

# Pricing and Patient Access Framework to Support Universal Coverage in Thailand

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จุฬาลงกรณ์มหาวิทยาลัย  
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POWERFUL INSIGHTS. SMARTER DECISIONS.

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## Executive Summary

Thailand is a pioneering example of the success of universal coverage in low and middle income countries (LMICs). Through the National Health Security Office (NHSO), Thailand has expanded medical coverage to its entire population and has continuously strived to improve access to medicines. As part of this effort, it requested Chulalongkorn University to advise on reforming its pricing and patient access (PPA) system to ensure broader, better, equitable, sustainable and secure access to quality medicines. Chulalongkorn University along with academics from other select universities partnered with IMS Consulting Group to study existing Thai PPA system as well as benchmark PPA systems in select countries around the world. Building on this analysis, several meetings and workshops with different Thai stakeholders were conducted in 2015 and 2016. These workshops were held to familiarise the stakeholders with the details of the existing system including the institutional context, inform how PPA systems in the select benchmark countries work, understand priorities of different Thai stakeholders and consequently arrive at specific recommendations to reform the Thai PPA system.

The recommendations, which are presented in this report, covered three areas. First, it addressed the balance of priorities of the Thai stakeholders. A health system must balance competing objectives – maximal/broad access to medicines (number of medicines reimbursed), equitable access, rational use of medicine, quality, supply security and sustaining innovation to address remaining unmet needs – within the resources available to it. The exact prioritization depends on the socio-political priorities of the different health system stakeholders. The workshops helped articulate the relative priorities in Thailand and this helped the design of a reformed PPA system.

Second was the design of the PPA system itself. This system identifies different types of medicines and different types of situations faced by payers and sets out how to set price and patient access for these types of medicines and situations. The overall summary of the recommended system are laid out in the graphic on the next page.

Third, the report highlights the requirements for successful implementation. These include creating awareness of the need for reform and the recommendations among different stakeholders, building consensus around the reform, ensuring that the reform builds on the existing institutional structure and context, and acquiring the right resources, skills and capabilities for operationalization of a reformed system.

This report is about Thailand. It is about the progress it has made and the progress it needs to continue to make.

But this report is also about other LMICs who are embarked on the journey to universal coverage and who can learn from the Thai experience to improve access to medicines for their populations.

