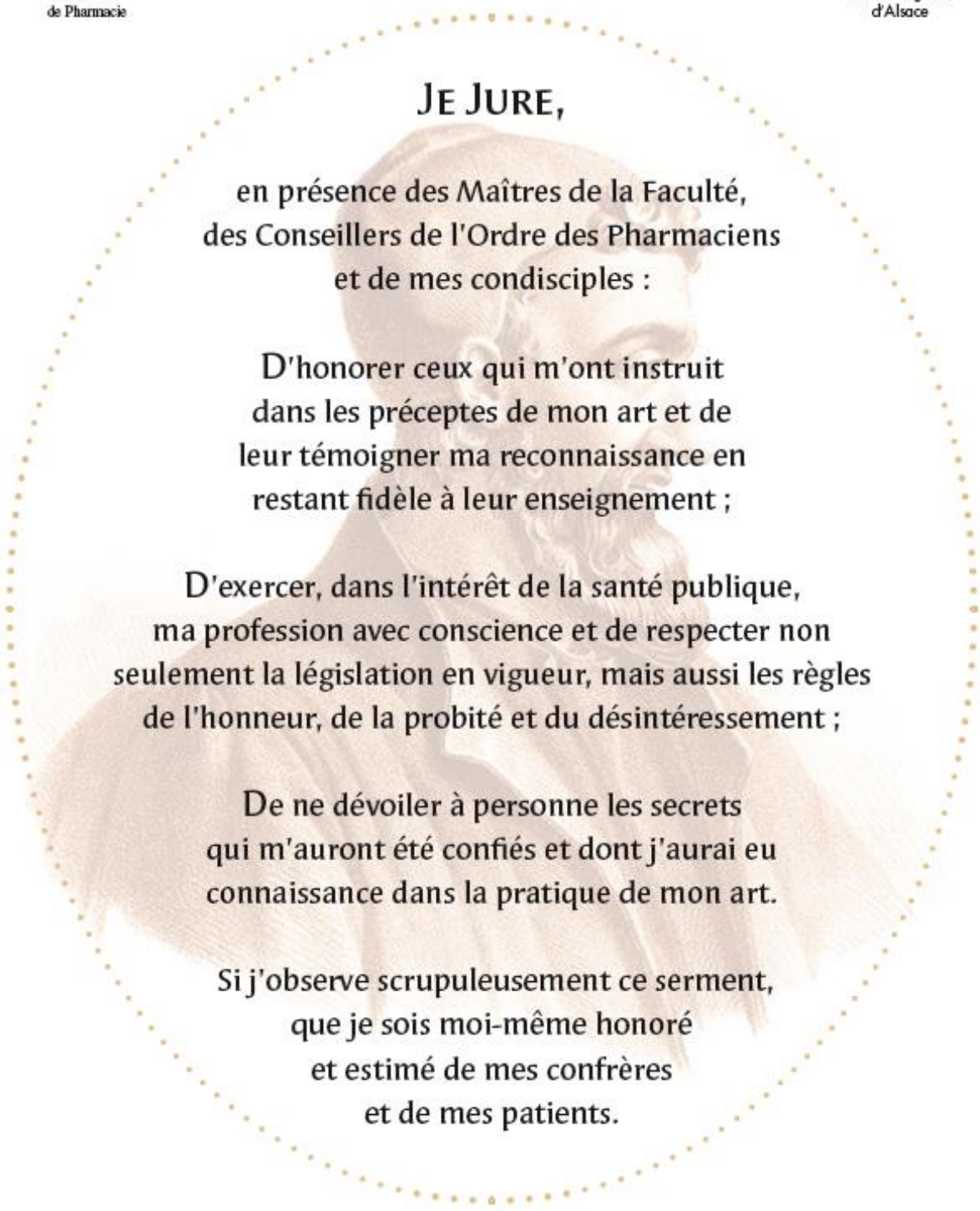

Je Jure,

en présence des Maîtres de la Faculté,
des Conseillers de l'Ordre des Pharmaciens
et de mes condisciples :

D'honorer ceux qui m'ont instruit
dans les préceptes de mon art et de
leur témoigner ma reconnaissance en
restant fidèle à leur enseignement ;

D'exercer, dans l'intérêt de la santé publique,
ma profession avec conscience et de respecter non
seulement la législation en vigueur, mais aussi les règles
de l'honneur, de la probité et du désintéressement ;

De ne dévoiler à personne les secrets
qui m'auront été confiés et dont j'aurai eu
connaissance dans la pratique de mon art.

Si j'observe scrupuleusement ce serment,
que je sois moi-même honoré
et estimé de mes confrères
et de mes patients.

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Contents

List of Abbreviations

ASEAN: Association of South-East Asian Nations
CAGR: Compound Annual Growth Rate
CEA: Cost-Effectiveness Analysis
CSMBS: Civil Servant Medical Benefit Scheme
DRG: diagnosis-related groups
EMA: European Medicine Agency
EU: European Union
FDA: Food and Drug Administration
GDP: Growth Domestic Product
GDP-PPP: GDP Purchasing Power Parity
HAS: Haute Autorité de Santé
HCV: Hepatitis C Virus
HEOR: Health Economy and Outcome Research
HIV: Human Immunodeficiency Virus
HTA: Health Technology Assessment
IDP: International Differential Pricing
IMF: International Monetary Fund
IRP: International Referential Pricing
KAM: Key Account Manager
KOL: Key Opinion Leader
NLEM: National List of Essential Medicines
NICE: National Institute
MA: Market Access
MoPH: Ministry of Public Health
MNC: Multi-National Company
OECD: Organization for Economic Cooperation and Development
OTC: Over the Counter
PA: Public Affairs
PRC: People's Republic of China
RA: Regulatory Affairs
R&D: Research & Development
RWE: Real-World Evidence
SSS: Social Security Scheme
TFDA: Thai FDA
UCS: Universal Coverage Scheme
UK: United Kingdom

Introduction

The Market Access in the pharmaceutical industry has gained tremendous importance in the pharmaceutical industry as the economic slowdown, increase of healthcare costs and aging population has pushed all the governments to adopt cost containment policies.

As a result, pharmaceutical companies face unprecedented challenges to get access for their products. The legal, clinical, and pricing requirements are now extremely strict and a fail in the approval or reimbursement process can have terrible consequences on the product commercial success.

Therefore, the companies had to adapt and establish an efficient market access strategy through a dedicated team. Thus, in the innovation-driven companies, this Market Access Department has seen its importance exploded in their global strategy.

If in the more mature markets, the access process is now well established, it is not the case in emerging markets: in constant evolution and often with a lack of transparency, the Market Access department is even more challenged. These emerging markets, also known as pharmerging, are now the driving force of growth in the pharmaceutical economy, and it is critical for the companies to succeed in these markets.

We understand that in the current situation, a customized market access strategy is the need of the hour. A Market Access framework with specific strategic tools will help companies to address these challenges in order to plan, organize, and implement access solutions at the benefit of the company and the patient.

In the first part, we will present an overview of what is the market access today, its different components, and current trends. In a second part, we will develop the notion of emerging markets in the pharmaceutical landscape, present the tools that we can use to best analyse these markets and list the different aspects of the Healthcare environment to focus on in order to build an efficient market access strategy. In the third part, an application of these tools to Thailand and a presentation of the different aspects of its healthcare system will be proposed. As a conclusion, recommendations to best succeed in the Thai market and other emerging markets will be given.

I- The Market access today

What is the Market Access?

In a generic and general definition, the Market Access encompasses a lot of parameters. In the simplest way, it can be defined as the ability of a company to sell its product in a particular space. Most of the time, we use this term for a company willing to export its products and service abroad, across the borders of its originate country. When it does, it can face a wide variety of challenge and barrier, such as the legal barrier, the import tax or even the sociocultural acceptation. These challenges and the capacity of the company to overcome them are the framework of the Market Access. But this discipline is not limited to international trade: we can talk about market access even

for a domestic business entry, presenting barriers as well. The parameters of the Market Access and their weighting in terms of importance, and therefore the resources the company has to allocate to them, are highly specific to every business sector, timing and area. In a free trade environment, along with a similar culture such as two countries members of the European Union (EU), the Market Access has low or non-existent barriers on the legal or fiscal. The EU members share most of their legislation: around 80% of the laws are now voted at the European Parliament. Therefore, a company authorized to sell its product or service in a member country, will be in most of cases able to do the same in the other countries, import tax free due to the free trade agreement. In that case, the investment in Market Access will be in general much lower. But many other parameters still exist, such as the language (24 official languages in UE), the cultural differences and the current trends among the population. But again, these differences will be lower between France and Spain than between France and China, for example. On the opposite of a free trade environment, in some case the Market Access and therefore the entry barriers can be difficult if not impossible to overcome: an embargo to a specific country, a situation of conflict or war, the hostility from the population toward foreign companies, a historical or punctual disagreement between two governments, or a protectionist policy from a government, legal or fiscal.

According to the context, the time and location the approach of Market Access can be entirely different. The difference between the types of industry also shows a huge gap: the Market Access considerations concerning the mobile phone industry will be entirely different compared to the pharmaceutical industry. To develop a Market Access strategy, we have to define the current business environment of the target market and the relevant industry current environment. As the Pharmaceutical industry is far from a typical business, the definition of the pharmaceutical Market Access will be very different from all the ones of other industries, with very specific parameters.

The Market Access in the pharmaceutical industry

The Market Access in the pharmaceutical industry is one of the most complex and rich one compared to other industries. It encompasses many various disciplines and their integration is mandatory to run a successful Market Access strategy. To be the most synthetic possible, we can define the pharmaceutical Market Access as the process ensuring the right patient to get a rapid and continued access to the product at the right price. Simple in appearance, the process is complex, involves almost all stakeholders of the healthcare environment and almost every department of a pharmaceutical company. From the early stage of the product development to the post-market real-life studies and including the regulatory requirements, reimbursement, communication, public affairs and more, the Market Access is present at every steps of the medicine life cycle. Without a successful Market Access strategy, the whole process can collapse and will prevent the patient from gaining access to the best treatment for his condition.

For a long time, the marketing and sales muscles have been the drivers of a company's commercial success. They were targeting mainly the prescribers (physicians), pharmacies and the motor of the demand, patients. As the offer was lesser and the economic situation more favourable, the governments were more willing to reimburse new drugs, without taking a deep look into their real clinical contribution. However, for the last two decades this environment with limited stakeholders has operated an important transition, seeing the considerable rising importance of another stakeholder, payers. The payer can be of different nature: he can be the government through its

social security, the private health insurances, the patient directly (out of the pocket expenses) or a mix. The origin of this evolution can be found in the global economic slowdown and the increase of healthcare costs. These two parameters have put countries health budgets under pressure and to keep their health system sustainable, many developed countries started to limit health expenditures. In order to do so, they used the legislation and gave strict scientific and economic considerations of the medicines value through the Health Technology Assessment (HTA) and the evidence-Based Medicine (EBM) for example.

In the case of France, the first attempt to regulate health expenditures can be found in the 1995 "plan Juppé". If the reform failed to pass, some cost containment reforms were saved, like the National Objective for Healthcare Spending (ONDAM), a budget target for the health expenditure. The ONDAM also includes technical directives for the reduction of healthcare spending. It will wait the following decade to see deep reforms for the control of healthcare spending, such as the implementation in 2005 of the notion of productivity at the hospital with the Diagnosis Related Groups (DRG)-based system (T2A, tarification à l'activité).

In 2016, France spent 11.8% of its GDP in healthcare, ranking 3rd for the OECD countries behind the USA (17.4%) and Netherlands (11.9%); it provides a universal coverage to all citizens and is considered as the best healthcare system by the World Health Organization, but in a context of increasing public debt (from 64.3% of GDP in 2007 to 96.5% in 2016) and very low GDP growth (1.2% in 2016), maintaining this level of service has become a difficult mission.

1. A-The components of the pharmaceutical Market Access

The different positions composing the market access department, if any, can vary markedly from one company to another. The Importance of the department vary accordingly to the nature of the company: for an innovation-driven company selling innovative and expensive drugs will need a fully operational Market Access team; which might not be the case for a company selling mainly OTC and companies focused on generics and biosimilars. It also varies according to the company's strategy in the market: do they focus more on opportunists and fast sales? Or do they have a long-term strategy involving building reputation and relationships with local stakeholders? Is the health environment in the target market creates a need of a strong Market Access department? These questions have to be answered from the very beginning. The Market Access department may include the following functions:

- Market Access Management
- Health Economics and Outcome Research (HEOR)
- Pricing & Reimbursement (P&R)
- Key Account Management (KAM)
- Public Affairs (PA) and Health Policy

The boundaries between these functions or their content are specific as well to each company. This can be explained by the relatively recent existence of the Market Access departments compared to the others. More differences can also be found inside a company: between the branches, or

between the branches and the global level. We can however find essential responsibilities for each function.

I.A.1- Market Access Management

This function, at the heart of the Market Access department, plays a pivotal role. As we discussed before, its goal is to allow the patient to gain quick and continuous access to the product at the right price. The Market Access manager develops and conducts adapted Market Access strategies. His/her main challenge is to prove to the payer the value of the product. If in the past the position was almost only focusing on the reimbursement file to be submitted to the payer, its role starts now from the early stage of the product development until the end of its life cycle.

The Market Access Manager has 4 main missions. The first one is to consider how the new product can impact the market healthcare by looking at the actual clinical results through working with the Medical Department; the second mission is to evaluate the product economic burden for the payer by conducting health economic studies with HEOR, but also the economic benefits it can receive from a cure; by doing that one can determine the value of the product in term of clinical improvement, economic, societal and innovation. At this step one can develop the value proposition of the new product, which is the main argument to convince the different stakeholders. If needed and relevant in the market one can also build the value dossier with the HEOR, P&R, and the medical department. The third mission is to forecast and understand what impact the market environment can have on the new product. To do so, one has to analyse the competition, their own strategy and the pipeline, the coming approval and arrival of generics or biosimilars, the coming regulation reforms (regulatory surveillance, with the Regulatory Affairs [RA] department); as a 4th mission, one also has to take account the current trends and projects of policy makers, and if possible try to influence them: for this, a specific position can exist in the department, in charge of the health policy management. The governmental affairs can also be a department on its own.

As we discussed, to achieve these objectives the employee in charge works in parallel with the other employees of the department: one builds the reimbursement dossier and the HTA submission with the person in charge of HOER and P&R.

One also works in synergy with the other departments: one can build the value dossier with the Medical department and the possible assistance of the Communication department. To measure the impact of a possible reimbursement of the molecule on the payer budget, one also needs the back up of the Marketing and/or the Business Intelligence (this department can have many names: commercial effectiveness, commercial excellence…); feedback on a regular basis from the Sales department can also give useful hands-on field insights.

Thus, the Market Access department can have for some companies a central and pivotal role. This is particularly true for the innovation-driven pharmaceutical companies, where they need a complete and synergic strategy to ensure the commercial success of their products.

We can highlight 3 main steps in the Market Access management of a new product:

- Value identification and strategy

The first step for the MA department is to identify the value of the product. It has to conduct an analysis of the product environment in the market: for example, in the therapeutic area of the molecule, benchmark the competitors based on clinical and economic evidences; conduct epidemiology and disease burden studies. By engaging the stakeholders, get their insights and find unmet needs and improvement opportunities. The payer(s) strategy has to be scanned, detected and understood in order to anticipate one's expectations and requirements. After the analysis, the department can identify in the new product key characteristics that stakeholders will consider as added value and/or competitive advantage.

If obtaining the reimbursement is a key moment of the commercial life of the product, preparing it has to be a main concern and timing optimized. Therefore, the Market Access strategy has to be well processed and insight driven with the same rigor as the traditional commercial strategy.

The mission of the MA especially on the global level can start at an early stage: by assessing the economic value of a molecule in development and not only its medical aspect, it is possible to decide whether or not the company should continue the development, stop it or adapt the investment. An early engagement of the stakeholders can give precious insights on the payer's need in term of economic analysis and clinical evidence (for example, which medical endpoint is the most important for him/her, and might guide a clinical study toward a specific sub-group of patients).

- Value demonstration

After identifying the product value, the department has to demonstrate it to the different stakeholders and especially to the payer. The department will have to produce different analysis and value dossiers through the Health Economy and Outcome Research (HEOR) data. The analysis can be based on clinical outcomes (meta-analysis, systematic review), on the economic impact for the payer (budget impact analysis), or a mix of both: the cost-effectiveness (CEA), cost utility or Cost benefit, Cost Minimization, Cost Consequences (only in the UK). Once this data is created, the value dossier can be built. The value dossier is a summary of all clinical, economic, societal data and supporting evidence of the molecule. After the adaptation to the local requirements, it will be in the end submitted to the payer to gain reimbursement. Some countries possess a health technology assessment organization, in charge of evaluating the value of the product. The pricing is also an important aspect of the Market Access, and will be highly dependent on the payer's willingness to pay and the existing competition. The different methods of pricing, the managed entry agreements or risk shared agreements and the use of real-world evidence will be discussed in I.A.2. Pricing & Reimbursement.