**Recommended PPA Approach per Product Type (applies to both inpatient and outpatient medicines)**

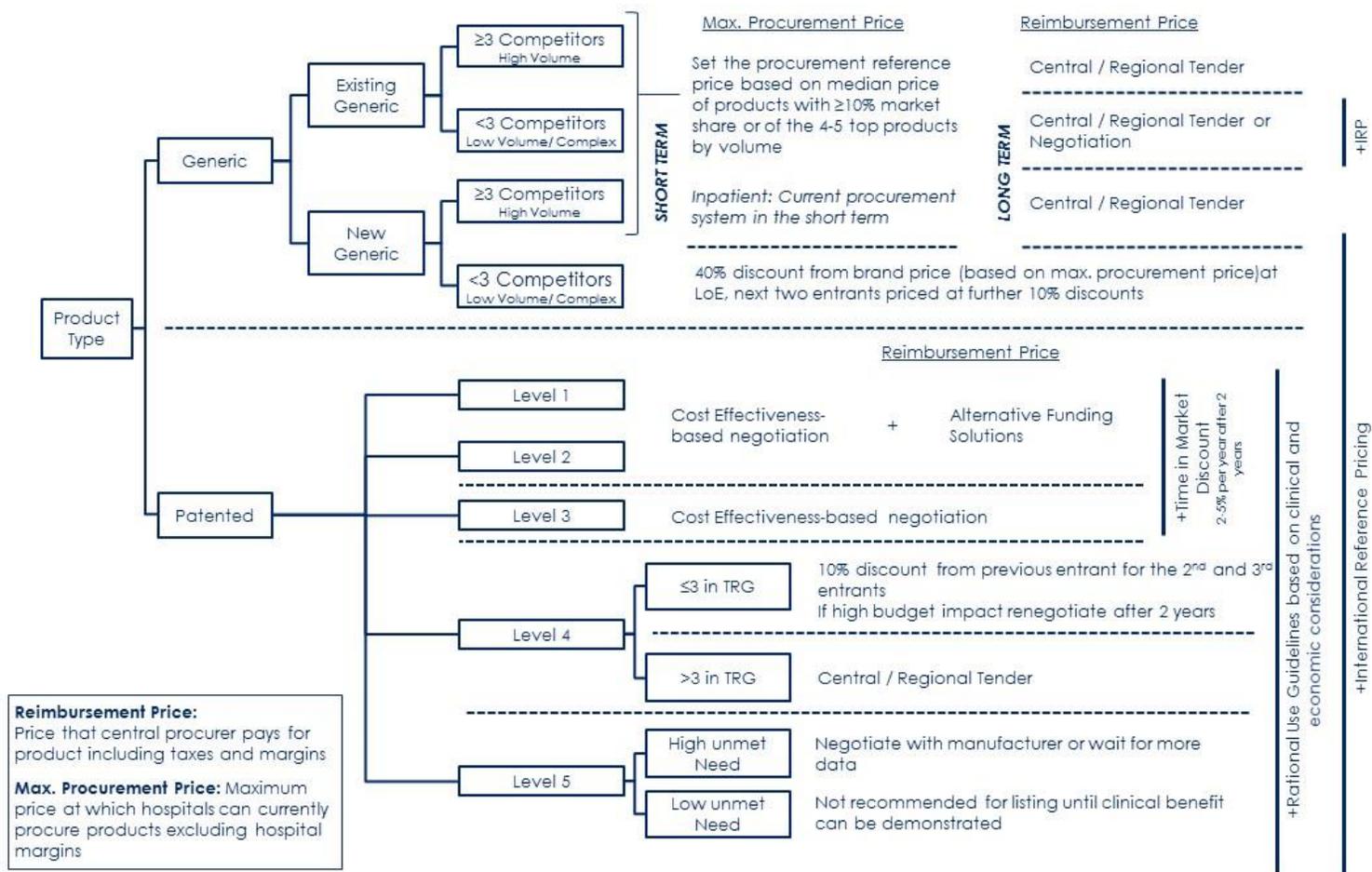


Exhibit shows the decision flow for which pricing methodology is recommended, based on product type. The methodology for generic pricing is further split into short- and long-term in order to accommodate the current system, whilst also laying out the recommendation for future reform, which includes moving from the procurement price-setting system towards a reimbursement price.

## Contents

<b>1</b>	<b>Introduction .....</b>	<b>3</b>
1.1	Study Objectives and Scope .....	4
1.2	Approach and Methodology .....	4
1.3	Report Structure .....	6
<b>2</b>	<b>Current PPA System in Thailand .....</b>	<b>7</b>
2.1	Overview of the Thai Healthcare system .....	7
2.2	Admission to reimbursement .....	9
2.3	Clarification of Pricing Terminology in the Thai system.....	11
2.4	Current pricing mechanisms .....	11
2.5	Challenges in the Pricing and Patient Access System in Thailand .....	12
<b>3</b>	<b>Lessons in PPA from Benchmark Countries .....</b>	<b>16</b>
3.1	Benchmarking Patient Access to Medicine (ATM) .....	16
3.2	Benchmarking Pricing and Patient Access Systems .....	24
3.2.1	Objectives of Pricing and Patient Access Systems .....	24
3.2.2	Pricing and Patient Access Framework.....	25
3.2.3	Pricing and Patient Access Tools .....	27
3.3	Patented Pricing and Access Approaches .....	30
3.4	Generic Pricing and Access Approaches.....	32
3.5	How Effective PPA Systems Provide Tools to Improve Access.....	35
<b>4</b>	<b>Recommendations for PPA Reform in Thailand.....</b>	<b>38</b>
4.1	Objectives for the Thai PPA system .....	38
4.2	Guiding principles for the reform of the Thai PPA system .....	39
4.3	Recommended PPA Framework.....	40
4.3.1	Step 1: Determine Product Type .....	42
4.3.2	Step 2: Applying HTA and Pricing Tools – Generic Medicines .....	42
4.3.3	Step 2: Applying HTA/ Pricing Tools – Patented Medicines .....	45
4.3.4	Step 3: Innovative Solutions for High Importance Drugs .....	52
4.3.5	International Reference Pricing .....	54
<b>5</b>	<b>Implementation of PPA Reform in Thailand.....</b>	<b>63</b>
5.1	Guidance for Implementation .....	63

<b>6</b>	<b>Appendix .....</b>	<b>66</b>
6.1	PPA Frameworks in Benchmark Countries .....	66
6.1.1	France .....	66
6.1.2	Germany .....	68
6.1.3	Italy .....	69
6.1.4	UK.....	70
6.1.5	Australia .....	72
6.1.6	New Zealand.....	73
6.1.7	Canada .....	75
6.1.8	South Korea .....	77
6.1.9	Brazil .....	79
6.1.10	Taiwan .....	81
6.2	Impact of PPA system on Access to Medicine .....	84
6.3	Benchmarking Access to Medicines Across Developed and Developing Countries .....	85
6.3.1	Methodology .....	85
6.3.2	Baseline Diagnostic – Accessibility .....	88
6.3.3	Baseline Diagnostic – Awareness .....	89
6.3.4	Baseline Diagnostic – Availability .....	90
6.3.5	Baseline Diagnostic – Affordability .....	92
6.3.6	Baseline Diagnostic – Adherence .....	99
<b>7</b>	<b>Glossary .....</b>	<b>100</b>

# 1 Introduction

In recent years, Thailand has seen a marked enhancement in healthcare access. Thailand introduced Universal healthcare for Thai citizens in 2002, and as of today, approximately 99% of Thai population is covered by one of the three schemes: 75% by Universal Coverage Scheme (UCS) and the rest by the Civil Servants Medical Benefits Scheme (CSMBS) and Social Security Scheme (SSS). The CSMBS covers government employees, retirees and dependants. The SSS covers private sector employees. Since implementing these changes, Thailand has improved its ability to provide access to a broad range of health services to its population<sup>1</sup>.

This has been supported by an evolving drug reimbursement decision-making process with the establishment of a process for determining and updating the National List of Essential Medicines (NLEM). These medicines are reimbursed all the three schemes. There is also a process in place to set the reference price for these medicines, which is the maximum price at which these medicines can be procured by public health hospitals.

As Thailand has expanded access to medicines, some limitations to the current price and access setting mechanisms have become apparent.<sup>2</sup>

- Different stakeholders – Ministry of Public Health (MoPH), National Health Security Office (NHSO), public hospitals, Group Purchasing Organisation (GPO) and sub-committee to select NLEM – are involved in price setting. This leads to a fragmented and complex approach to price setting.
- The current system has evolved to address the specific pricing and access challenges posed by different types of medicines such as large volume generics, small volume generics, patented medicines with alternatives and patented medicines with no alternatives. While individually, some of the rules can often be effective in achieving fair and competitive prices (e.g., median pricing if applied appropriately and consistently for setting maximum hospital procurement prices of generics), taken as a whole, the pricing system is not properly structured and coherent.
- Given this complexity, not all stakeholders – government, industry and civil society – know how the prices of different medicines are set. There is no one codified process with rules that is available publicly for these stakeholders to reference and understand how prices are set.
- The system also breaks down in specific situations. For example, median pricing can lead to a race to the bottom, where prices fall so low that either drugs are not available or the ones available are of poorer quality. Another example is high cost oncology or orphan medicines, where the cost per QALY threshold of 1 times per capita GDP prevents them being listed on the NLEM.
- There is no current consensus among the different stakeholders in Thailand on how pricing and reimbursement for medicines should be determined in Thailand. This is

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<sup>1</sup> Health Insurance System Research Office (HISRO). 2012. Thailand's Universal Coverage Scheme: Achievements and Challenges. An independent assessment of the first 10 years (2001-2010). Nonthaburi, Thailand

<sup>2</sup> Based on discussions with MoPH, NHSO and academic stakeholders in and out of workshops conducted as part of this project.

important as a sustainable and effective system needs broad support from all relevant stakeholders – the different insurance schemes, MoPH, Thai FDA, Ministry of Commerce, health economic assessment bodies such as Health Intervention and Technology Assessment Program (HITAP), the generics and innovative pharma industry and civil society.

The NHSO is looking to address the above limitations and set up a Pricing and Patient Access (PPA) system that allows it to expand and ensure effective access to medicine for all citizens in Thailand. This study has been conducted to support NHSO to achieve this goal.

## **1.1 Study Objectives and Scope**

**The objectives of this study were to:**

- Benchmark PPA systems in select countries and draw lessons for Thailand
- Develop PPA policy framework to provide effective, affordable and sustainable access to medicines
- Outline the structure and process for the effective implementation of a PPA system
- Specify International Reference Pricing (IRP) and other tools to set and/or negotiate prices with manufacturers
- Provide specific examples to illustrate PPA levers, in particular IRP

The benchmark countries included developed countries such as France and Germany, developing countries such as Brazil and geographically relevant markets such as Korea and Taiwan.

## **1.2 Approach and Methodology**

The study was conducted in three phases with the advice, input and guidance of a core team of academics from Chulalongkorn University, Prince of Songkla University and Khon Kaen University.

### **Phase I: Research and Benchmarking PPA and IRP Systems**

We benchmarked PPA systems in 10 developed and developing countries to understand different approaches used and to inform the different PPA system options for Thailand. The countries studied were Australia, Brazil, Canada, France, Germany, Italy, New Zealand, South Korea, Taiwan and the United Kingdom. These countries were selected to cover the spectrum of PPA systems that are in practice today. Further, all these countries have universal coverage with significant reimbursement for medicines. The benchmarking was done based on IMS expertise of how PPA works in each of these markets<sup>3</sup>. This was supplemented by secondary

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<sup>3</sup> IMS Consulting Group has a Centre of Excellence in Pricing and Patient Access and has extensive and up-to-date information on PPA systems in many of the major countries in the world.

research of relevant literature and national websites containing relevant information about the PPA systems of these countries.

In addition to analysing PPA systems in other countries, we also assessed the situation in Thailand and outlined how pricing and access to medicines is set today in Thailand. This was based on reports from Thai government bodies including the NHSO as well as interviews with Thai academics and NHSO representatives working in the area<sup>4</sup>.

The results of Phase I were presented at a workshop in Thailand hosted by the NHSO. This workshop was attended by representatives from NHSO, Thai Food and Drug Administration (FDA), CSMB and academics working in the field of access to medicines. The workshop helped achieve the following objectives:

- Provided attendees with a common understanding of how PPA systems work in select countries (representative of different geographies, income levels and PPA approaches)
- Helped arrive at an initial common understanding of PPA works in Thailand today, which helped refine our understanding of the Thai system
- Informed priorities and questions to be addressed in the next two phases.

## **Phase II: Developing and Assessing Alternative PPA Framework Options**

In phase II, we focused on two areas:

- Understood what objectives a Thai PPA system must address
- Developed and assessed alternative PPA framework options for Thailand for patented and generic medicines
  - These were developed with specific pricing tools and examples of how these would apply to the different types of medicines

We then held a one-day interactive workshop with key stakeholders including members of the NHSO, academics and the Ministry of Public Health (MOPH) to get input on the objectives for a Thai PPA system as well as the PPA options and supporting tools. The full list of institutions whose representatives participated in the workshop is below.