- The value communication

Beside identification and demonstration of the product value, the MA department has in charge the communication of this value to the stakeholders. Engaging the payers and the key stakeholders in order to obtain or maintain a reimbursement is a permanent mission in MA. Through the value story of the medicine, educational trainings and workshops, support to the group of patients and patients' advocacy the department has to communicate the value of the product. The value story is an

important part of the Market Access strategy, and a key part of the value communication strategy. It takes form and evolves all along the product lifecycle. If other documents produced in the MA department like the value dossier are often rich and complex in scientific data, the value story has to deliver key messages to the key stakeholder. This simplicity and efficiency has to be supported by the same scientific rigor and integrity. Different stakeholders, different expectations. Adapting the message to the stakeholder is mandatory; their expectation can strongly vary, and managing the stakeholders is a key mission of the MA department.

Table 1: Adapting value story to the stakeholder

Key stakeholders and factors	**Expectations to meet**
Patients	Can I afford the product? Is it effective? Is it easy to use? What do I risk?
Healthcare provider	What is the best treatment available?
Payer	Is it effective? Is it cost effective? Is the budget impact acceptable? Does it bring value compared to existing treatment?
Regulator	Is it safe?
Economics	HEOR analysis conducted (see I.A.2)
HEOR Strategy	Plan new HEOR studies to improve the product coverage and pricing potential in the future
Literature Review	Finding the relevant studies supporting the value of the product

The management of key stakeholders can include 5 steps. First, the identification of the stakeholders, on a general overview first (payer, provider, patient…) and then develops it to the individual (Mr. X involved in the social security reimbursement process, Doctor Y, group of patient Z…). Then, the engagement to the stakeholders; the approach will be completely different according to the stakeholder but the outcome expected is to gain support for the product. The approach can be for example an early engagement of the payer's reimbursement process or a support to a group of patient or patient advocacy.

After the identification and engagement of stakeholders, the department has to diagnose these relationships by evaluating their potential for threat and potential for support. Using a strategic framework (figure 1) one can then classify the relationships with the stakeholders according to their influence/impact on the company and their interest or availability in 4 generic categories: the influential observers, the key players, the active players and the spectators.

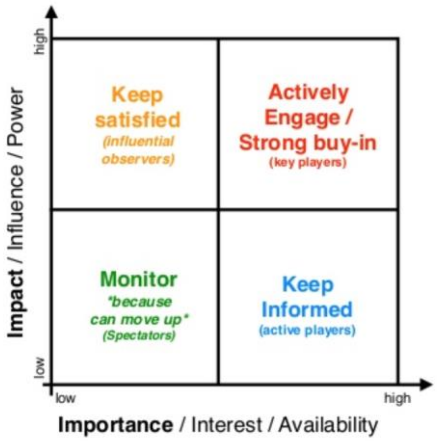


Figure 1: Stakeholder Management Framework (1)

The influential observer has a high influence but a low availability or interest. Decision makers are usually in this category. Despite their importance, they lack availability or interest to be engaged actively.

The key players have a high impact and are available. The Key Opinion Leaders are an example usually in this category. These stakeholders are the first priority of the stakeholder management; they can support or be opposed to the company project and have to be managed carefully. The company usually can actively engage them.

The active players have a high availability but low influence. Their supporting potential is often neglected but they can be important partners in certain situations. The group of patients can be present in this category, depending on the market: almost not existent in emerging countries for now, they have however a huge influence on policy makers in the USA.

Spectators have low influence and availability. They have a marginal importance in the stakeholder engagement, and have to be efficiently monitored. The group of interests, for example moral or ethic can be usually included in this category.

Many other classifications are found in the literature, and have to be internally integrated and adapted to the company and product nature and the market of interest.

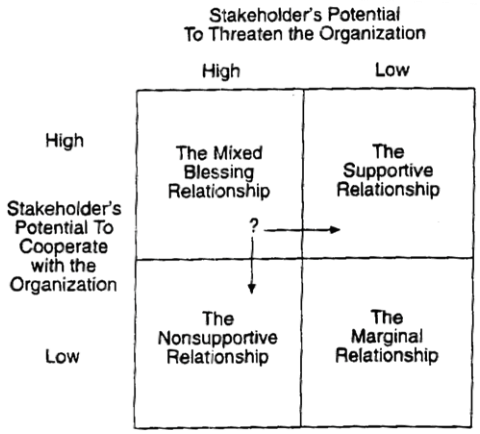


Figure 2: the stakeholder relationship diagnosis (2)

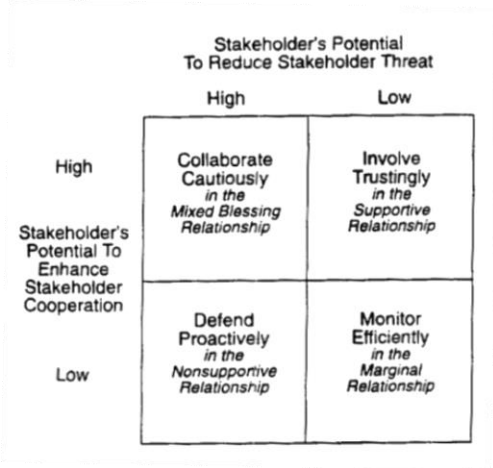


Figure 3: Strategies for managing stakeholder relationships (2)

These frameworks, built by Freeman originally, present the stakeholders with a potential to threaten or a potential to support (3). Here, stakeholders are classified as mixed blessing, supportive, non-supportive and marginal relationship. Freeman proposes different strategies to manage these categories of stakeholders.

If the specificity of the pharmaceutical industry has to be integrated in this management, it is a useful tool for the Market Access department for the organization, prioritization and can be a Key Performance Indicator for the stakeholder management (4), (2).

These relations, with institutions and individuals, have to be carefully written, validated and updated on a regular basis. A mapping of the stakeholders (5), their behaviour toward the company and the strategy to be adopted for each of them is also required for an efficient stakeholder's engagement approach in a particular market. It is even more important in emerging countries, where the key stakeholders are more difficult to identify and the methodology to engage them much less processed and transparent than in Mature Markets.

The figure 4 presents the role of the Market Access from the early stage of a product development until the end-cycle management.

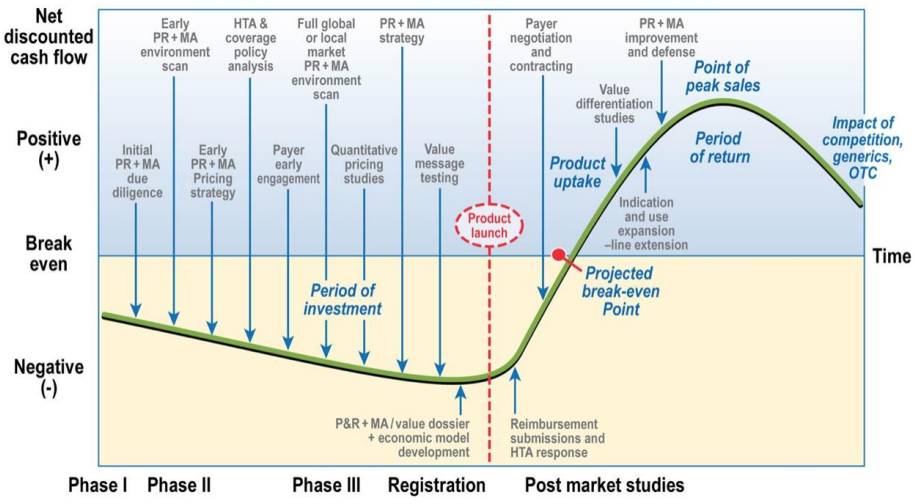


Figure 4: Market Access planning of the product lifecycle (6)

PR = Pricing Research; MA = Market Access; HTA = Health Technology Assessment

I.A.2- Health Economy & Outcome Research

The Health Economy and Outcome Research function is the more strictly economic part of the Market Access department. The employee in charge of it usually comes from a Life Science background, with more and more often have been trained or have experience in Health Economy as the level of competencies requirements has increased with the rise of the Heath Technology Assessment. The health economy practice determines the costs associated with a new health product. The Outcome Research practice determines the outcomes of this product accordingly to the audience: in general, for a patient the outcome will be the clinical benefit, for a private health insurance it will be the cost of the product, and for a public payer, a mix of both.

The job of the HEOR manager is notably to conduct different analysis based on clinical outcomes cost and efficiency: The Market Access department can decide to conduct an analysis of the clinical benefits of a new or existing molecule, in order to measure the clinical value and to benchmark its clinical outcomes compared to the competitors, if any. Most of the time these studies will be literature reviews, like a meta-analysis or a systematic review.

A meta-analysis is a statistical analysis that combines the results of multiple clinical studies presenting a similar methodology. By doing that, it increases the power and accuracy of the results by volume effect and decreases the uncertainty over individual clinical studies.

A systematic review is a comprehensive and precise plan and search process established a priori in order to reduce bias of individual studies, by collecting, critically analyse and synthesizing all the relevant studies or papers concerning a particular topic. In the end, we have an exhaustive summary of the current literature for this topic. A systematic review may include one or more meta-analysis. In the case of a medicine, systematic review including meta-analysis of multiple randomized controlled trials are the key of health technology assessment and evidence-based medicine. It has the strongest level of evidence a company can provide in its value dossier, in order to obtain a reimbursement from a payer. Therefore, it's a critical part of the product life. Both processes are long, demanding and usually involves many people. It can be done internally if the company has the human resource or externally by academic stakeholders or by a Contract Research Organization (CRO). This decision of internalizing or not the different functions of Market Access is an important choice of strategy and it has to be done accordingly to the resources and the specificities of the market.
The department can also conduct Efficiency studies for a product: the cost effectiveness analysis (CEA). This is a central part of the value dossier the Market Access will submit to the payers. In the healthcare world, it's an economic analysis comparing the relative costs and outcomes of a medical intervention. It is usually resulting in a ratio between the gain in health as denominator from a chosen parameter as the number of years of life gained, neonatal death avoided, delay on the first symptoms appearance. The numerator is the overall cost of the intervention. The most used outcome measure from an intervention is the quality adjusted life years (QALY), measuring the health improvement in years. It includes the quality of life lived (the number of years lived in perfect health) and the quantity of years lived (number of years gained with the intervention). One QALY represents one year in perfect health. It is the reference measure for assessment of a health technology. The Distributional Cost-effectiveness Study (DCEA) is an extension of the standard CEA

allowing the assessment of the distribution of outcomes among the population, highlighting the health inequality according to different parameters. It can be useful to conduct this analysis especially in countries with poor equality in terms of access to healthcare, providing a strong argument to the payer, when he is publicly funded (see the case of Thailand).

A particular attention to the trend in the payer's expectations in the specific market is needed: in some countries, the focus will be the clinical outcome, especially in developed countries. In emerging countries, the payers will more likely focus on the costs. It is an important parameter in the strategy of the department. Though, with the global trend of budget constraints, the cost is now a global preoccupation for the payers. Therefore the CEA is essential and its importance is still growing and developing with for example the real-world evidence. The primary analysis is now just the first step and the economic analysis will continue during the whole life cycle of the product.

The understanding of the existing reimbursement systems and HTA requirements in mature markets can help to forecast which type of reimbursement model the emerging country is heading to.

I.A.3- Pricing & Reimbursement

After determining the value of the product with the HEOR tools, the company has to demonstrate it to the payer. To do so, at least in OECD countries, the company will have to build a value dossier. This value dossier and the requirements from the payer in terms of content can vary significantly according to countries, such as for the language and the different institutions. Having an in-depth knowledge of this reimbursement process is again essential for the success of the market access mission. Without this reimbursement, the patient might not have access to the treatment, especially concerning the poor and for innovative products. Before describing some reimbursement process, we have to define what is a value dossier and the Health Technology Assessment (HTA).

How countries and payers in general manage the reimbursement of drugs can vary widely. It is true for the reimbursement process application, the actual health provision for the patient, the different coverage schemes, and also for the pricing. The pricing for pharmaceuticals and health technologies in general is a difficult exercise, with many parameters.

As discussed, we entered in a value-based pricing era, only the USA and certain poor countries still presenting a "free-pricing" system. In this context, payers and especially countries chose different strategies to apply this concept of value-based for the pricing of medicines. We can observe two main approaches: the evidence-based pricing and the reference-based pricing.

For the evidence-based pricing, a country decides to assess on its own the right price for a medicine. To do so, he can develop internally different instances having in charge of the Health Technology Assessment of the drugs, evaluating their price in regard of their clinical outcomes within, in theory, a transparent and systematic framework. In that case, the pricing of a molecule requires the exploration of its value and in the same time establish a price reflecting the society's willingness to pay for it.

A good example is the current HTA style of the National Institution for health and Care Excellence (NICE). It is an executive non-departmental public body of the Department of Health in United Kingdom, having in charge notably the assessment of efficacy and cost-effectiveness of drugs. The resource allocation in the UK is based on cost-effectiveness. We can represent this system by a bookshelf of healthcare resource allocation (see figure 1), a relevant metaphor.

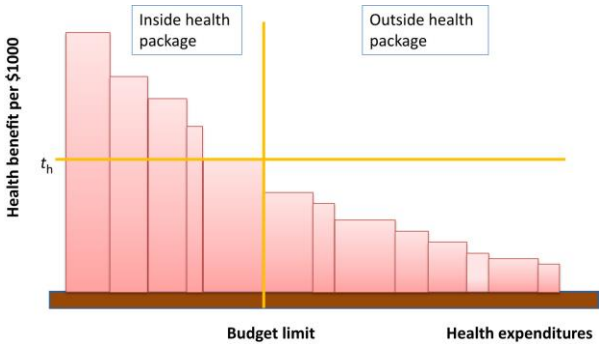


Figure 5 The bookshelf of healthcare resource allocation (7)

The height of the books represents the cost-effectiveness of the intervention, in "health benefit per $1000 invested, and the width of the book represents the total cost of the intervention. By ranking these books from left to right and implanting the budget limit on the abscissa, we can determine the cost-effectiveness threshold ($t_h$on figure 1), based on the last intervention still included in the health package covered by the public payer. A new intervention will have to be at least as cost-effective as this last included intervention to be reimbursed, except of the budget limit is extended. If this is an effective way to contain public spending, it can let people in need of treatments with limited health benefit (under the threshold) but with no other alternatives and too expensive for many people, like orphan drugs.

The French system doesn't present this threshold. The institution in charge of HTA, the Haute Autorité de Santé (HAS), assesses the health benefit of the product and then the benefit compared to the existing treatments. If the new product brings value compared to the existing treatment, the social security will reimburse the product regardless of the budget limit. If it allows all patients to have access to the best treatment, it is a problem concerning the budget constraint. For the countries practicing the reference-based pricing, there is often no proper national HTA organization.

I.A.3.a- Evidence-based pricing through the Health Technology Assessment

In the past, it was enough for the payer to reimburse a medicine based on the promise of the outcome. With the budget constraints, the society ability to pay and willingness to pay has strongly decreased.

There are as many definitions of Heath Technology Assessment that there are different HTA processes and organizations, but they are all considered as a tool to help decision-making of health stakeholders at all levels of a healthcare system. The HTA can be defined as the evaluation of the characteristics, impact and/or effect of health technology and it aims to inform the decision maker. These characteristics assessed include the safety, efficacy, the real-world effectiveness, the cost and cost-effectiveness but also the legal, ethical, social and political impact. It encompasses many disciplines and ideally strongly relies on strict and transparent scientific methodology. A more complete definition of HTA from the WHO is available in the appendices.

For the pharmaceutical industry, the most important end point of HTA is to reimbursement of their product through the demonstration of its value. The public funding HTA organizations are the most important to ensure the coverage of the patients under public social security, if any, which allow the broadest access to the treatment. However, a health technology is not limited to pharmaceuticals. A health technology is defined as an intervention used to promote healthcare, to diagnose, prevent and/or cure a condition; provide rehabilitation and long-term care; guarantee the health delivery. Therefore, beside the pharmaceuticals, it encompasses as well the medical devices, vaccines, procedures, guidelines organizing healthcare.

If the countries are usually the most interested by the HTA because of the budget constraints and in order to bring the best treatment to their citizens, the private-health payers are also relying on HTA. In a study published in 2011 (8), 8 private insurers in the USA were asked about they use of HTA. All of them declared to use the reports of at least one HTA organization, with a majority using 3 or more organizations. It is even more true for the new technologies like the personalized medicine (the use of patients genomic to guide the health decision), where they declared to rely more on HTA then for classic treatments, reflecting the higher need of HTA for payers concerning the new technologies.

Some HTA organizations, like the NICE in the UK or the HAS in France, have earned a growing influence both domestic and external. For most of public HTA organizations in western countries except the USA, there is a centralized coverage scheme ensuring healthcare to the population. It may be under a universal coverage, public/patient co-payment and public/private co-payment. In France, the first step for the application to state reimbursement of a health technology starts with the assessment of its value by a committee of the High Authority for Health (HAS), the equivalent of NICE in France. According to the nature of the technology the committee will be different, for the medicine it will be first the Commission de Transparence (CT). The CT assess the absolute clinical value of the medicine, regardless of its cost, and also its added value (improvement of health benefit, ASMR) compared to existing therapies. There are 4 levels of ASMR which will define the level of reimbursement of the drug. Then the company will send a clinical/economic dossier to the economic committee (CEPS) that will decide whether or not to reimburse the medicine and at which repayment rate based on the cost-effectiveness of the product. It also leads the price negotiation with the company (9). The NICE has a similar process but with different types of committees, and at the end the “bookshelf of healthcare of resource allocation” is applied. These systems of centralized social security give these countries a high-bargaining power, allowing them to strongly lower the prices of the medicines.

Since the budget constraint policies appeared in these countries, a re-evaluation of the benefit of medicines occurs every 4–5 years or triggered by the different stakeholders (the company, the public

institutions) based on new therapeutic data (for example from real-world evidence), the introduction of new drugs, a change of price, or a change of indication. For example, in France, a HTA re-evaluation of led to a de-reimbursement of this family for their high blood pressure indication. A reimbursement can also be granted for an established product (EPs, marketed for 8 years or more) receiving approval for a new indication (10). This can include an extension of indication for the treatment of another condition (the example of Pfizer's Viagra, originally a treatment for high blood pressure) or a new route of administration (example of Roche's Herceptin).

It is interesting to note that the United States Food and Drugs Administration (USFDA), has no proper HTA department and usually assess efficacy and safety in order to decide the approval of a health technology, but does not conduct cost-effectiveness studies, for example. Most of big players of the private health insurance in the USA have a HTA department, and many other independent organizations exist like the Blue Cross Blue Shield Technology Evaluation Center (BCBS TEC). Most of the time, the HTA's process, conduct and scope of private payers along with the Pharmacy Benefit Management (PBMs) organizations are not accessible to the public (11). The US system is very specific and for now almost no countries are leading toward it, mainly due to the high cost of healthcare in the country (around 17% of the GDP).

As discussed, the HTA has grown exponentially over the last decades, and many countries even the non-member of OECD are now acquiring a HTA system. This rapid evolution in some emerging countries has to be closely monitored, anticipated in a proactive way. In-depth knowledge of the HTA system of the country and its evolution is also essential to define the Market Access strategy.

I.A.3.b- Reference-based pricing

But not all countries are willing or have the possibility to establish these organizations, and prefer to choose the reference based pricing (12), which can be external or internal.

In the case of the internal reference pricing, the reimbursement price is set according to the price of other molecules in the same therapeutic area. The price is a function of prices of domestic substitute products.

In the case of the external reference pricing, or International Reference Pricing (IRP), the country will scan the work of other countries' HTA and the resulting drug pricing. They can directly use the same price or derive a benchmark from the prices of multiple countries (13). This way, they calculate a reference price for a product that will be used for the price negotiation with the company. More rarely they can set their own price based on the recommendations from the other country's HTA organization and adapted to their IEPR threshold. As an example, Slovakia (European Union member) will use the second lowest price of the medicine in the EU, and revise the prices every 6 months. This system drives the prices to a common minimum, and the logic is simple and understandable: the price is fair because the company sells at this price in other countries. By using the reference based pricing, a country can bypass all the socio-economic and politic requirements of an evidence-based pricing. Indeed, the set up of an evidence-based pricing system with for example a whole HTA organization needs time, long-term political engagement and investment, as long as

qualified people. Therefore, Research on this topic suggests that health technology prices do not change according to the macroeconomic factors of the different markets, suggesting that the reference-based pricing is the most common system around the world (14).

However, evidence-based pricing and reference-based pricing are not opposed: in most of countries where a HTA organization can be found, the payer also uses prices from other countries to support their decision.

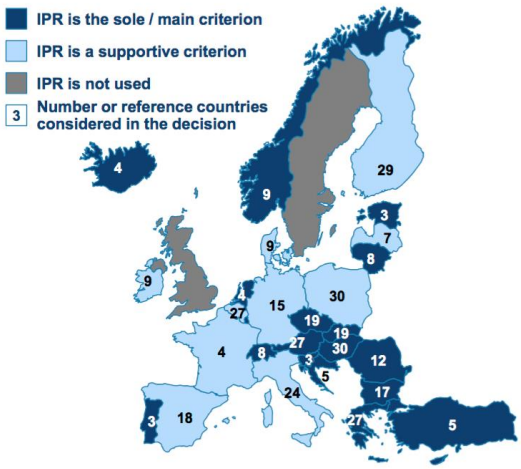


Figure 6: **International price referencing in Europe (15)**

The International Reference Pricing can be limited by the price list the country uses. On these lists, it is most of the time impossible to know the exact end price of the product, as all the rebates and discounts the company can offer at local, regional or even nationwide are more likely to stay confident. However, some policies like in Germany and the sharpening of the HTA and pricing processes tend toward more transparency and stability for these off list prices, easing the IRP. MSD started in 2017 to release a list disclosing the average and net price increases and the discounts offered to payers. Adding the fact that countries look more and more at the final net price in their own country to compare with other countries' price, it's becoming difficult for companies to maintain differential prices between countries.

If the IRP can improve the access of treatment in the different countries, it assumes that pricing of a product is transposable between countries without consideration of the health system, economic situation or value assessment. It also relies on partial or poor and non-controlled data, with many possible interpretations and limitations. The evolution of IRP will most likely lead down the prices toward the marginal cost, reducing the profit for the pharmaceutical companies. The reference based pricing might not be efficient in the long run, because it is likely to limit innovation.

I.A.3.c- International differentiation pricing

In this context, we can understand why the big companies are now exploring the implementation of International Differential Pricing to replace the widely spread reference based pricing system. The IDP can be considered as a will from the manufacturer to keep the flexibility of the Evidence Based

Pricing while adjusting it to local realities. In a differential pricing, the same product has a different price between countries for any reason, for example price controls or marketing and prescribing habits. This generic definition can result in two types of global pricing: the discriminatory pricing, result of profit maximization strategies from the company and in equity pricing (16).

In the "equity pricing", the countries or even individuals would pay a price that varies according to their income or any other measure of economic affordability, the particular disease burden within a country or the patient need. It is also called tiered, preferential or access pricing.

Differential pricing can be found in everyday life. As an analogy, we can take the example of the senior, children or unemployed people receiving a discount because their income result in a lower ability and willingness to pay. The theoretical foundations of differential pricing are found in Ramsey's pricing principles, applied on a global and segmented market (the pharmaceuticals) and suggesting that a monopolistic producer can generate higher profits if the price discriminates (17), when prices rise with income. However, the correlation between prices and country income is weak and we found that drugs can present a higher price in poor countries than in high-income level countries (18).

If in theory it would be the most equitable for the payers and so the patients, sustainable for the company and so the R&D and allowing the best access to innovative medicines, it presents some challenges.
The first one is to create by consensus a "benchmark price", based on what countries will adapt their price according to local conditions. By choosing a benchmark country, the nations would lose the pricing autonomy. After that, countries formerly under reference pricing can see their drug price increase when they shift to differential pricing. For example, a very high-income level country such as Singapore or the Luxembourg might see their drug prices explode compared to their neighbours. Luxembourg, part of the EU, currently uses reference pricing based on prices in Belgium, France and Germany. If the country switched to differential pricing, Luxembourg could see the drug prices at least double. It is also complicated to apply it in a country because of income distribution and regional disparities. For example, as we will see in the case of Thailand, the region of Bangkok has an average GDP/capita at least 5 times higher than the north-eastern region, ISAN. Therefore, including measures of income dispersion like the Gini index might be needed. Also, a particular disease different burden might question the differential pricing between two countries.
The second challenge to IDP and maybe the most complicated to solve, is the reflux trade: the artificially low-priced drug sold in a low-income country would be leaked and re-exported to high-income countries. If in the previous analogy, a child sells his discounted cinema ticket to an adult, the theatre might abandon this discount policy and therefore prevent other kids to enjoy movies.

Therefore, to set an efficient global IDP, the cross border sales have to be prevented, which is a difficult task in the globalized market where trade and movement of goods can be easy if not free as in the EU. If the IDP is appealing, key technical and political challenges remain to shift it from theory to reality. No full-scale implementation process is ready for now in the pharmaceutical companies, but some big groups are preparing for it. Roche, for example, plan to apply it based on GDP per capita adjusted for Purchasing Power parity (GDP-PPP per capita) and in exchange of a great improvement of patient access[1]. It is also part of the Access Strategy Framework 2015 of Novartis,

[1] https://www.roche.com/sustainability/access-to-healthcare/innovative-pricing-solutions.htm

and they already implement it on certain market and currently track the results[2]. In both cases, the purpose of implementing IDP is to expend the access of the innovative products to the patients in emerging markets. We can roughly identify 3 challenges for a company in implementing IDP:

- Decide a benchmark price, and adapt it to the local realities
- Avoid reflux trade
- Make sure access is expended in the countries that benefit from IDP

In the future, it is likely that developed countries will continue the reference based pricing, while the emerging markets will use IDP to negotiate a lower price. The integration of IDP in the global pricing policies of the pharmaceutical company is a promising market access strategy to ensure the access of the most innovative drugs to all patients in the world at the early stage of its life cycle.

I.A.3.d- Real-World Data and Real-World Evidence

Real-world data (RWD) and real-world evidence (RWE) are playing an increasing role in health care decisions.

According to the FDA:

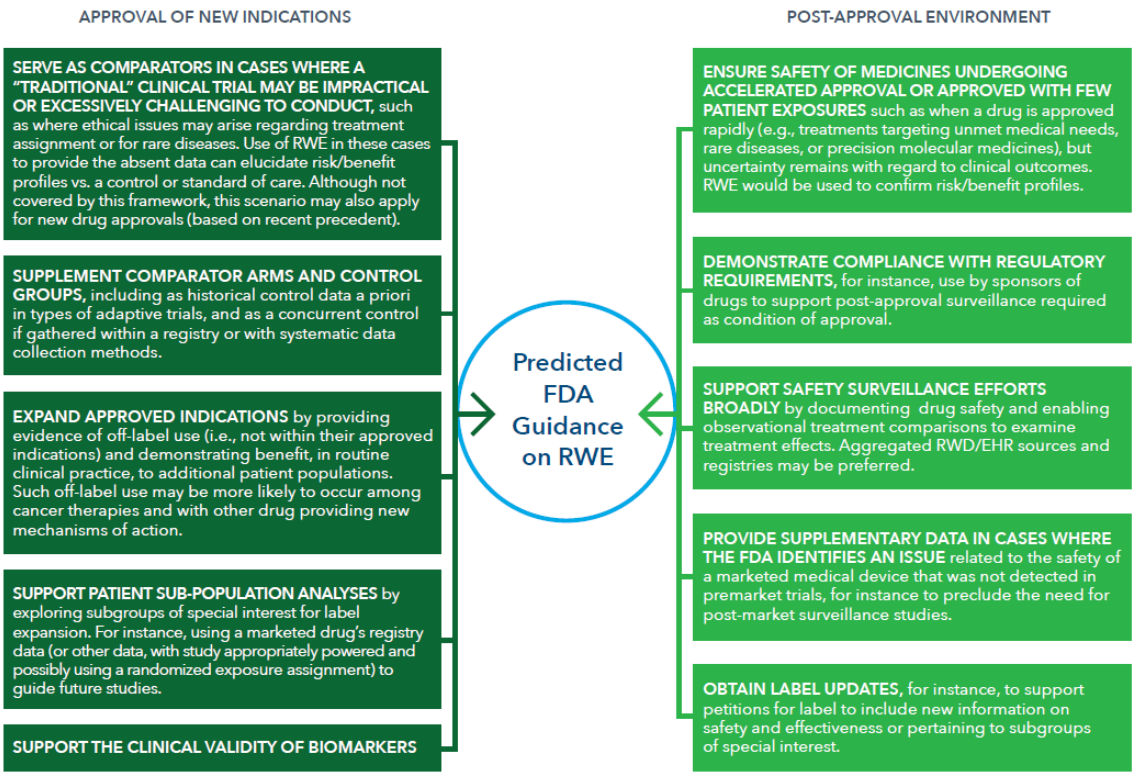
"Real world ***data*** are the data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. RWD can come from a number of sources, for example:

- Electronic health records (EHRs)
- Claims and billing activities
- Product and disease registries
- Patient-generated data including in home-use settings
- Data gathered from other sources that can inform on health status, such as mobile devices

"Real world evidence is the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD"

The benefits are many and its usage will most likely increase in the coming years. These new concepts, however, are not used in the Pharmerging markets and will not be used until they possess the needed infrastructure and patient data. Figure 7 below shows the positive impact RWD and RWE may have on the approval of new indications and on the post-approval environment.

[2] https://www.novartis.com/our-company/corporate-responsibility/expanding-access-healthcare/innovative-pricing



Source: FDA. Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices. Guidance for Industry and Food and Drug Administration Staff Document. Aug 2017; Sherman RE, M.D., M.P.H., et al. Real-World Evidence — What Is It and What Can It Tell Us? N Engl J Med 2016; 375:2293-2297; IQVIA Institute Analysis, Feb 2018

Notes: RWD = Real-World Data; RWE = Real-World Evidence.

Figure 7: possible benefits of RWD and RWE on approval and post-approval environment (19)

I.A.3.e- Outcome-based contracts

This contract between the industry and the payer involve a payment for the treatment based on the success of this one. For long, payers didn't see any interest in this concept, as in case of non-response, the patient could just stop the treatment. But with the appearance of a new specialty with a very high cost and the coming biotherapies presenting a tremendous punctual cost, the payers are more likely to get all interest in this concept. In the US, many of these contracts are not publicly disclosed. For now, 24 were disclosed and are forecasted to reach 65 in 2022. The huge administrative and technological requirements of such contracts will also avoid the Pharmergings to use this concept for now. The table below shows the next generation biotherapeutics that will most likely require outcome-based contract between health insurances and manufacturers, or a staggered payment.

GENE THERAPIES			CELL THERAPIES
Adeno-associated virus-based gene therapy	Genetic therapy	Plasmid-based gene therapy	Cell engineering
Adenovirus-based gene therapy	Genetically engineered autologous cell therapy	Retrovirus-based gene therapy	Cell transplantation
DNA vaccines	Genetically engineered autologous cell vaccine	Targeted gene repair	Somatic cell therapy
Gene expression regulation	Herpes virus-based gene therapy	Tumor suppressor genes	Stem cell therapy
Gene technology	Lipid-based gene therapy	Viral vector-based gene therapy	Stem cell transplantation
Gene transfer system	Non-viral vector-based gene therapy		Tissue engineering
			Tissue regeneration
			Tissue therapy
			Xenogeneic transplant

Source: IQVIA Institute, Feb 2018

Figure 8 the next generation biotherapeutics mechanisms and types (19)

II- The Pharmerging markets

II. A- Definition and classification of the pharmerging markets

The concept of Pharmerging markets was first introduced by the pharmaceutical industry consulting group IMS Health (now IQVIA, after its merging with Quintiles) and is formed from [Pharm (aceutical) + (e) merging]. These countries are emerging countries targeted by the Pharmaceutical Industry. They are defined by the IQVIA Institute based on per capita income below $30,000 and a five-year aggregate pharmaceutical growth over $1 billion. (19)

This definition reflects the intersection of health systems that are growing because of unmet medical need and where growth has acted as an incentive for life sciences companies to invest in addressing those needs.

In practice, though, a wide disparity can be observed between these countries. Therefore, these markets are usually separated in 3 groups: Tier 1, Tier 2, and tier 3:

- Tier 1: China.
- Tier 2, the other countries of the BRIC: Brazil, Russia, and India
- Tier 3, the fast followers, whose list is evolving every year:

Argentina	Mexico	Saudi Arabia
Ukraine	Turkey	Columbia
Egypt	Algeria	Nigeria
Thailand	Indonesia	Pakistan
Bangladesh	Kazakhstan	Vietnam
Philippines	South Africa	Chile

II. B—The Pharmergings as motor of growth

With the continued attempt from developed countries to reduce to costs of medicine, the Pharmerging markets are now the motor of growth for the pharmaceutical industry. The global share of medicine spending from these markets has risen from 13% in 2007 to 24% in 2017. It corresponds to an increase in value from $81 billion in 2007 to $270 billion in 2017.