- Ministry of Public Health
- NHSO
- Thai FDA
- Social Security Scheme
- NLEM Committee
- HITAP
- General Controller Department
- International Health Policy Program
- Health System Research Institute
- Health Insurance System Research Office
- Thai Drug Watch Group
- Health Consumer Protection Program

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<sup>4</sup> The understanding of the Thai system was continuously refined during several workshops with Thai government, academic and expert stakeholders.

- Government Pharmaceutical Organisation
- Buriram Hospital
- Prince Mahidol University
- Chulalongkorn University
- Khon Kaen University
- Prince of Songkla University
- Silpakorn University

The input from this workshop informed Phase III, where we developed recommendations for a Thai PPA system.

### **Phase III: Develop Recommended Framework for PPA System**

Finally, in phase III, we developed the recommended framework and guidelines for a PPA system in Thailand that would help it to provide effective, appropriate and sustainable access to medicines. The recommendations include approaches and tools to set the prices of both patented and generic medicines. The recommendations were presented at a workshop with NHSO, MoPH and academics, whose input has been incorporated into this report.

## **1.3 Report Structure**

This report first provides a summary of the current system in Thailand and discusses the need for a reformed PPA system. Second, it draws lessons from benchmarking of select countries with different PPA systems. Third, it provides recommendations for a new PPA framework for Thailand. Finally, it discusses implementation considerations for moving from the current system to the new recommended one.

In addition, the appendix of this report provides additional detail and supporting information on several countries benchmarked in this study.

## 2 Current PPA System in Thailand

### 2.1 Overview of the Thai Healthcare system

Over 99% of the population in Thailand have access to healthcare and medicines via one of three health insurance schemes: Universal Coverage Scheme (UCS), Civil Servant Medical Benefits Scheme (CSMBS), and the Social Security Scheme (SSS). Around 76% of the population are covered by UCS whilst 15% are covered by SSS and 8% are covered by CSMBS.

The beneficiaries of all three schemes are eligible for pharmaceuticals that are included in the National List of Essential Medicines (NLEM). In cases of emergencies, the beneficiaries might also receive medicines that are not included in the list, but technically, prior authorization from a physician is mandatory<sup>5</sup>.

As Exhibit 1 shows, the UCS is available for people who are not eligible for the CSMBS and SSS. This covers both inpatient and outpatient services including reimbursed medicines. Funding in the UCS system is through a capitation system based on the population covered by the different hospitals and health centres adjusted for specific local needs (e.g., based on age distribution).

The CSMBS was established to provide healthcare to government employees, dependents, and government retirees. It provides coverage for inpatient and outpatient services, emergency services, and medicines. The CSMBS uses prospective payment (following a diagnosis-related group (DRG) approach) for inpatient services, and a fee-for-service type of payment for outpatient services.

The SSS is a compulsory insurance scheme for employees in the private sector and it covers only the employees themselves. Its inpatient and outpatient services are provided through both private and public hospitals. The SSS funding is also on a capitation basis and co-payments are added for some necessary but expensive services.

Both UCS and CSMBS schemes are funded through government taxation, while the SSS is based on contributions from employers. Hospitals are funded through all three schemes, and given that CSMBS funding is higher than UCS on a per patient basis, it is likely that some hospitals indirectly cross-subsidize UCS patients.

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<sup>5</sup> While this is possible for all schemes, members of the CSMBS are more likely to have better access to innovative and high-cost medicines that may not be on the NLEM.

**Exhibit 1:** Key Characteristics of Health Insurance Schemes in Thailand

	<b>Universal Coverage Scheme (UCS)</b>	<b>Compulsory Social Security Scheme (SSS)</b>	<b>Civil Servant Medical Benefit Scheme (CSMBS)</b>
<b>Legal status</b>	National Health Security Act	Social Security	Royal Decree
<b>Established since</b>	2002	1990	1980
<b>Responsible agency</b>	NHSO	Ministry of Labour, Social Security Office	Ministry of Finance, Controller General Dept.
<b>Beneficiaries</b>	People who are not covered by SSS & CSMBS	Private sector employees, no dependants	Government employee, pensioners, dependants
<b>Population coverage</b>	49 million (75%)	10 million (15%)	5 million (7%)
<b>Financing source</b>	General taxation	Triparties, 4.5% payroll, 1.5% each	General taxation
<b>2011 expenditure/capita</b>	2900 Baht (US\$ 97)	2134 Baht (US\$71)	11000 Baht (US\$ 366)
<b>Benefit Package</b>	Comprehensive, exclusion list	Comprehensive, exclusion list	Comprehensive, no exclusion
<b>Providers</b>	Mostly public network	Competing hospitals > 100 beds; (60% private)	Public provider only, selected diseases
<b>Registration with provider</b>	Required limited choice to domicile district for OP	Required, annual choice if needed	Not required
<b>Choice of provider when ill</b>	Limited to registered network of contractors, plus referral	Limited to registered contractor network	Free Choice to any public, no referral required
<b>Choice of providers for accident and emergency</b>	Free choice	Free Choice	Full Choice
<b>Gate keeping function</b>	Yes for OP	Yes for OP & IP	No
<b>Provider payment method<sup>6</sup></b>	OP: Capitation (age adjusted) IP: DRG with global budget	Capitation inclusive of OP & IP; DRG for IP DRG >2	OP: Fee for Service IP: DRG multiple base rate
<b>Additional payment</b>		Fee schedule for select conditions	
<b>Co-payment</b>	No, full pay if unregistered providers w/o proper referral	No, full pay outside contractor	Full pay in private

<sup>6</sup> OP: Outpatient; IP: Inpatient

## 2.2 Admission to reimbursement

The National List of Essential Medicines (NLEM) is the primary mechanism for patients to obtain access to products that are deemed necessary for the prevention and control of all major health problems. The NLEM constitutes the list of drugs that are reimbursable in the three public health insurance systems. It is also used as a tool to encourage the rational use of medicines. The cost of prescribed drugs outside the NLEM is borne by individuals under the SSS and UC systems; however under the CSMBS system coverage for drugs outside of the NLEM requires that three attending physicians give their approval for use.

In order to determine which new products are included on the NLEM, National Expert Panels from each drug group select and put forward a draft list of products to be included on the NLEM. A screening working group then reviews these products and assesses them according to clinical value, cost effectiveness, equity and national affordability. The clinical value and cost effectiveness of the drug are key criteria to determine its inclusion on the NLEM.

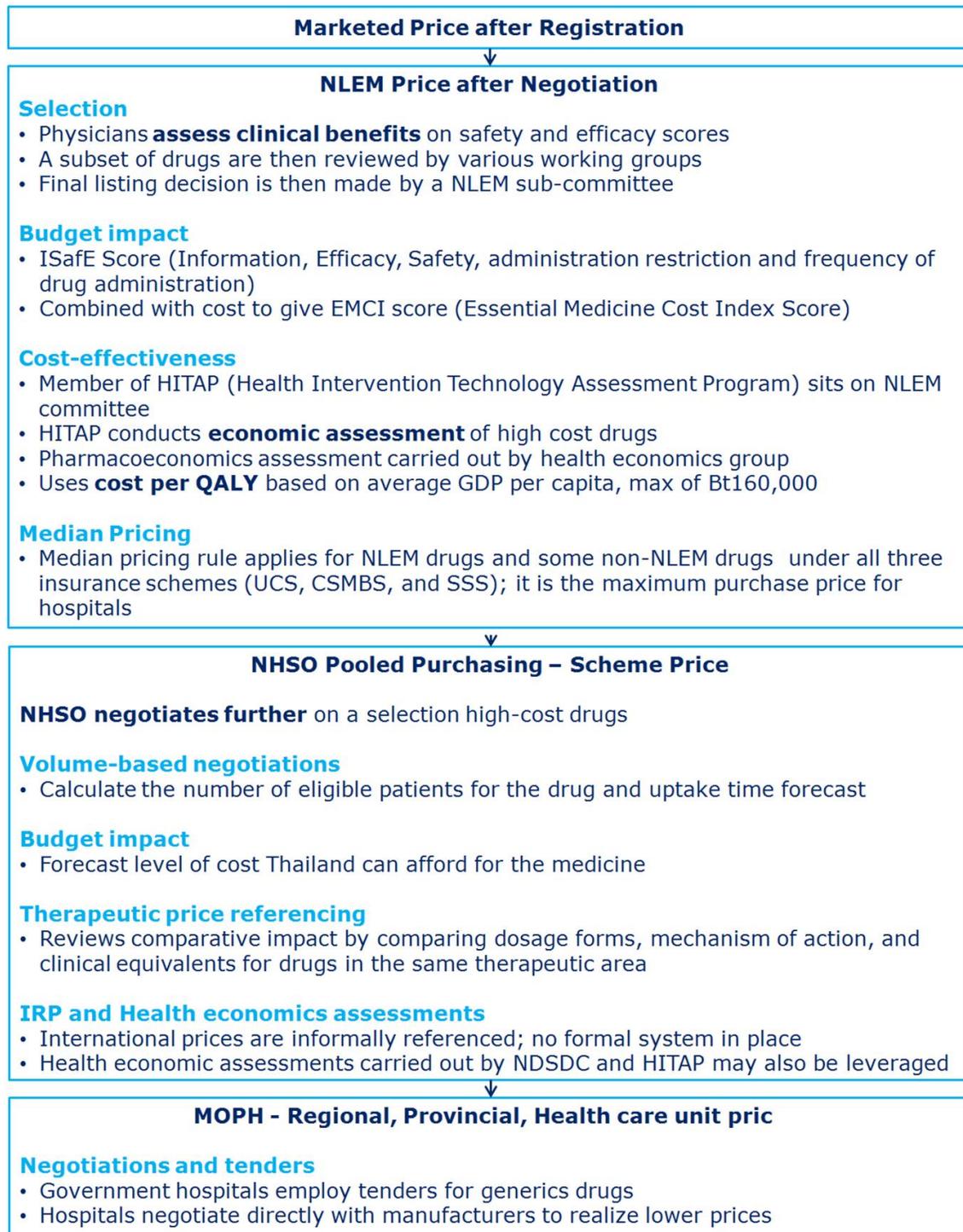
In order to determine the clinical value of a new product, the efficacy and safety of the product is assessed using the ISaFE (Information, Efficacy, Safety, administration restriction and frequency of drug administration) tool and a score is assigned to the product. The ISaFE score is combined with the relative price of the product to give the Essential Medicine Cost Index Score (EMCI). A committee including representatives from the NHSO, MoPH and expert physicians makes the final decision for inclusion on the NLEM. Products that have lower EMCI scores are more likely to be included on the NLEM.