The growth in spending seen in the pharmerging markets from 2007–2017 was driven both by governments' efforts to expand access to healthcare for their people and by the investments of multinational manufacturers who expanded operations, acquired or partnered with local companies and significantly expanded their revenues from these countries.

With the rapid growth of the pharmaceutical spending and a total Market Size for these markets forecasted to reach $2.3 trillion, we understand the need for the pharmaceutical industries to invest in the Pharmergings. However, the majority of medicine use and spending in these countries continues to be for generic medicines, and payment continues to be predominately out of pocket for consumers, ultimately tying medicine spending growth to economic growth of their overall economies. The new specialty drugs remain out of reach for many of the national payers in these markets.

On overall, this growth will keep reducing for the coming years. China, the biggest Pharmerging is forecasted to grow by only 5 to 8% in the next 5 years, and is already taking measures for a wide usage of generics, covered with the social security, and made locally. Tier 2 countries will keep more important growth for the next 5 years: 9–12% for Russia, more than 10% for India and 6 to 7% for Brazil, however, will present a 6 to 7% growth but already constitutes the biggest Pharmerging market after China. The Tier 3 countries growth in drug spending will average 6 to 9%, with a wide disparity between the countries: for example, Turkey, Pakistan and Bangladesh will present a growth of almost 15%, while Saudi Arabia and Thailand fewer than 5%.

If cost containment of these countries is already happening, the implementation of modern social securities is also increasing the most welcomed Access for the patients.

III- Strategic Analysis of a Pharmerging Market

In order to develop a tailored Market Access Strategy, in-depth knowledge of the market business environment is required. To do so, many strategic tools have been developed. We can define a strategic analysis as "a process of methodological research on a market environment in which the company operates or plan to penetrate and on the company itself, in order to formulate a strategy" (19).

If the Strategic analysis definition and scope may vary, common attributes are associated with it:

- Identification, extraction and evaluation of relevant data for the strategy formulation
- Definition of internal and external environment to be analysed
- Analytical methods or tools used in the analysis

These tools include, for example:

- SWOT analysis
- PESTEL and variations
- 5 Forces of Porter
- Four corner's analysis
- Value chain analysis
- Early warning scans
- War gaming

Yet, the most advanced tool is a Strategic Early warning system as defined by Bisson (2013). It encompasses market moralization, scenario analysis, war games and scanning. Furthermore, qualitative and quantitative analysis can be used combined with Artificial Intelligence.

They are important to guide and ensure the methodology level of rigor required by the strategic analysis. For the strategic analysis of a market in order to develop an Access Strategy, we will conduct a business environment analysis with a PESTEL, a SWOT, and use the model of Porter. By analysing the business environment, it is possible to find trends, opportunities and threats for the company, and adapt the access strategy of the company. After the business environment, an exhaustive analysis of the Healthcare environment in the market has to be conducted.

III. A- Business environment: PESTEL, SWOT, and the 5 forces of Porter

III. A.1- PESTEL

A PESTEL analysis is a strategic tool and framework used to analyse a country Macro-environment in order to develop the best market entry or expansion strategies. It emphasizes 6 aspects of a country environment: Political, Economic, Social, Technological, Environmental, Legal, and must go from the general to the particular, in our case the healthcare industry, to be relevant. The aim is to identify the current external factors the company has to face, the factors that are most likely to change in the future, and finally to feed the SWOT analysis to best exploit the opportunities or avoid the threats these changes may result in.

- The P stands for the Political environment. It describes the political factors and how it can impact the healthcare industry and the company's operations in the country.
- The E stands for the Economic environment. It describes the economic factors that may have an impact on the business of the company, its potential revenue and growth, for example. It can include the population income, the economic overall growth of the country or a particular industry, the inflation, the volatility of the currency or the interest rates. We will focus here on the Health Economy in Thailand.

- The S stands for the Social factors, or socio-cultural factors. It includes the demographic aspect, the pyramid of age, the education, and in our case the population awareness and involvement about healthcare.
- The T stands for the Technological Factors. It describes how the new technologies are implemented in the country and how they can have an impact on a company. It includes the production, distribution and communication, for example.
- The second E stands for the Environmental factors. It includes different parameters that could be found in other parts of the PESTEL: the population and political attitude concerning the environment, the effect of climate change on the country, the environmental laws and in our case for example the impact of environment on the population health.
- The L stands for the Legal factors. This last factor describes the regulatory environment of the country: in the healthcare industry it will concern the consumer rights, the safety requirements, and the entry barrier generated by the law. It is a useful indicator on how the country tends to be an open market or on the opposite use the legislative arsenal for protectionist purpose.

If the PESTEL is a comprehensive tool to conduct an environmental research for a project, it also presents limitations. Its accuracy and effectiveness depends on the quality of data collected, its timely updates, and the conduction of surveys to best *proof* it. The use of additional tools can reduce these limitations and extend its utility. This is not a onetime research and needs consistency in order to be effective. To do so, companies need a responsible and effective team, often outsourced to consulting agencies.

III. A.2- SWOT Analysis

The SWOT analysis is a simple and widely used in strategic analysis. Simple, it gives a clear understanding about the strengths, weaknesses, opportunities and threats of a business activity or project. The first step is to define the objective of the business or project and by the identification of the external and internal factors important to achieve this objective. Usually, the strengths and weaknesses are internal factors of the company, while the threats and opportunities are typically external. A simple 2x2 matrix is usually used to represent this strategic tool:

Figure 9: SWOT analysis matrix (20)

If the tool creates a powerful overview of the business or project positioning, it should not be used in isolation. In that case, it may remain superficial, biased and potentially counterproductive if generated by untrained individuals.

III. A.3- Porter's 5 Forces

The Porter's 5 forces Framework is a strategic tool to analyse the competition within an industry. This model identifies and analyses 5 competition forces to determine the industry's attractiveness in a market:

- Threat of New Entrants in the industry: the first force assesses the ease for new rivals to enter the market. The easiest it is to enter the market, the high the competition is.
- The threat of substitutes: the second Force evaluates the possibility of a new good entering the market and driving down the established products sales.
- Power of Suppliers: the third Force is the bargaining power of the suppliers. It evaluates how easily the suppliers can influence the price of a good.
- Power of customers: the fourth Force is the bargaining power of the customers. As for the suppliers, this evaluates how easily the customer drives down the price. In the pharmaceutical industry, it will depend on the nature of the product: for OTC, the buyer is the patient; in oncology, the customers are hospitals and/or HCPs.

- Competitive rivalry: this last force is used to sum up the level of competition within an industry. If there are a multitude of players all trying to undercut each other, then profit margins will reflect that.

Bisson (2016) added to the 5 forces the following ones:

- Bargaining power of (skilled) workers: this factor evaluates how easily the workers, here the HCPs, to influence the competition and drive the price of the health technology
- Bargaining power of distributors: this Factor evaluates how easily the distributor can influence the price of the good.
- Complementary products/services/technologies

The 5 Forces of porter also present weaknesses. First, it assumes a relatively static market structure, and only provides a snapshot of the wider industry. If this can be useful for informing short-term strategy, the window of applicability for the information coming out of Porter's five forces has also been narrowed by rapidly evolving external factors. These are trends like globalization and rapid technological advances that weren't as prominent when Porter devised his framework.

Finally, the model is based on the idea of competition only, and assumes that companies try to achieve competitive advantage over competitors but also over suppliers and buyers. Strategic alliances and mutually beneficial strategies between stakeholders can be preferred, especially in the pharmaceutical industry where the endpoint is the patient Health. Porter himself recently spoke about a needed evolution toward a "social progress beyond profit", and created the Social Progress Index (SPI) ranking countries on multiple dimensions of social and environmental performance.

The most useful part of this model, and the reason why it became so widely used by companies, is that it encourages them to look beyond their immediate business operations and to their industry as a whole to when setting their long-term strategy. This, however, needs additional tools and cannot be used alone to build a business strategy.

III. B—Healthcare Environment

The Healthcare environment of a country is indeed the major concern of the pharmaceutical industry. To succeed in a new market, a company should conduct a comprehensive analysis of the healthcare environment. Different components must be developed in the Analysis:

Concerning the Healthcare system:

- Health insurance and funding
- Health policies
- The primary care network
- The hospital sector
- E-Health

- Healthcare professionals
- Public Health: key statistics concerning the Health status of the population
- Prescribing and dispensing: practice, policy and controls, formularies.
- Pricing: system, trends, cost-containment, hospital purchasing, margins and discounts
- Regulatory environment
- Quality Standards
- Intellectual Property
- OTC
- Sales & promotion

And concerning the Pharmaceutical Business environment:

- Operating environment
- Industry structure
- Free trade agreements
- R&D
- Generic market
- OTC
- Sales & Marketing

IV- Market Access Strategy: the example of Thailand

Thailand is a complex example of economic success and political incertitude, and a surprising combination of emerging and mature market elements concerning the healthcare industry. The understanding of this ecosystem is a major stake to develop a successful market access strategy in the kingdom.

In the first part we will discuss the current business environment in Thailand with a PESTEL analysis and develop a SWOT analysis. In a second part, we will discuss the healthcare system in Thailand and the different stakeholders, institutions and processes. After integrating this collected information in the Market Access framework we developed previously, it will finally be used to develop a local strategy.

III. A- Business environment in Thailand: a PESTEL analysis

III. A.1- Political environment

The Kingdom of Thailand is a constitutional Monarchy since 1932, ruled by the king Maha Vajiralongkorn or Rama X since the death of his father King Rama IX in October 2016, who ruled the country for 70 years. Starting from 2005, a series of events led to a period of political crisis. Acute

tensions occurred in 2013 and 2014 between the Red shirts, mostly composed from the popular and rural class and supporting the former Prime Minister Thaksin, and the yellow shirts mainly composed of an urban middle and upper class, ultra-royalists and opposed to a western-style democracy. Following these tensions, the military led by the General Prayuth Chan-o-cha took over the executive and legislative powers after a coup in May 2014.

The junta, so-called the National Council for Peace and Order (NCPO), dissolved the parliament, forbid manifestations, established the censor, suspended the constitution and imprisoned political opponents. The new National Assembly members were all appointed by the Junta and there was no democratic election ever since. The junta communicated in the press in November 2017 that local elections were soon to be held, but what might be a first step back to democracy seems compromised as the candidates will have to fulfil a list of requirements set by the military, limiting or avoiding any possibility of political independence for them. The Prime Minister Prayuth Chan-o-chan also promised general elections to be held in November 2018.

Since the accession to the throne in 1932 of the previous King Rama IX, Thailand has known a dozen military coups, and 7 aborted attempts. This permanent political instability was, however, balanced by the strong moral, diplomatic and political legitimacy of the Royalty, which always kept the Realm united. The military somehow presented itself as a resort in time of political instability and was most of the time supported by the Royalty and the Thai elites.

The failure to date to establish a Political stability complicates the resolution of the different challenges the country has to face:

- The insurgence of some Muslims in southern districts next to Malaysia to gain independence, which caused more than 6000 deaths since 2005
- The management of the Rohingyas fleeing the persecutions in Myanmar by boat to South East Asia
- The human traffic, essentially concerning the sex industry, the forced labour and more lately concerning the Rohingyas. In July 2016 the biggest trial concerning human traffic was held, with more than 60 people condemned with 4 to 94 years of imprisonment, including a former general. The condemned were for most of them part of the human smuggling of the Rohingyas. NCPO declared fight against human traffic a “National priority”. The US included Thailand in the Tier 2 of the Trafficking in Persons Report 2017 where it was in Tier 3 the year before, highlighting and encouraging the efforts of the government.
- The corruption: Transparency agency ranked Thailand number 101 over 176 countries in their 2017 annual ranking. The implication of the elite, politics and army makes the fight against corruption complicated in Thailand despite some effort like the creation of the Anti-Corruption Organization of Thailand.
- The freedom of the press: Reporters Without Borders ranked Thailand 142 out of 182 countries in the world in 2017. Reuters reported in 2015 that the Prime Minister said he would “probably just execute” those who “did not report the truth” (21). January 9, after a press conference, he put a cardboard cut-out of himself for the journalist questions and answers before leaving, reports CNN.

Political impact on the healthcare industry

The overall unstable political situation of Thailand has for now little influence on the healthcare industry, thanks to a solid and lasting protection of foreign investments and companies. On the opposite, the health policy has a major impact on shaping the Thai Healthcare Environment, and the government takes a very active role into the healthcare industry. Its committed and ambitious health policy is remarkable for an emerging country, and has resulted over the last decades in very popular and lasting reforms. The most note-worthy was the introduction in 2002 of the Universal Coverage Scheme (UCS), providing almost 80% of Thai Citizens with a free health insurance.

The Healthcare System, its success and challenges will be further discussed in part III. B—Healthcare Environment in Thailand. It is mandatory for the Market Access department, the most sensitive to the health policy, to be fully aware of these specificities.

III. A.2- Economic environment

Between 1960 and 1996, the kingdom has known an economic boom with a CAGR of 7.5% during this period supported, by openness to foreign investments, development of industry and tourism. In 1997, the country goes through the Asian Economic crisis or "Asian Contagion".

After a period of impressive economic growth, the "tiger economies" (Thailand, Indonesia, Malaysia, and Philippines and minus Vietnam) saw their currencies and equity market brutally devaluated. Like in most financial crisis, the origin was due to a series of asset bubbles. The growth of economies brought huge amount of foreign investments, leading to an overestimation of the real estate values, unwise corporate investments and public projects funded with high interest borrowing from banks. The increase of interest rates, the decrease of foreign investments led the estate market to be unsustainable, confirmed by the bankrupt of Somprasong Land, a major real Estate Company. Then, the currency traders attacked the Baht, resulting in a huge devaluation of the currency leading to an inflation that spread to other implicated countries, the tigers, Singapore, South Korea and even Japan. The different currencies lost as much as 38%. With the help of the IMF, lending money in exchange for strict budget constraints policies, the countries were recovering by 1999.

After the crisis, Thailand's economic growth went back to 5% between 1999 and 2005, followed by a slow down at 3.5% and even 2.5% during the junta from 2014 until now. With the end of the mourning time for King Rama IX and if the politics follow by a return to democracy and structural reforms, the Thai economy is forecasted to grow again the coming years.

With a GDP of more than 400 M$ and a GDP per capita of $6000 per capita, Thailand is now classified as an upper middle income country and ranked 26th in terms of GDP in 2016 by the World Bank. It is a diversified economy; the main sectors of activities are the manufacturing sectors, which include the automobile sector, electric and electronic equipment;

GIni index is a coefficient measuring the inequality among people in a country. A high score indicates a high inequality. Thailand as a high Gini index score: 48.40 according to the CIA, higher than France (29), US (45). The main explanation is the huge income gap between the cities and the countryside in Thailand.

The Thai Board of Investment (BOI) proposes tax incentive to investments. It includes reduction or exemption of import tariffs for machinery and raw materials, mostly for merchandise not produced in the country. It includes as well reductions or exemptions of tax. Beside the fiscal incentives, they propose permission to bring foreign workers, modifying quota case by case.

The pharmaceutical manufacturing is included in these incentives, especially to encourage pharmaceutical companies to produce locally. They also promote retirement houses, care centres with advanced equipment. This may be a good opportunity for MNC to increase their chance of getting their drug to enter the NLEM, or get tax reductions.

Thailand was 36th in the World Bank's "Starting a Business" ranking. (New Zealand was 1st, France 25th). However, "It was ranked 26th in the category "ease to do business".

Thailand is part of The Association of Southeast Asian Nations (ASEAN), a political and economic group of 10 countries comprising Indonesia, Singapore, Malaysia, Philippines, Thailand, Brunei, Cambodia, Vietnam, Laos and Myanmar. It aims to harmonize legal procedures, establish free trade and free flow of goods, services and people, on the model of EU. However, it is still far from to reach that goal. The ASEAN Economic Community (AEC) was introduced in 2015. The AEC Blueprint 2025 consists of five interrelated and mutually reinforcing characteristics, namely: (i) A Highly Integrated and Cohesive Economy; (ii) A Competitive, Innovative, and Dynamic ASEAN; (iii) Enhanced Connectivity and Sectorial Cooperation; (iv) A Resilient, Inclusive, People-Oriented, and People-Centered ASEAN; and (v) A Global ASEAN. These characteristics support the vision for the AEC as envisaged in the ASEAN Community Vision 2025.