Pharmacoeconomic assessments are also applied to the decision process to reimburse drugs through the NLEM. A health technology assessment agency under the MoPH, Health Intervention Technology Assessment Program (HITAP), is primarily responsible for conducting economic evaluation of some drugs, especially expensive ones. Its major mission is to efficiently and transparently appraise health interventions and technologies. It does its assessment in several steps. For instance, every year HITAP asks various stakeholders – health-care providers, academics, hospital purchasers, payers, and patient advocacy groups – across the country for potential drugs that should be evaluated. The NLEM committee can also ask HITAP to assess certain products to help with its decisions.

HITAP has its own experts to conduct pharmacoeconomic evaluations. It has developed not only national guidelines for economic evaluation but has also incorporated the World Health Organization guideline that average GNI per capita be considered as a cost-effective threshold. Recently, this threshold based on GNI per capita is set at Bt 160,000 per Quality Adjusted Life Year (QALY). HITAP assessments have sometimes been used to successfully negotiate drug prices with manufacturers before the drugs are listed on the NLEM.

For products that are not included on the NLEM, but considered high priority for patients in Thailand, the NHSO may conduct negotiations with manufacturers and reimburse these drugs separately, or reimburse them by providing them directly to hospitals. Government owned hospitals can also negotiate directly with manufacturers to obtain lower prices for new products. A schematic of Thailand's current pricing and patient access process is shown in Exhibit 2.

**Exhibit 2: Current Pricing and Patient Access Process in Thailand**



## 2.3 Clarification of Pricing Terminology in the Thai system

For clarity and common understanding, in this report, we will use the following definitions for different types of prices that are used in the Thai system today.

**List price:** The publicly visible ex-manufacturer price of a drug.

**Median price or reference price:** The maximum procurement price that hospitals can pay to purchase a reimbursed drug. These prices include distributor or wholesaler margins as well as the value added tax (currently 7%), but exclude any hospital margins. While the term median is used, the actual methodology to set the median price can vary. For example, sometimes a mode is used. Further, which specific prices are included or excluded for setting the median price is not clear as sometimes outliers are excluded. There is no clear rationale to why outliers are excluded or a standard method to define what an outlier is.

**Hospital procurement price:** The price at which public hospitals actually pay to purchase a reimbursed drug. It includes the ex-man price, the distributor/wholesaler margin and the value added tax. This price is usually, but not always, available to MoPH's data centre, Drug and Medical Supply Information Centre (DMSIC). Some of the hospital procurement prices are confidential. The DMSIC data is used by the MoPH to set the median price.

**Reimbursement price:** The price which is reimbursed to the hospitals by CSMBS. This is the median price plus hospital margins. Given this the hospitals make money from drug prescriptions to CSMBS patients. This includes both the hospital margin and the retained discount negotiated by the hospital below the median price. This funding is used by the hospitals to pay for other services; and it can be an implicit cross-subsidy for services provided to patients in the other insurance schemes. Both UC and SSS pay hospitals on a capitation basis and do not usually reimburse hospitals for medicines separately.

In addition to the above, the NHSO may directly procure some medicines, especially higher cost patented medicines. In this case, the NHSO can directly negotiate with manufacturers and the price it pays includes ex-man price, and applicable margins and taxes.

## 2.4 Current pricing mechanisms

As Exhibit 2 shows, a range of mechanisms are used in Thailand to help regulate the prices for products listed on the NLEM or benefit package. Regulation mandates that the Ministry of Public Health (MOPH) should develop the NLEM and a "median price" or "reference price" for each drug in the NLEM. Median pricing is used to set the maximum price that hospitals can use to procure reimbursed prescription drugs covered by the NLEM.

The reference or median price is set by the Committee for the Development of the Medicine Price List and is based on collective information on purchasing prices of similar drugs from all public hospitals. Where this information is not available or if the MoPH determines otherwise, a reference price can also be set by MOPH (applicable to medicines listed or unlisted in NLEM). The public hospitals are required to purchase at this reference price or below.<sup>7</sup>

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<sup>7</sup> The median or reference price is used to set the maximum procurement price for hospital purchase of reimbursed medicines.

In some instances, the National Drug Systems Development Committee (NDSDC) also informs price setting by using international reference pricing from a small set of countries – Canada, Australia and UK.

Prices for select high cost products in the NLEM that are not fully covered under capitation as well as for reimbursed products outside the NLEM are typically set through negotiations with manufacturers. Several tools are currently being employed to achieve mutually acceptable prices.