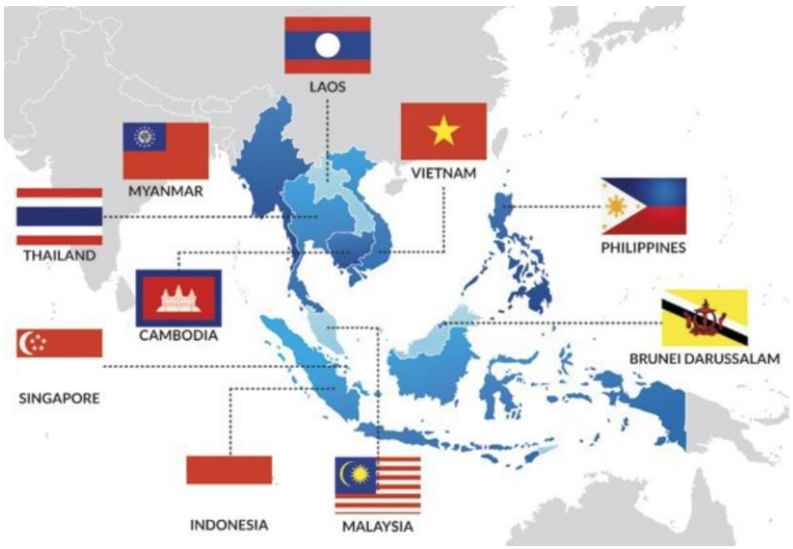


Figure 10: **Map of ASEAN. Source: United Nations.**

To overcome this “middle income trap” the government launched the concept of “Thailand 4.0” comprising various strategies to modernize the country and ensure a pursuing of its economic growth based on innovation and value-based industry.

Figure 11: **Thailand 4.0 (source: USA Royal Thai Embassy)**

III. A.3- Social environment

As of 2017, the population of the country is 69 million, ranking number 20th in the world and with a 0:25% growth, reducing: the Worldbank forecasts a 10% decrease of the population by 2040. The population density is 135/km2 and with a 51.6% of people living in cities, Thai population is mostly rural and concentrated in the agricultural regions of central, north and northeast regions. Almost 10 million people live in the capital, Bangkok (Krung Thep in Thai). It ranks 5th in South East Asia, behind Vietnam (95M), the Philippines (105M) and Indonesia (264M) and before Myanmar (53M), Malaysia (31M), Cambodia (16M) and Singapore (5.7M). The median age is 38.3 years old, more than the average in South East Asia (28.8) and less than the average in Europe (41.8).

There are around 70 ethnic groups in Thailand. The Thai and assimilates represents 95% of the population, among them 34% of Central Thai, 25% of Thai Lao, 10% of Khon Mueng (Northern Thai) and 7.5% of Pak Thai (Southern Thai). In the Eastern Region is present most of the 1.4 million people Khmer ethnic group (2.3% of the population). The Malays mostly present in the Southern Region account for 2.5% of the population. Beside the conflict with the Muslim in the south of the country, the different ethnic groups live in long lasting harmony.

The Thai, central Thai or Siamese is the official language of the Kingdom and is spoken by more than 95% of the population. Like Chinese, it’s a tonal language, with 5 tones. It is related to languages in Laos (mutually intelligible with Laotian language), Burma, northern Vietnam and southern China as part of the Tai-Kadai family. The Isan or north-eastern Thai spoken by 20M people in Thailand, northern Thai by 6M, and Southern Thai by 4.5 are included in the same family. The other languages spoken in Thailand include Lao, mainly spoken in the region close from Laos, Khmer next to Cambodia, Malay next to Malaysia and the Karen languages next to Myanmar. The Burmese is also

present and important through the more than 1.4 million (legal) workers from Myanmar in the country.

The state Religion is the Theravada Buddhism but the freedom of Religion is insured by the constitution. Followed by 93% of the population, it has an important influence of Chinese Traditional Religion like Taoism among the Thai Chinese especially. The second religion is Islam with around 6% of the population practicing it, mostly by the Malay group in southern Thailand and the Cham in the east. Christians account for around 1% of the population. Important communities of Sikh and Hindu are also present.

According to the King Vajiravudh, 3 pillars found the stability of Thailand: the nation (Chat Thai) and its language (pasa Thai), the religion (satsana), and the loyalty to the royal dynasty. The loyalty to the monarchy is a very important part in the Thai identity. The portrait of the king can be found in almost every shops and houses in Thailand, and the loss of the previous King Rama IX was followed by a whole year of mourning by the entire population.

An important number of expatriates live in Thailand, for work, studies, leisure or retirement (22). Among them, 1.43M are from Myanmar (50% of the total number of expatriates), 500,000 from Cambodia, 130,000 from Laos, and 150,000 from PRC. 200,000 expatriates from Europe are also present along with 50,000 North Americans.

Thailand is also a major place for illegal immigration. The estimation of illegal immigrants is between 1 and 2 million people in 2016. Last November 95 people got arrested in Phuket for overstaying their visa, and according to the government around 100,000 foreigners would be currently in the same situation in Thailand. More than 100,000 refugees would also be present in Thailand, a growing number since the Rohingya issue in Myanmar.

Concerning education, the Ministry of Education through the Education Act provides all Thai and non-Thai children with a free education until 15y old. This universal access to education led in 2016 to a 96% literacy rate in 2016. 20% of the total government total expenditure goes to education, making it its biggest part. However, the Programme for International Student Assessment (PISA) of 2015 have seen Thailand ranked 54th among the 70 countries participating to the survey (23). It was created by the OECD in 1997 and assesses the 15y old students performance in mathematics, science and reading. This result also shows a geographical inequality of the education, as big city schools presenting better results on the test than rural schools.

Concerning the habits and tastes of the population, a difference has to be made between the Y generation (15–35 y old) and the people in their late 30's and more. According to a survey (24), the Y generation comprises 20.8 million Thais and the older people 34.3 million. The Y generation has a higher purchasing power and is more willing to borrow money from the bank. They prefer chains and fast-food restaurants, unlike the older generation who prefer homemade food and healthy food, but they both eat many times a day: three quarters of the population eat more than 3 times a day. The Y generation prefers convenience stores over Hyper and supermarkets, preferred by their elders. For the online shopping, the Y generation shops more often but spend less per purchase. The younger generation buying habits is driven by discounts and promotions, while the older is more driven by the value for money campaigns like buy-one get one. 75% of the Y generation has a

smartphone compared to 36% for the older one. They both watch a lot television: respectively 3.44 h and 3.2 h par day, with 98% adults watching TV everyday.

Another study conducted by the Boston Consulting Group (BCG) segmented the Thai older than 20 by income and by sex. The study highlights different aspects of behaviour and trend among the Thai population:

-The strong growth for the products offering experience (luxury products, smartphones, leisure travels, restaurants) and indulgences (from ice cream to frozen meals). The interesting thing to note is that Thai people are more likely to spend on it than other people in South-East Asia, and are ready to take debt for it.

—The brand name is very important for Thai people and they are very brand-loyal. They would be the most brand-conscious and brand loyal in South-East Asia, where people in other countries are more likely to switch brand according to the price. 75% of people answered that they look for their favourite brand and buy it, compared to 40% in Vietnam and 39% in the Philippines, for example. This is an important aspect of the buying behaviour of Thai people, and the companies must invest in their brand-awareness.

—The Thai women have a high buying power. They are more educated than men: in 2015 almost 9M had at least a high school diploma, compared to 8M for men. Thailand has one of the highest employment rates for women in the world: 64%, compared to 58% in the OECD countries. They are qualified, earn money and on overall more independent than in other Asian countries. Therefore, women are more likely to be the main decision maker for the family purchases, they do more primary research online before purchasing (27% versus 21% for men) and buy more online (29% versus 18%). Another survey by BCG indicates that Thailand has the biggest ratio of single women in South-East Asia: 31%, compared to 23% in Vietnam and 26% in Indonesia.

—The E-commerce is rising and new social medias are driving it. According to the survey, Internet influences 40% of purchases in Thailand, and 50 to 60% of the research are made on Apps and websites like Instagram, Messenger, Facebook and Line. For now though, Thai don’t feel comfortable with the online purchasing of health products

-The rising of convenience stores, shaping the customer behaviours. The increasing demand from the population and of the number of outlets make the convenience stores the fastest growing distribution channel in Thailand. The consumers buy more often but in smaller quantity. The most famous convenience store company is 7-eleven, and possesses 10,000 outlets across the country. It is open 24h/7 and is selling 3000 different OTC drugs in the world, including paracetamol and ibuprofen. Its competitors, family mart and Lawson, are also growing.

For the Healthcare industry, the importance of the brand-loyalty will depends on the category of medicine the company specialize in: if this is important for a company specialized OTC products, a company specialized in oncology will not see any leverage on this point. The digital rise has yet to influence the prescription medicine, as Most of Thai patients rely entirely on the physician opinion for now, especially the older generation. This can be observed as well with the absence or weakness of patient groups in the country. In the future though, the digitalization can increase the health awareness in the population, who will more likely conduct their own research on Internet

concerning their disease, their treatment and exchange with other patients. The education of the patient and his health awareness will have to be prioritizing in the coming years by the pharmaceutical industry, by supporting the formation of patient groups or leading disease awareness campaigns as examples.

III. A.4- Technological environment

Infrastructure: transport communication

The World Bank ranked Thailand 45th on its Logistics Performance Index (LPI) ranking. The LPI is an indicator of the trade logistics performance in a country. The World Economic Forum ranked it 71st on 140.

Concerning the transportation, Thailand still relies highly on the road transportation (82.5% of the logistic costs of the country). Transportation represents 35% of the energy consumption in the country. Therefore, a 10 years plan started in 2015, to modernize and develop the transportation infrastructure with around a $70 bn budget. It will essentially develop the rail network, a transport much cheaper than the road (around 86%, THB 1.9 trillion) (figure 8). This plan will create business opportunities and an important reduction of the logistic costs. (25)

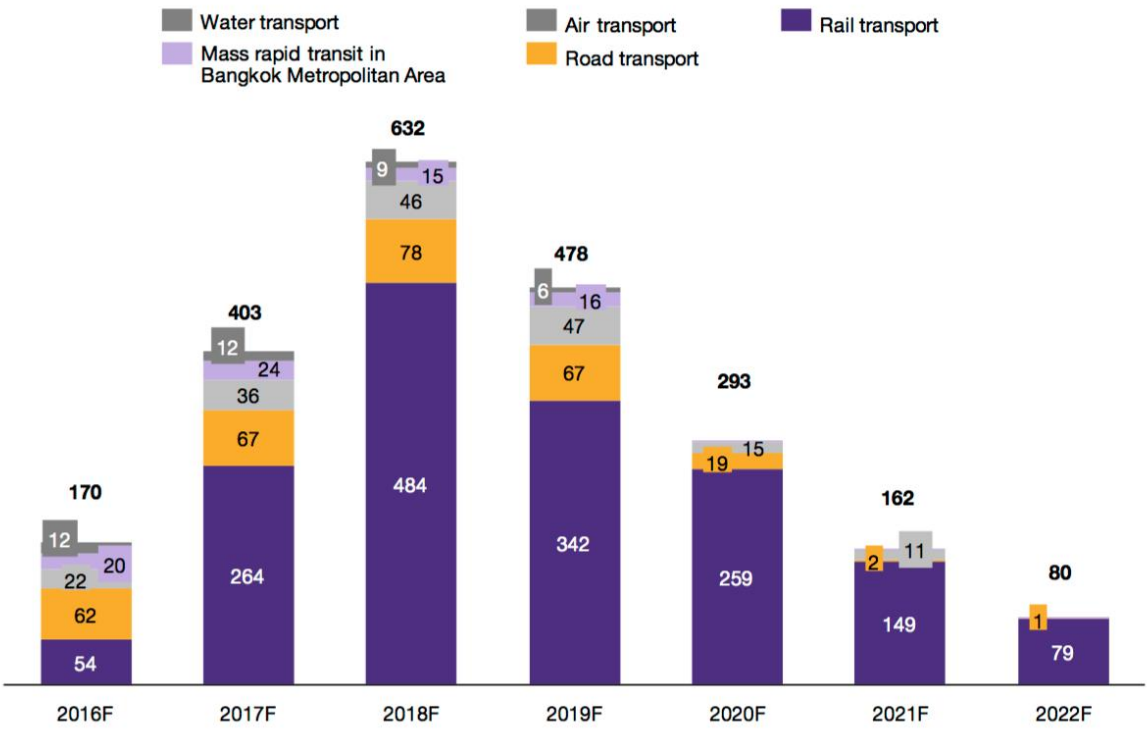


Figure 12: **Estimated Public Transport Investment (2016–2022) (source: EIC analysis based on data from the Office of Transport and Traffic Policy and Planning**

In the past, Thailand has underinvested in Research. However, with the economic slowdown, the government realizes the need to develop an industry with a stronger added value through technology. Since 2014, the government invested in Biotechnology, with a creation of numerous institutes like the National Center for Genetic Engineering and Biotechnology, [BIOTEC] part of the National Science and Technology Development Agency [NSTDA]. Compared to 10 years before from the pharmaceutical perspective, Thailand has succeeded in producing the world's first commercial biosensor for avian influenza. Currently, it is in process of producing its first drug to treat malaria. However, the country is not likely to compete with Singapore or Malaysia in the short or mid term.

Concerning the technology in hospitals, it is it one of the most advanced in South East Asia, but cannot match with Singapore.

Thailand has a high Internet penetration rate: 67% of the country has an access to Internet [smartphone, desktop and others], compared to 46% in APAC).

Figure 13: **key statistical digital indicators in Thailand. Source: Hootsuite, data from United Nations (2017)**

These data, however, show huge differences according to the region:

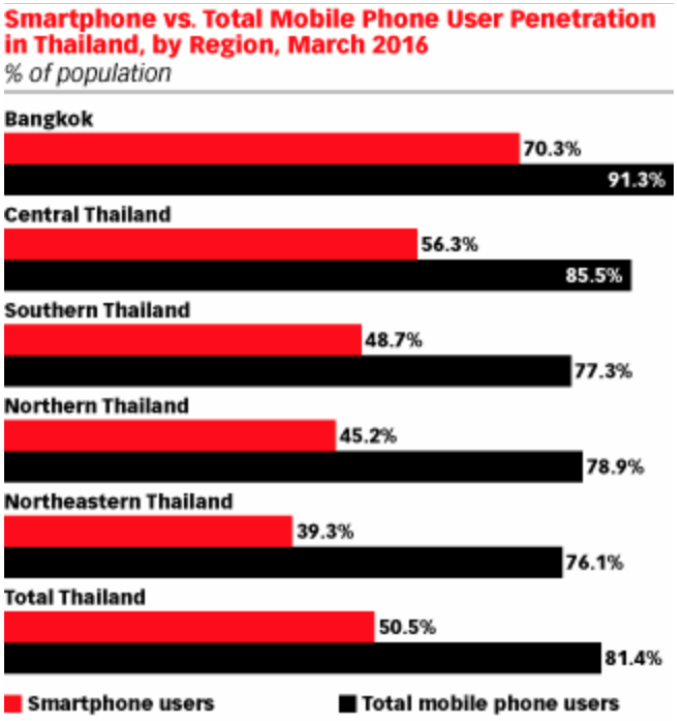


Figure 14 **source: eMarketer, data from "National Statistics Office of Thailand" 2017**

III. A.5- Environment

The various effects of climate change poses risks on public health, through changing weather patterns and indirectly though changes in water, air, food quality and quantity, ecosystems, agriculture, livelihoods and infrastructure. Thailand is categorized by the United Nations as one of the most vulnerable countries to the impact of climate change over the next 30 years.

The average temperature is expected to increase by 1.74 to 3.43 °C by 2080, the number of typhoon by 10–20% along with an increase of floods. The level of sea rise by 30-60cm per decade in the Gulf of Thailand. The air pollution level has increased dramatically in urban areas with the industrialization of the country. In Bangkok especially, air quality monitoring performed by the Pollution Control Department for the past 10 years revealed that the levels of Particulate Matter (PM10) have exceeded both annual and 24 hours national standards, resulting in sharp increases in patients' visits and hospital admissions for respiratory diseases. The government has put less effort to control air pollution than for water pollution. The waste management is very weak in Thailand, especially for plastic, with 70 billion plastic bags for example used every year.

III. A.6- Legal Factors

The legal system in Thailand is based on the Civil Law, or Roman law. Despite the corruption, foreign companies especially Multi Nationals Companies (MNCs) can expect an impartial trial.

In addition to ASEAN, Thailand is part of the World Trade Organization and the Trans Pacific Partnership, signed between Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam signed on 4 February 2016; the United States withdrew from it in 2017 after Trump's election.