- **Price volume agreements:** the number of eligible patients for the product is calculated and the uptake duration is forecast, which is used to agree a maximum volume threshold. Any cost amounts that exceed the set threshold are covered by the manufacturer
- **Budget impact:** a budget impact analysis is conducted to assess the cost of the medicine and determine if it is affordable
- **Therapeutic reference pricing (TRP):** a price is set by reviewing the dosage forms, mechanism of action and clinical equivalence for comparable drugs in the same therapeutic area which already have a reference price.
- **International reference pricing (IRP):** currently in Thailand international prices are informally referenced occasionally by the NDSDC or NHSO to support negotiations with manufacturers.
- **Risk share agreements:** a price is set based on the number of patients who respond to a certain treatment; spreading the risk between the payer and the manufacturer

While the above tools are occasionally used, there is no one overarching cohesive system that provides systematic guidelines for the use of these tools.

## 2.5 Challenges in the Pricing and Patient Access System in Thailand

The Thai government has made significant progress in recent years towards achieving the goal of providing access to healthcare for the whole population. It has also expanded access to medicines and adjusted quite well to develop and deploy different tools to set price and access as described above. However, as an evolving system, there are still some limitations to the PPA system in Thailand as described below<sup>8</sup>.

### Inequitable Medicine Coverage

There is disproportionate dispensing of non-NLEM drugs across the insurance schemes. Due to the fee-for-service payment, beneficiaries of the more generous insurance scheme, the CSMBS, tend to have access to more products outside of the NLEM. CSMBS covers 7% of the population; it accounts for 45% of branded medicine sales. The CSMBS is perceived as a privileged health plan while the UCS and SSS are sometimes viewed as standard schemes by the public. In general, equity across these schemes is a matter of concern. The aspiration is

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<sup>8</sup> These are likely outcomes given the system, however, empirical analysis is needed to understand the magnitude of the problems.

to provide similar access as in CSMBS to other schemes, especially the UCS. However, to do this effectively and sustainably, Thailand would need to reform its PPA system to both prioritise what medicines it covers and to set price and access levels for prioritized medicines.

### **Inequity due to financial incentives**

Public hospitals are funded by population based capitation for UCS and SSS patients. For CSMBS, the funding is through in-patient DRGs and outpatient fee for service. As mentioned above, hospitals charge full reimbursement price to CSMBS (median price plus hospital margin).

This system creates the following incentives for hospitals.

- Buy medicines as cheaply as possible. This may sometimes cause quality issues, especially for non-branded medicines prescribed to UC and SSS patients.
- There is a financial incentive to under-prescribe medicines to UC and SSS patients given capitation based payment, and over-prescribe medicines (especially branded medicines) to CSMBS patients.
- Under prescription in the UC scheme is somewhat mitigated by outcome based measures (assuming they are applied effectively).

### **Inequity due to median pricing system**

The current system allows hospitals to negotiate procurement prices below the median price. Larger hospitals or ones with more skilled negotiation staff may be able to negotiate lower prices than others. These hospitals with higher margins, therefore, are able to fund more and better services for its patients. This can create inequities in the amount and quality of services offered by different hospitals to their patients.

### **Race to the bottom**

Continual lowering of median prices can lead to very low prices. This can be seen in the next section, which shows that Thai generic prices (after discount) are some of the lowest in the world. This has the potential to lead to either medicine shortages or poor quality of medicines.

The MoPH understands this problem, therefore, it has adjusted the median price to be higher than 50th percentile and considered other factors a revised median price is announced. However, this leads to the next problem – lack of predictability and clarity in the price setting system.

### **Lack of predictability and clarity**

Aside from a race to the bottom, the median price setting faces other challenges. Sometimes, there may be limited competition, and a median price approach may not achieve the desired price levels. In addition to these issues, not all hospital procurement prices are available to the DMSIC, so the median price may not reflect all the actual prices in the market.

Due to these issues, the MoPH has faced challenges in implementing a standardized system with a standard formula to set the median price. It is not clear what price to use when it deviates from the 50<sup>th</sup> percentile. It has sometimes used the mode, for example.

It is also not clear which prices are included in the basket and which are not (e.g., the prices not submitted by some hospitals). Further, the median price setting committee can also decide to include or exclude outliers; and there is no commonly accepted definition of outliers.

As a result, the pricing system is not predictable or clear. Manufacturers and other stakeholders face a lot of uncertainty in what approach will be used and therefore, what the pricing outcome will be.

### **Lack of transparency**

Thailand wants to ensure transparency in price setting. However, this is limited to the final median price that is set, but not to the process that sets the price. As discussed above, the process to set the median price can seem to be arbitrary and unpredictable. Similarly for higher cost medicines, there are no publicly available common rules to set prices, which again means that the process is not transparent (or predictable).

Further, some prices are publicly available while others are confidential. For example, the hospitals that voluntarily submit data to DMSIC make their prices public. However, others keep their discounts below the median price confidential.

Generally, the price cannot be kept confidential when the body that negotiates the price is not one who actually procures the drug. For example in case of patented drugs, if NHSO centrally negotiates the price but GPO procures the drug, this price will be public. However, if the negotiation and procurement are done by the same institution (e.g., the hospital) the actual procurement price can be kept confidential.