We can highlight 2 different cases where the government can have a direct impact on a pharmaceutical company and its operations in Thailand:

- Patents can be overcome "in case of emergency" by the government through the Government Pharmaceutical Organization (GPO), which occurred for example with the compulsory licensing of Merck's Efavirenz in 2006 or Abbott's Kaletra in 2007
- The Biosimilars yet to have differentiate legal status from the generic as in Europe or the USA. This led the arrival on the market of locally made copy of biologics considered as NCBS or "Non Comparable Bio-Similars" by the foreign pharmaceutical companies. This legal void allow these companies to overcome the FDA and EMA regulatory requirements for biosimilars approval, such as new clinical studies proving them similar to the biologics they yearn to copy.

III. B—Healthcare Environment

III. B.1 Background

As we discussed in the Political Environment part of the PESTEL, Thailand has won a place of leader among the Asian countries in the healthcare sector, due to multiple factors.

As we discussed in the Economic part of the PESTEL, Thailand is a big market relatively to its GDP, is growing and is forecasted to grow the next years. We will further discuss the Thai Healthcare Market in the first part—Market overview and forecast.

The Universal Coverage Scheme (UCS) is part of the 3 government coverage schemes, along with the Civil Servant Medical Benefits Scheme or CSMBS, the health coverage destined to civil servant and their relatives, and the Social Security Scheme or SSS, which concern the private sector employees. We will develop these schemes in part 3: Provisions.

Through this voluntarism policy from the Thai government, the country is now a hub for healthcare in ASIA and beyond, with high-end hospitals, well trained health professionals and overall low cost of treatments. On a domestic point of view, the healthcare is also a success. Public health efforts led to a significant decrease of child mortality and an increase of life expectancy (75.5 years old in 2016).

III. B.2- Pharmaceutical Market Overview and Forecast

Thailand is a healthcare leader in South-east Asia. It is strong on the domestic side; mainly due to the efficient coverage schemes the government has set, covering more than 99% of the population with free healthcare (26).

The Kingdom of Thailand allows 4.1% of its GDP to the healthcare, which is the average in South East Asia (4%) but far from the OCDE countries (12% on average) (27). In 2016, the total healthcare expenditures in Thailand represented THB 892bn ($25bn), and is estimated at THB 946bn ($27.5bn) for 2017, a +6% increased (+8.5% in $).

The Thai pharmaceutical market now represents $4.6 billion and is forecasted to grow at a 4.4% Compound Annual Growth Rate (CAGR) until 2020, making it the second largest pharmaceutical market in South East Asia after Indonesia. The Kingdom imported in 2016 more than $2.2 billion, compared to 1.8 in 2014. In 2016, the sales per capita of medicines were $75, and is expected to reach $125 in 2024. More than two third of the medicine consumption is done by the Thai hospitals, making them the primary target for the pharmaceutical industry.

Thailand is also an important hub for the medical tourism, with many patients coming for example from countries like the UAE, a rich country but with a poor healthcare offer (28).

In Asia, around 90% of medical tourism is concentrated in Thailand, India and Singapore. Thailand is now the first destination in the world for medical tourism due to the high qualifications of the

healthcare professionals, the low cost of treatment and the low cost of accommodation. Most of it concentrated in the capital Bangkok, which presents the best offer.

You just have to walk around the Bangkok General Hospital observe it: patients and their entourage have access to luxury Hotels of all kinds, they line up for an Americano at Starbuck, have a meal at KFC or more fancy restaurants and end up in a spa for a massage. The Bumrungrad Hospital has 21 VIP suites and a Macdonald on one of its mezzanine. Among the patients, people from all around the world are present to get the best health care available in the capital. Emirati looking for a better healthcare offer, Americans unable to afford the most expensive healthcare system in OECD, and impatient English avoiding the long waiting list in their country. In many cases patients are accompanied, an entourage coming to support the patient and not displeased, in the meantime, to enjoy the tourist attractions Bangkok has to offer. The UAE represent 25% of the revenue in the biggest private hospital in Bangkok, the Bangkok General Hospital.

On the ethical point of view, if the country economy benefits from this most welcome tourism, it can, however, be problematic for the Thai patient. With a ratio of 3.9 doctors for 100,000 people, we can wonder how the Thai patients can get proper care. In these hospitals, the waiting list for an appointment with a specialist is extremely low compared to public hospitals (1 to 2 days for a dermatologist). Many physicians prefer to work in these private hospitals if they can, essentially for the pay: health professionals earn around 3 times what they would earn in a public hospital. The cost of health care is also not affordable for most of Thai people.

In Asia, around 90% of medical tourism is concentrated in Thailand, India and Singapore. Finding accurate data about medical tourism across the world is for now impossible, but Thailand is now one of the first destination in the world for medical tourism due to the high qualifications of the healthcare professionals, the low cost of treatment and the low cost of accommodation. Compare to the USA, patients can save up to 75% on the overall treatment cost in Thailand (29). Most of it concentrated in the capital Bangkok, which presents the best offer. This is also a testimony of the unequal repartition of wealth and public service among the different regions of Thailand. The private hospitals expend and benefit the most from this growth of medical tourism. The government, through the Ministry of Public Health and the Ministry of Tourism, is currently drafting a 10 years plan destined to improve medical tourism services proposed to foreign patients in Thailand and increase its awareness from the rest of the world.

III. B.3- Healthcare System

As discussed before, the three schemes existing in Thailand are the most important part of Thailand healthcare system. Before their introduction in 2002 and as they now exist, a third of the Thai population was not insured, despite all the reforms started in 1975, with four different schemes:

—The Medical Welfare Scheme to the poor, the elderly and children under twelve years

-The Social Health Insurance for private sectors employees

-The Civil Servant Medical Benefit Scheme for the public sector employees, retired and dependents

-The publicly subsidized voluntary health insurance, for the informal sector

27 years after the first reforms appeared the 3 schemes, as we know today. It is essential for the market access to have an in-depth understanding of them. We will now detail these 3 schemes, their characteristics, challenges and future evolution.

III. B.3.a- The Universal Coverage Scheme

The universal coverage, also known as "the golden card" scheme has been introduced in 2002 and is the combination of the two schemes discussed above: The Medical Welfare Scheme to the poor and the publicly subsidized voluntary, along with the rest of the non-covered population. It was the first Asian country introducing a health universal coverage (30).

The Kingdom of Thailand has proven that with a well-conducted research, a deep understanding of the health economy and a strong political commitment, a performing and affordable healthcare system can arise. With a realistic approach concerning the actual economy of the country, the country managed to provide to a majority of the population a wide range of health services, from basic healthcare to more complex treatments. In 15 years, this scheme reduced amongst others the infantile mortality, the financial burden of health to the family, and reduced the number of employees' sick days.

It is the main coverage system in Thailand, covering 75% of the population or around 47 million people (31). For the government, it represents more than 17% of the Kingdom health expenditures. The other health expenditures include the CSMBS scheme (12%), the SSS scheme (8%), the private insurance, the Out Of Pocket (OOP) spending (27%) and other public spending such as staffing and facilities of the Ministry of Health. The different characteristics of USC are listed below:

The UCS covers all the Thai people that do not enter the others schemes (CSMBS and SSS) and concerns mostly people from the non-formal economy. The different characteristics of the UCS are listed below:

- It is funded by general tax, and a voluntary-based co-payment
- Payment method: the payment method work by capitation for outpatients services, and global budget + Diagnosis Related Groups (DRG) for inpatients services[3]
- Health delivery: the healthcare service is provided by a registered contractor, public hospital or private hospital, notably within the district health system, acting as contracting units for primary cares (CUP)
- Per capita expenditure: the expenditure per patient per year is around $79
- The Ministry of Public Health (MoPH) is in charge of this scheme, which is financed and managed by the National Health Security Office (NHSO)

[3] Inpatients refers to patients that overstay a the hospital, outpatients concern the ambulatory or day time care

Concerning the pharmaceutical products, patients under the Universal Coverage Scheme the access to subsidized medicines are mostly registered on NLEM, the National List of Essential Medicines, largely dominated the generics and not the recent, most innovative products.

The Nationalist List of Essential Medicines

The National List of Essential Medicines (NLEM) is the list of drugs reimbursed in the frame of the Universal Coverage. For most of them, drugs are listed by the government itself and are generics. If a company wants to register one of its branded molecules, it has to build a reimbursement file that can be submitted only every 6 years, variable, and whose content is mostly a cost-effectiveness demonstration much more focused on the cost than on the clinical outcome like in Europe, for example.

The application follows multiple steps. The application has to be sent to the drug bureau, which gathers information and classify and send it to the NLEM committee. The listing starts at this point, and comprises 6 important steps (Figure 11):

1- The NLEM committee will review and distribute to specialists the reimbursement dossier
2- The Specialist Committee for Drug Selection (SCDS) will prioritize, prepare & review data the dossier contains, then send it to the Coordinating Committee (CC)
3- The Coordinating committee will exchange with the Price Negotiation Committee and agree to go or not for price negotiation. In parallel, the CC will exchange with the Economic Committee about the cost-effectiveness & budget impact of the drug.
4- The coordinating committee will then gather all the information collected during the step 3 and transmit it to the NLEM committee
5- The NLEM chairman together with representatives from the 3 healthcare schemes will consider affordability and finally present it to the National Drug Committee for signing and announcement

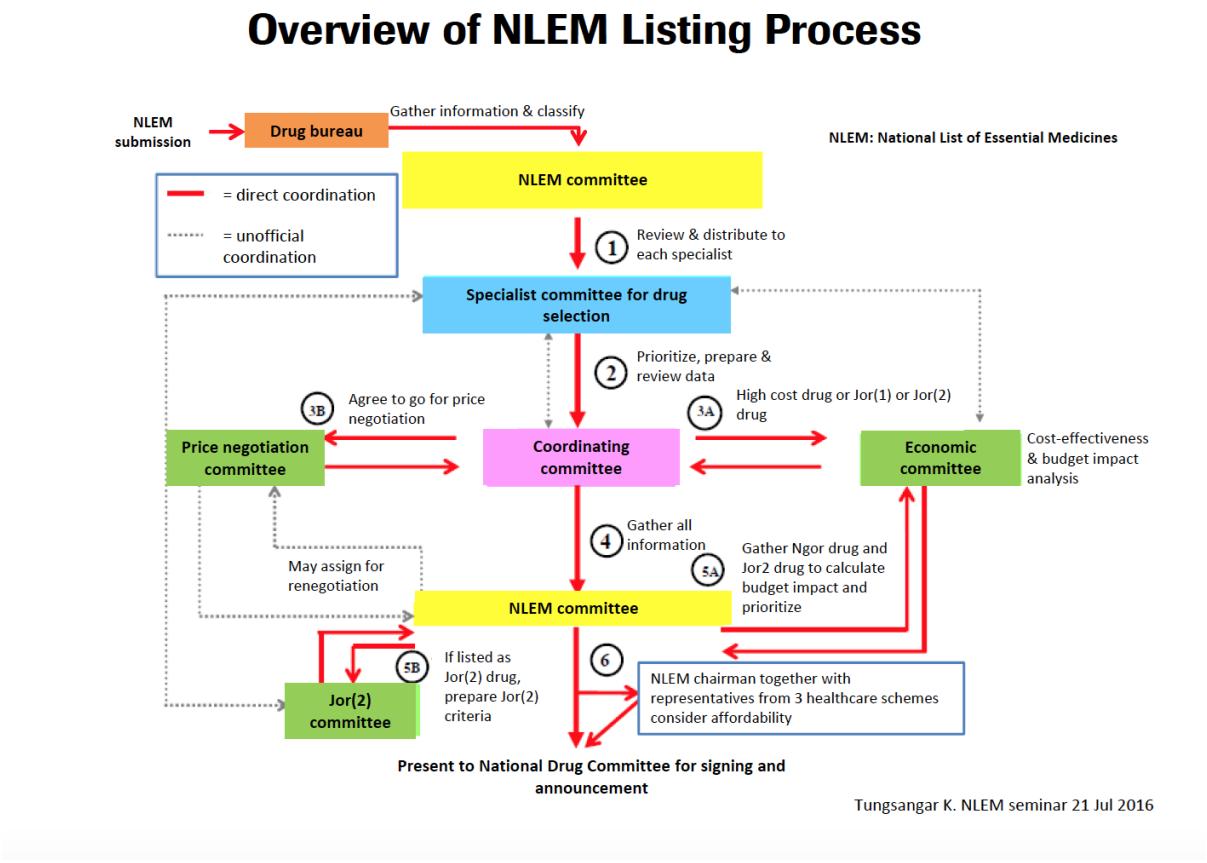


Figure 15: **NLEM listing process**

These steps present the official and direct coordination. An important unofficial coordination, not transparent, also exists.

We can quote amongst the molecules integrated in the list oral contraceptives, anti-neoplastics, antibiotics, anti-epileptics and anti-retroviral/anti hepatitis.

For all these molecules, the patients under UCS don't have to pay anything when diagnosed in registered contractors

Even so the UCS does not cover some expensive treatments and mainly propose generics, this scheme still covers some high cost treatments. It includes drugs or operations, which price overcome 1% of the Thai GDP per capita so more than $600. Among these figure organ transplantation, orthopaedic hips or knees, cancer treatments, HIV (Human Immunodeficiency virus treatment) Hepatitis C (HCV), rare disease treatments (less than 5 case per 100,000 patients). In 2013, the National Health Security Organization added on the list of expensive medicines 8 molecules available for the UCS patient. It includes now 15 drugs, including:

- Darunavir, an antiretroviral for the treatment of HIV
- Linezolid, a resistant Gram + antibacterial
- Peginterferon Alfa 2a and 2b for hepatitis C (HCV) treatment
- Ribavirin for HCV treatment
- Bevacizumab, a biologics for the treatment of Age-related macular degeneration (ARMD)

- Linezolid, an antibacterial for resistant Gram + bacteria
- Voriconazole for aspergillus infections
- Antithymocyte Globulin (ATG) for the treatment and prevention of acute rejection in case of organ transplantation and treatment of aplastic anemia
- Imiglucerase for the treatment of Type 1 Gaucher's disease

Co-payment

The UCS was also previously known as the "30 baht scheme", coming from the 30 baht flat user fee per consultation the patient had to pay, but certain population was exempted. The exemption of this fee concerned:

- The very poor
- The children under 12 y old
- The aged population after 60 y old
- The volunteer health workers.

This co-payment system was abolished in 2006, making the UCS totally free. Today, the 30THB co-payment is voluntary based, and authorities are now discussing a possible extension of the co-payment. For this voluntary contribution, the patients are asked to pay this fee at the start of their treatment in the hospital, except in "healthcare promotion and disease prevention hospitals", previously known as the government primary care facilities.

The supporters of this possible reform argue that people with an entirely free healthcare tend to visit the hospitals even when it's not necessary, for benignant diseases or injuries. 30% to 40% of Thai people visiting government hospitals would present these minor conditions, which do not require a hospital visit. Therefore, these supporters want a reform of the UCS to create a co-payment scheme, which would remain completely free for the poor and those entering in the previous 30 THB exemption list we discussed before. Therefore, poor people would not see their treatment deny at the hospital.

Challenges

We can discuss 3 challenges the UCS has to face. The increasing cost of healthcare in the country, which increases faster than the overall growth of the country. The regional inequality of access to healthcare: there are calls for widening access to CSMBS to farmers and household staff.

The first one, as for general economy, is the inequality of healthcare service across the country. The North-East Region of Thailand, Isan, presents the poorest healthcare offer in the country, whilst the best offer is concentrated in the capital, Bangkok. Therefore, the poor and old people in rural areas have difficulties to access the benefits of UCS, and we observe that in rural areas, the use of these benefits is much lower than in urban areas. This regional distribution issue is compounded by the complexity and differences between the coverage schemes, concerning the benefits or by the organisms they rely on.

The second one is the use of this offer among different population part of UCS. A study published in 2015 (32) showed that mostly low income or unemployed people, patients with chronic diseases are the biggest users of the UC scheme and the results showed that this population:

-Have greater healthcare needs

-Receive a wider range of services from the designated public facilities

-Pay the least for both inpatient and outpatient services.

This study indicates that the UCS is pro-poor and can adequately respond to patients under UCS scheme needs from a vertically equity point of view. However, it also found out that many patients use “out of network” services, showing a lack of universal access to services in a horizontal equity point of view.

In 2015, the ACTION study (the ASEAN Costs in Oncology) conducted by the Georges Institutes for Global Health (33) in 8 South East Asian Countries including Thailand examined the human cost of Cancer in these countries. It provides information on the impact of cancer on households in Thailand, and highlights the difficulties of the UCS to cover and treat efficiently the patients with cancers, especially in rural areas where the access to diagnosis and treatment is more difficult than in urban areas. The key points of where studies are

- Cancer is the number one cause of deaths, responsible for 19% of them in the Kingdom.
- Aging population and rising cancer cases are increasing the burden of cancer on the UCS
- 26% of Thai cancer patients die within 26 months, with higher numbers in rural areas

III. B.3.b- The Civil Servant Medical Scheme CSMBS

The Civil Servant Medical Benefit Scheme covers the government employees, their relatives, pensioners and dependents, covering around 6 million people in Thailand. It has always been the most important scheme for the pharmaceuticals multination companies, as they are reimbursing branded drugs. For a company like Roche Pharmaceuticals, selling mainly expensive cancer treatments and immune-therapies, the CSMBS represents more than 90% of their revenue. Therefore, even if it represents only 8% of the population, it represents 12% of the country health expenditures, compared to the 17% of the UCS.

On this scheme, patients have access to the best treatments available. However, since 2008, the government started to introduce new policies to contain the cost of this scheme. The coming discussion will notably concern the unification of the 3 schemes, which would most likely decrease in the end the access in terms of medicines for this scheme.

To understand the advantage granted by this scheme, we have to look into the civil servant salaries. For example, the same position for a teacher in a private university will be at least twice the salary as a teacher in a public university, but the last one will benefit health coverage from CSMBS. The different characteristics of the CSMBS are listed below:

- Target population: government employees, their parents, wife or husband, and up to 2 kids under 20y old
- Funded by general taxation and non contributory
- Payment method: the payment is a fee for service for outpatients, and a DGRs for inpatients
- Health delivery: free choice of public providers, no registration required. Treatment in public hospitals only, but private hospitals in case of emergency and for specific diseases.
- Per capita expenditure: the expenditure per patient per year is around $400.
- Administered by the Ministry of Finance
- Controlled by the Comptroller General's Department (CGD)

The internal process of the CGD, unlike the NLEM committee, is not available to the public. The reimbursement of drugs and interventions is not controlled in a transparent way, but some efforts are made for a few years since the cost of the CSMBS is a huge burden for the government compared to the population it covers.

III. B.3.c- The Social Security Scheme

The Social Security Scheme (SSS) concern and is mandatory for the employees of the formal private sector. It covers around 11 million people, or roughly 16% of the Thai population. 3 parts finance it: the employee, the employer and the government. The population included in the SSS has the lowest utilization rate amongst the 3 insurance schemes, reflecting the much younger age of the users and their higher income, allowing them to get OOF services more easily. It is administered by the Ministry of Labour and controlled by the Social Security Office.

The relatives of the SSS population do not benefit from this scheme, and they do not benefit from this scheme anymore when they lose their job or retire. If they do, they join the Universal Coverage Scheme.

The different characteristics of the SSS are listed below:

- Target population: private sector employees, excluding their relatives
- Funded by tax payroll, tri-partite contribution 1.5% of salary equally by the employer, employee and government
- Payment method: the payment is a fee for service for outpatients, and a DGRs for inpatients
- Health delivery: free choice of public providers, no registration required. Treatment in public hospitals only, but private hospitals in case of emergency and for specific diseases.
- Per capita expenditure: the expenditure per patient per year is around $106.
- Administered by the Ministry of Finance
- Controlled by the Comptroller General's Department (CGD)
- Target population: employees of the private sector

Health insurances: evolution and trends

The healthcare cost is growing everywhere in the rest of the world, and also in Thailand. The government health budget is under pressure, and it seems difficult to maintain the system with the current economic situation. Nonetheless, the government stays committed to maintain the universal coverage system. The quality and availability of care in Thailand keeps being enforced, as we can see with the enforcement of regional health institutions. The payment system and the benefits of the schemes will also continue to be strengthened, as we can see with the extension of the list of high cost treatments for the Universal Coverage Scheme.

Despite a fail to merge the 3 Health Insurance schemes, the policy makers put effort on harmonizing the benefits of the schemes and increasing the efficiency of the system, to make it sustainable and more equal. The creation of a commission for the Harmonization of Healthcare System will soon be established, and will set standards in the benefits of the 3 schemes, concerning specific diseases such as HIV or HCV and access to NLEM drugs.

The need of a global reform of the existing health system is growing. The principal organizations in charge of healthcare in Thailand, the MPOH, NHCO, NHSO and Thai Health, are working together to create a People-oriented Health Region to focus more on patient-needs. The 13 Regional Health Committees created will serve the Ministry of Public Health to achieve its 20-year National Strategy that we will develop in the Health Policy Part.

III. B.4- Pricing

In the public hospital, medicine prices are controlled by the “median price” pricing scheme for the drugs listed on the NLEM, and by different purchasing process such as the electronic bidding. Private hospitals and pharmacies have more liberty to set the prices but are still constrained by market forces. Pharmaceutical companies have to print the price on the drug packaging, mainly to control high drug costs in private hospitals, as the hospital can only charge the printed price.

NLEM Pricing

For the drugs listed on the NLEM, the median price mechanism is applied as a cap on reimbursement prices. At first, this median price was calculated according to all the versions of a product on the NLEM. But now, it calculates weighted median prices and reflects sales volumes too. As it takes account the prices of generic, the median price is now much lower than the list price of branded molecules. If the NLEM price is the reimbursement price, the actual hospital purchase price is usually lower to keep a dispensing margin. In certain public hospital tenders, this median price is only the starting point of negotiations with the company.

Under the Universal Coverage, public hospitals usually select the lowest priced product of a listed molecule. In case of high price drug with not alternative, the cost-effectiveness is used and prices can be reduced by 60 to 70% to meet the threshold. This is a huge counterbalance of the benefits from getting listed on the NLEM: if the company fails to reduce prices, the product is removed from the list.

Non-NLEM Pricing

The Thai government also put a strong pressure on non-listed product prices. In 2013, the MoPH created the National Clearing House to ensure the harmonization of prices between the 3 schemes. The plan to extend the median price to non-listed products has started, which might result in a huge drop of sales value for certain innovative companies. In October 2014, the CSMBS started its median pricing strategy, planned for long. Around 500 molecules were concerned, and pharmaceutical companies saw their product price dropped by an average of 50%. In the innovative drug sector as well, the median price arrived in January 2017: anti-lipids and angiotensin receptor blockers were two categories affected, and their price was cut up to 50%. These cut continues in 2018.

“I think if we look at nearly every one of our issues that we’ve had and we’ve been working on for the past couple of years, the underlying driver has been cost containment. Whether it’s the drug bill and some of the pricing issues that ran on it, whether it’s median pricing, whether it’s the government procurement and the e bidding, it’s all cost-containment. That will continue to be, because they haven’t fixed their budget on this yet and I think in terms of being how they’re going to make UC system work” (MNC Association Executive).

Retail Pharmacy Pricing

Even though the drug price is printed on the drug packaging, the price is still negotiated by each pharmacy. Patients often visit different pharmacies to compare the price.

Concerning the OTC, the manufacturer has to register the product price at the Ministry of Commerce. The pricing is free, but once it's registered it is complicated to increase it as the company has to prove an improvement of their product. Therefore, the company usually set the highest price possible at the registration point.

E-bidding

The e-bidding process was introduced in 2015, to improve the efficiency of the procurement process. The process is expected to reduce prices when bidding for public hospital tenders.

Hospital Purchasing

The hospital purchasing is changing for the last years since the NHSO tries to reduce the spending on drugs and to increase transparency and cost-effectiveness. The State Procurement Bill enforces the Government Pharmaceutical Organization (GPO) role as a preferred supplier of drugs: it does not need TFDA approval to produce, sell or import drugs; also, as a manufacturer, it will win the tender's bidding if its offer is similar to other companies.

In public hospitals, around 80% of the drugs sold are generics; where in private hospitals the emphasis is on original brands. Selling branded drugs is also part of the quality image the hospital wants to promote. Tenders are also present in private hospitals, with in some case centralized purchasing for all hospitals within a group.

Key developments and trends

If the merge of the 3 schemes will not happened anytime soon, the government is, however, planning the harmonization them and especially concerning the pricing through the median price, for example.

The E-bidding is expected to drive down the generic prices, already very low in Thailand, but is unlikely to have any effect on innovative drugs.

The lack of predictability and transparency is difficult to manage for MNCs and will keep on lobbying for the creation of more transparent, clear and open process.

The cost-containment policy in the public hospital sector will benefit the private sector, as MNCs will be more reliant on the sales to the private sector to maintain their revenue.

III. B.5- Health policies

The Ministries of Public Health, Foreign Affairs, Commerce, Agriculture, NHSO, the Thai health promotion foundation, NHCO and other civil organizations developed the Thailand Global Health Strategic Framework 2016–2020. The framework includes and promotes 5 focus points:

- Health security
- Fair and secure Health system
- Thailand's role and responsibility in global public health
- Health policy coherence with other countries
- Capacity of health by increasing human resources and organization

ThaiHealth is the main organization for the promotion of health and prevention of diseases. If its focus was traditionally on communicable disease, it has extended to chronic diseases over the last decades.

In September 2014, the MoPH launched a national campaign for the prevention of heart conditions.

The Health Policy in Thailand continues to improve the access to healthcare for all Thai patients. The 11th National Development Plan highlighted the growing importance of growing diseases. The NHCO tries to develop the patient's health awareness.

The pharmaceutical companies may find opportunities by supporting these health policies and the creation of new ones. Supporting patient awareness, patients groups and public health policies have to be integrated in a public affairs long-term strategy to ensure access to all patients.

III. B.6- Public Health

According to the UN in 2016 in Thailand, life expectancy at birth was 75.5 years (79.3 for women, 71.8 for men) and is increasing. With one of the lowest growth rate of population (forecast of 0:05% CAGR between 2016 and 2020), Thailand is an aging population (second behind Singapore) and even considered sometimes as the “old man of ASEAN”.

Infectious diseases are still a big problem in Thailand. According to the MoPH, 426,000 people are HIV+ in Thailand. However, they are now well treated under the UCS and prevention campaigns reduced the new infections by 83% since 1991. Concerning the vaccines, 99% of children are now vaccinated for polio, tuberculosis, Hepatitis B and measles, and DTP. Dengue impacted Thailand with 140,000 new cases in 2015.

If the communicable diseases remain higher than the world’s average (18% of deaths), the non communicable diseases as cancers, cardiovascular diseases, and chronic respiratory are the major cause of death in Thailand (59% of deaths). It is interesting to note, even if not of the MoH responsibility, that Thailand present the second highest rate of death per inhabitant in the world after Libya, for a total of 35,000 deaths.

According to the diabetes association of Thailand, half of Thai with diabetes are not aware of their condition. Thailand has the highest rate of obesity in South-East Asia: 40% of adult women are overweighed, 30% for the adult males. The UCS provides various screening of the population do for an early diagnosis of diabetes and hypertension.

For pharmaceutical companies specializing in these new “western” diseases treatments due to aging and change of habits, as long as for vaccines and infectious treatments, Thailand present good opportunities.

III. B.7- Regulation

The Thai Food and Drugs Administration is responsible for the approval of pharmaceutical products. The drug approval timeline is quite long for original as well as generics with an average of two years, mainly because of a shortage of staff. To address this issue, the agency is now recruiting more internal reviewers. The recent introduction of the e-submission is expected to reduce the approval timeline in the near future. PRIVUS, a product registration system currently piloted for food products, will be extended to medical devices and drugs if it succeeds. The move toward harmonization of regulations between members of ASEAN will accelerate this regulation efficiency on the long term.

In some cases, the TFDA asks for locally made clinical data. It is part of a government will to push the local clinical studies, and incentives are made for the MNCs to conduct it in Thailand. This can be an interesting investment both for the scientific value, the lower cost than in high-income country, and to ensure good relationship between the company and the public institutions.

The Drug Act, in discussion for more than 10 years now, has yet to arrive. It is expected to have a big impact on the regulation environment in Thailand.

III. B.7- E-Health

By law, all Thai healthcare facilities have to submit their data to the MoPH. These data include expenses, revenues, patient throughput, and epidemiology. These requirements have not been enforced for now, but the government shows some effort to improve data collection. An example is the National Clearing House (see III. B.4- Pricing) improving and facilitating the audit of pricing and prescription in Thailand.

Telemedicine is currently piloted in Chiang Mai's Saraphi district, where also health data surveys are operated on tablets and smartphones. In the big private hospital groups, a sophisticated system of data management is already set; and in the Samitivej hospital group and at the Bangkok General Hospital, patients can connect to the hospital through an app for information, appointment reminders, etc.

Different move toward an integrated electronic health information system have been made lately. A National Health Information System is being developed to link public healthcare facilities. The Specific Logical Observatory Identifier Names and Codes (LOINC) has been adopted, it allocates to each drugs a code to track the prices charged to hospitals.

In 2016, the MoPH hired VMware Inc., a cloud infrastructure company, to consolidate the IT infrastructure of healthcare facilities in 76 provinces.

The Personal Health Record (PHR), an android app for Health Care Professionals and patients, was introduced in five provinces in August 2016. It provides a platform health history, check ups, treatments and health analysis.

These examples are a testimony of the willingness and ambition of the Thai government to reach a high level of digitalization. For the pharmaceutical companies, it represents a good opportunity to provide services along with their products, gaining competitive advantage through a "beyond the pill strategy".

III. C—Strategic Frameworks applied to Thailand

III. C.1- SWOT analysis: a pharmaceutical company in Thailand

The SWOT analysis for Thailand will depends on the company, its organization and the nature of its products. Below is an example of SWOT analysis for a pharmaceutical company in Thailand.

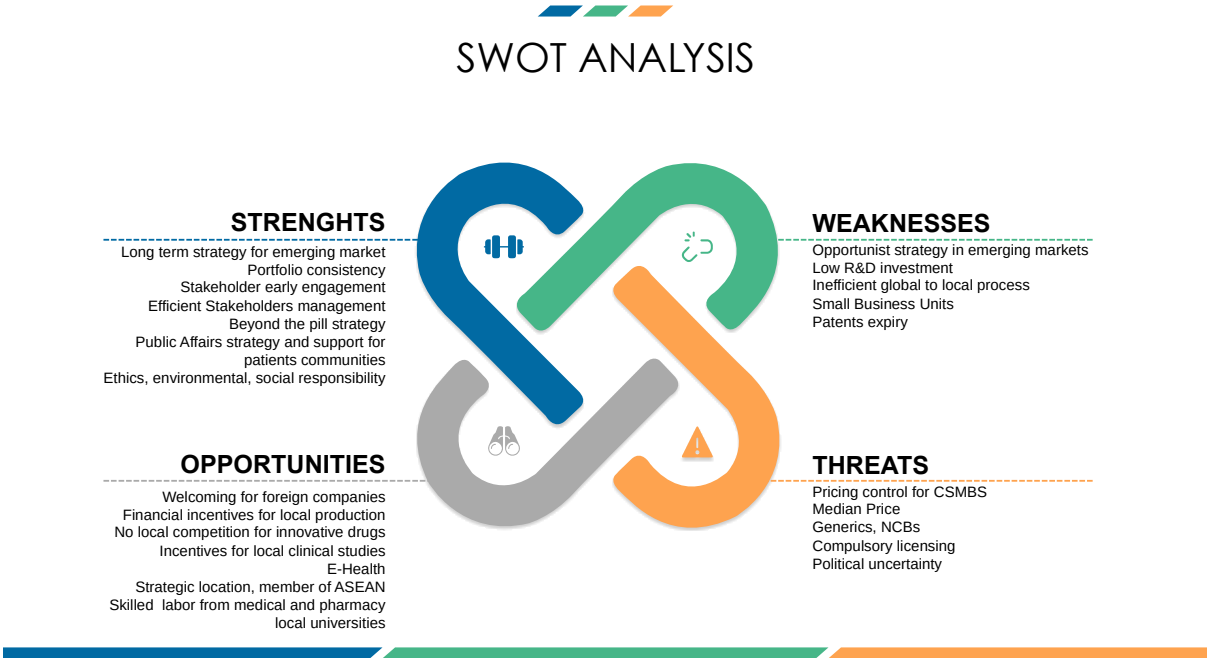


Figure 16: Example of a SWOT analysis of a pharmaceutical company in Thailand

III. C.2- 5 Porter's force of the pharmaceutical industry in Thailand

Below is a 5 Porter's analysis concerning the pharmaceutical industry (34) and in Thailand in particular:

- Competition rivalry: high
  The pharmaceutical industry is highly competitive and faced for the last decade many pressures and challenges, especially the cost containment policies of governments, the end of block-busters patents, a slowdown in global economy and innovation, a rising R&D costs and increased shareholders pressure. It is true as well in the Thai market, where all the big companies are already established. However, this rivalry highly depends on the nature of the company: a company selling an innovative product is less subject to this rivalry than a company selling out of patent drugs, generics or bio-similar.

- Threat of new entrants: low

  As the potential benefits are high in the industry, a steady flow of new pharmaceutical companies are created every year. A small team of scientists with a new and valid idea or product could easily find funders eager to invest in high potential start-ups. These companies are not threatening for the big pharmaceutical companies. In fact, they grow by buying out these companies and are almost part of their R&D budget.
  In Thailand, less pharmaceutical industry is created and almost all of them are in the generic industry. However, the recent and coming investments in Research (Thailand 4.0) might lead to the appearance of local rivals.

- Power of Suppliers: very low

  The suppliers have a very low bargaining power in the pharmaceutical industry. The raw materials come from the chemical industry, which are available from many sources. Only in very specific high-technology pharmaceutical sectors the equipment manufacturers can have the power to raise the prices.

- Power of Buyers: inexistent to high

  The pharmaceutical industry might be the only industry where the end-user, the patient, has no influence on the product prices. The prescriber of the drugs is not allowed, ethically, to profit from the drug sales, and has little influence on pricing except for some special KOLs. The payer, however, has found a tremendous increase of their bargaining power for the last decade. This is especially true in centralized public health insurance systems: to get their product reimbursed for a whole country, companies are ready to negotiate with the governments. For very innovative products, the payer has a lower influence, but can decide cost capping cost share agreements with the companies. In Thailand, the universal coverage gives a high-bargaining power to the payer, and is growing.

- Threat of substitutes: product dependent

  The threat of substitute depends entirely on the product. A new FDA approval with the “breakthrough therapy” accelerated track, under patent, treating a major condition and first to market will have for a certain time no threat of substitute. A patent drug, with existing competitors even if less efficient, will present a high threat of substitutes especially in countries with lower budgets as in Thailand. The compulsory licensing, allowing the government to produce drugs under patents, is increasing the threat of substitute in Thailand.

- Bargaining power of (skilled) workers:

  The pharmaceutical industry hires mostly highly educated employees. Therefore, they do their best to train them and keep them. However, the turnover is high (around 10% in OECD countries) and more in emerging markets. In Thailand, pharmaceutical industry employees have high income and benefits compared to other industries.

- Bargaining power of distributors: low

  The bargaining power of distributors is generally low as the possible providers are many. In many countries, wholesalers and pharmacists have a regulated mark up, avoiding any price

negotiation between the pharmaceutical companies and the distribution. In Thailand, the two main distributors are Zuelling Pharma and DKSH.

Recommendations

By studying the evolution of the healthcare environment of Thailand, the existing process and trends in mature markets, it is possible to draw a strategy and tactics for an innovation-driven pharmaceutical company entering or already established in the Thai Market. These access strategies will help the commercial success of the company's products and ensure the best access for the patients.

1- Empower the patient voice by developing the Public Affairs: this aspect has a now huge importance in mature markets, with patient groups and advocacy having an important influence on the payer. To gain this support, some companies have developed on the global level and locally in mature markets a public affairs strategy, and even sometimes a department on its own. The mission of this department is to build a win-win relationship with the patients communities: they support and sponsor them by financial support or with the creation of web tools and digital platforms. If patient groups are almost non existent in Thailand, finding the right patient and building patient communities through education and financial support will help format the company environment and find support in the population. This is applicable in all the emerging market and is part of a long-term access strategy. In the past, the group of patients with HIV has led to a national policy for the free access to treatments, this example proves the importance of this group of patients that will grow in importance in the coming years.

2- Development of a *Beyond the Pill* Strategy: the concept of going *"beyond the pill"* is to meet the current need of providing services along with the product itself, and provide higher value to the patients and HCPs. These services can include digital solutions, medical education and access program to poor patients. If these services are free, they will lead to many positive outcomes and in the end higher sales:

- Creation of a competitive advantage
- It makes the product more difficult to copy
- It improves the relationship with the patients HCPs and the government
- Digital solutions can provide real-world evidence and patient and HCP insights

These services, to be efficient, have to be developed with the patients and with the HCPs, and be validated by these HCPs. In Thailand, where the people are highly connected, the demand for these services is important. The patients are demanding for health information on the Internet, and the company has to be proactive on the question to ensure that the right information comes to the patient. The medical education will be an important trend in Thailand and even the HCPs are asking for these contents.

3- Build long-term relationship with the government: many pharmaceutical companies have an opportunistic approach of the emerging markets. To succeed in these markets, building a long-term relationship with the government is a key point.

- Part of the 4.0 strategy of the government to modernize the Thai economy, the company should conduct clinical studies locally. The government take is as a sign of good will, and demands it more and more in their Health Technology Assessment
- Improve and build digital systems in the Thai healthcare facilities. By doing that, the company will bring value to the HCPs and the patients. With an efficient system, the data collection and real-world evidence will also be easier to collect and in a more accurate way.
- The financial incentives from the Thai government to produce drugs locally may be a good opportunity for the pharmaceutical companies. By hiring locals in the production process will also be a huge argument in the access tactics. Another way is to form alliances with local actors.
- Developing CSR in these markets, by supporting charity and NGOs. This will increase reputation of the company to the different health stakeholders.

4- Increase the disease awareness of Policy makers: in emerging markets, public health policies are often limited or for some disease inexistent. Therefore, an efficient Health Policy strategy will educate the policy makers and guide them to create national plans leading to investments in the therapeutic area the company specialize in.

5- Building a stakeholder engagement strategy: involving all the stakeholders during the life cycle of the product is also a key to its commercial success. As the management of these relationships can be time and finance consuming, an efficient management framework is required. To best address the stakeholder engagement, specialized teams like Key Account Managers can be created in support of the Market Access managers. The different stakeholders are:

- The payer: the payer has grown to be the central stakeholder over the last decades. It is for sure the most influent as it is responsible for the clinical and economic assessment of the product, the pricing and the reimbursement of the product. It is also responsible for treatment protocols and largely influence the physician prescription. Its role in the Market Access will continue to grow in the next years, and must be the main priority of the department. He has to be engaged at the early stage of the product development.
- The patient: Patients are more concerned about the effectiveness of the drug than earlier, and they are not satisfied with just receiving treatment but also demand a cure. Indeed, the importance of drug effectiveness will further increase if there is no reimbursement or only partial reimbursement.
- Pharmacists: are key stakeholders who could influence drug access by controlling the availability of the product in the retail or out-of-pocket market. In cases of reimbursement, pharmacies could also influence the choice of brand through substitutions. Understanding their dispensing behaviour and securing the most shelf space are important for product success.
- Advocacy groups: are gradually growing a strong influence in healthcare policy shaping and indirectly affect treatment guidelines.
- Physicians and KOLs: have seen some reduction in their importance in the market access value chain over the years. The growing austerity measures have influenced their prescription behaviour to a considerable extent. As companies struggle to spend quality time with these important traditional channels, it will be a challenge to effectively engage and explore areas of common interest.

- Regulatory agencies: handled by the RA department and Pharmaceutical companies will need to effectively manage this extremely challenging group of stakeholders to succeed in the market

6- International Differential Pricing: IDP is possible new approach of pricing in emerging markets that some big companies like Novartis or MSD are currently piloting in certain markets. By pricing their products according to the country GDP per capita, the companies could ensure an optimal access for the patients to their products. However, in countries with an efficient insurance system as Thailand, the company has to make sure to have in return their innovative product to be listed on the NLEM, which would be again a win-win situation. This Strategy would also improve the reputation.

In addition to these recommendations, we can highlight 8 key success factors a company must adopt in order to succeed in emerging markets:

1) Integrated market access strategies, beginning from the product development stage

2) Developing a culture of team effort by facilitating effective collaboration among various business functions (e.g., sales, marketing, regulatory, etc.)

3) Key account management (KAM) or specialized teams dedicated to managing stakeholders

4) Adopting an integrated stakeholder management approach

5) Better understanding of the relationship between market access and stakeholders

6) Effective communication with internal and external stakeholders

7) Establishment of optimal processes, plans, and, most importantly, people

8) Build a Strategic Early Warning System to control the market, anticipate risks and opportunities and optimize actions in the market

Conclusion

As we discussed, the Emerging markets in the pharmaceutical landscape presents wide disparities and most of the time a deep complexity in the understanding of not only the different healthcare systems, rapidly evolving and in different directions, but also the business environment and cultural differences.

Only through an in-depth knowledge of these markets and a tailor-made strategy the pharmaceutical companies will in the future succeed in these markets, essentials to find a continued growth now difficult to find in most developed countries.

Despite the obvious economic interests that pharmaceutical companies will find in investing in the Pharmerging countries, it also brings an ethic dimension as it will increase the access to innovative medicine to a tremendous number of patients.

If the Pharmergings will be the motor of growth in the coming decade for the pharmaceutical industry, it is, however, interesting to see the beginning of a weakening of this growth in these markets, which may lead some companies to reduce their investments in these countries to focus more on developed, highly profitable markets like the USA in the future.

Appendices

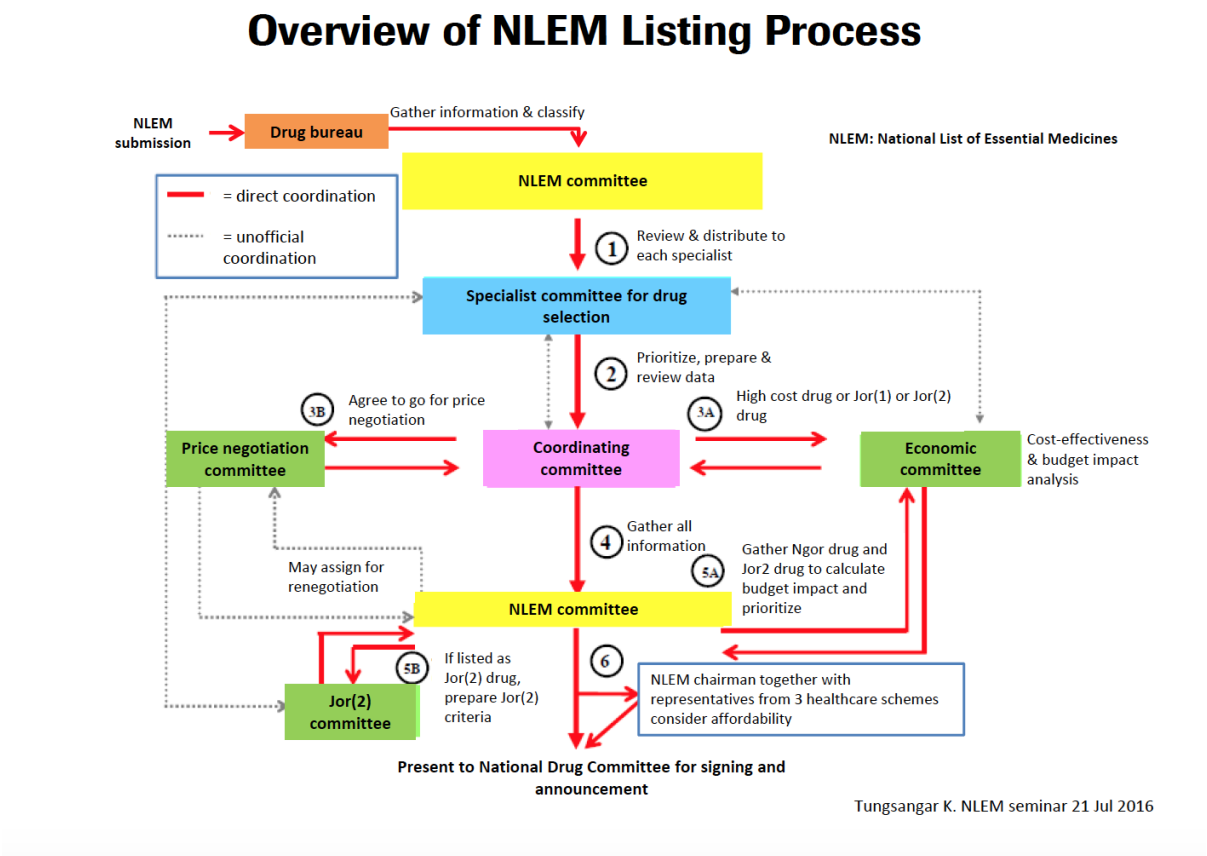
Table 2: Stakeholders Management Frameworks

NAME OF MODEL/FRAMEWORK/GUIDELINE/PROCESS	AUTHOR/S	DESCRIPTION
Stakeholder management framework (SMF)	Freeman (1984)	The stakeholder management framework outlines three levels at which the processes used by the organisation to manage relationships with stakeholders being the rational, process and transactional levels are applied. Each level requires different approaches to stakeholder mapping.
Linkages model	Grunig and Hunt (1984)	This model proposes that stakeholders are identified through the type of link they have with the organisation. The linkages include enabling, functions (both input and output), diffused and normative linkages.
Three part taxonomy	Donaldson and Preston (1995)	The three-part taxonomy is based on the three views of stakeholder theory being instrumental, descriptive and normative.
Primary and secondary stakeholder classification	Clarkson (1995)	The classification of primary and secondary stakeholders has implication for the way in which relationships are formed and maintained.
Stakeholder typology around the attributes of power, legitimacy and urgency Classes of stakeholders	Mitchell et al. (1997)	Power, legitimacy and urgency attributes are used to help identify and prioritise both dependent and influential stakeholders. Linked to this, these authors develop a prioritisation strategy around latent, expectant and definitive stakeholders. These authors further outline a classification of stakeholders.
Types of publics	Steyn and Puth (2000)	These authors outline stages that stakeholders go through in their awareness and level of activity.
Situational theory of publics	Grunig (2005)	The situational theory of publics (stakeholders) attempts to explain and predict why some publics (stakeholders) are active and others are passive. This theory can identify which stakeholder will communicate in different ways with the organisation about decisions that affect them.
Four-step process to prioritising stakeholders	Rawlins (2006)	The steps include: Step 1: Identifying potential stakeholders according to their relationship with the organisation. Step 2: Prioritising stakeholders by attributes Step 3: Prioritising stakeholders by relationship to the situation Step 4: Prioritising the publics

		(stakeholders) according to the communication strategy.
Communication strategy typology	Gregory (2007)	This author outlines a communication strategy typology around the model developed by Mitchell et al. (1997) where stakeholders are either informed, consulted, involved or partnered with, depending on their level of power, legitimacy and urgency.
GOREL process (Governance of relationships)	Falconi (2009)	This author describes a process of governing stakeholder relationships (GOREL). This process involves nine steps: Step 1: Step 2: Step 3: Step 4: Step 5: Step 6: Step 7: Step 8: Step 9: Envisioning Identifying and listening to active stakeholders Defining specific objectives Involving potential stakeholders Relating with issue influencers Convincing opinion leaders Contents, channels and "spaces" Content roll out Evaluation and reset Part of steps 2 and 4 is a stakeholder mapping phase which considers a stakeholder's awareness of organisational goals and their interest in relating with the organisation.

Scheme	**UCS**	**SSS**	**CSMBS**
Target population	Rest of the population	Employees of the private sector	Government employees, pensioners and their dependants
Number of insured	48 million (75%)	11 million (16%)	5 million (8%)
Source of financing	General tax ($96 per cap)	Tripartite rate 1.5% of salary ($106 per capita)	General tax (around $400 per capita)
Ministry in charge	Ministry of Public Health	Ministry of Labour	Ministry of Finance

Payment	Capitation for outpatient and global budget + DRG for inpatient services	Inclusive capitation for outpatient and inpatient services	Fee for service for out patient services + DRG for inpatients services
Annual spending and % of healthcare spending	100 bn THB ($3 bn) 50%	30 bn THB ($0.9 bn) 12%	60 bn THB ($1.8 bn) 38%



According to the World Health Organization (WHO): “Health technology assessment is the systematic evaluation of properties, effects and/or impacts of health technologies and interventions. It covers both the direct, intended consequences of technologies and interventions and their indirect, unintended consequences. The approach is used to inform policy and decision-making in health care, especially on how best to allocate limited funds to health interventions and technologies. Interdisciplinary groups using explicit analytical frameworks, drawing on clinical, epidemiological, health economic and other information and methodologies conduct the assessment. It may be applied to interventions, such as including a new medicine into a reimbursement scheme, rolling-out broad public health programs (such as immunization or screening for cancer), priority setting in health care, identifying health interventions that produce

the greatest health gain and offer value for money, setting prices for medicines and other technologies based on their cost—effectiveness, and formulating clinical guidelines." (35)

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Table of Figures

FICHE SIGNALÉTIQUE

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RESUME

This thesis aims to identify and consolidate the different components of the pharmaceutical Market Access and highlight the growing need of a tailor made strategy for emerging markets. It also presents a strategic analysis process to identify opportunities in these markets and help building a Market Access strategy. This process will finally be applied to Thailand as an example.

Mots clés

Market Access, Health Economy, Emerging Market, Pharmerging, Pharmaceutical Industry, Strategy, Thailand, PESTEL, SWOT, Porter

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