There are many factors, other than confidential negotiation, why some hospitals do not submit the actual purchased price to DMSIC. The price information shared by hospitals with DMSIC is not standardized. This means that some hospitals record the net price after discount, some use price listed on the invoice before discount, some use the average price of several invoices, some use the most current purchased price. In addition, some discounts come in other forms, such as purchase drug item A but provide extra amount of item B. Since the information system and data input process of each hospital is not standardised, each hospital chooses its own way to input the information. Therefore, DMSIC often doesn't have the actual acquisition cost from hospitals. This not only makes the process less transparent, it also compounds the clarity and predictability problem mentioned above.

Overall, this leads to a system where transparency is in the wrong place. NHSO's hands are tied in terms of negotiating confidential discounts as it needs to procure through GPO. This stops it from being able to access needed high cost medicines, where manufacturers may be willing to offer a large discount but only in a confidential manner through mechanisms such as managed entry agreements (MEAs)<sup>9</sup>. At the same time, where there is need for transparency, predictability and clarity, such as in median price setting, the process is often seen as arbitrary without clear and consistent rules.

### **Fragmented system**

As seen before in this report, there are many different bodies and several different tools being used to set prices. Often these tools are employed to address and resolve specific situations

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<sup>9</sup> Discussed later in the report

as they arise. There is no one cohesive, structured and commonly understood PPA system in Thailand that clearly lays down the rules of pricing and access for different types of medicines. This can lead to unpredictability, and therefore impact all stakeholders – MoPH, NHSO, CSMBS, SSS, hospitals and innovative and generic manufacturers negatively. This can lead either to unaffordable prices (and hence, lack of access, in some schemes) or to low prices that price quality manufacturers out of the market.

### **Inadequate ability to set price and access for innovative high cost medicines**

While the PPA system in Thailand works reasonably well for generic medicines, it faces significant challenges in setting price and reimbursement levels for innovative high cost medicines, especially in oncology and orphan indications. Many of these medicines are novel and provide high clinical benefit. They also do not have competitive alternatives. Further, they may only be for small patient populations. Given this, the prices set by manufacturers do not meet the QALY threshold in Thailand and therefore, these medicines do not make it onto the NLEM.

Further, some of these medicines come to market with more limited evidence (smaller trials, no H2H active comparator, small duration of trials, etc.). This further impacts how these medicines are valued by a standard pharmacoeconomic evaluation process. This problem is not unique to Thailand. Other countries also face similar challenges, and have taken different approaches to address these challenges. For example, the Cancer Drugs Fund (CDF) in the UK has been set up to provide access to novel medicines serving high unmet need patients that are not approved by the National Institute of Clinical Excellence (NICE). Thailand also needs a mechanism to address the access challenges posed by such medicines.

### **Limited Expertise, Data and Resources**

Setting prices and access for medicines is a complex undertaking. Thailand has made some strides in this regard through the NLEM committee and HITAP. It needs to go further and this requires investment in the following areas:

- Expertise in PPA frameworks, systems and tools
- Negotiation skills that allow for successful negotiations with manufacturers
- Data system that can track and update internal and external reference prices
- Governance structure that allows the setting of consistent prices across schemes in a structured manner
- Sufficient number of trained staff that can do the above

A new PPA system must address these challenges. In the next sections, we describe how other countries address these challenges and then recommend a new PPA framework for Thailand.

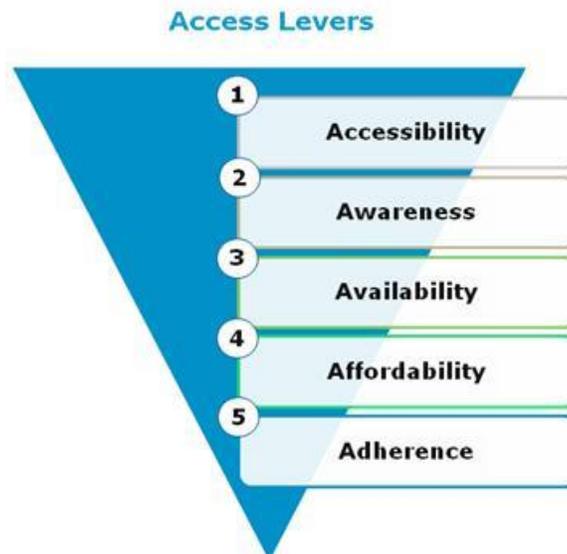
### 3 Lessons in PPA from Benchmark Countries

In this section, we benchmark selected countries in two areas. First on how well they do in terms availability and affordability of medicines. And second on the PPA systems used by a subset of these countries to set price and access of reimbursed medicines.

#### 3.1 Benchmarking Patient Access to Medicine (ATM)

Access to medicine is one of the key pillars of any healthcare system. It helps to lower overall healthcare costs by reducing the need for hospitalization and expensive, invasive procedures. After improvements to basic sanitation, access to clean water and immunization, access to medicines is one of the most cost-effective health-related services. For effective access to medicine, patients should be able to receive the right medicine at the right time without serious adverse financial consequences. To ensure that this happens, government policy must address five key levers as shown in the Exhibit below.

**Exhibit 3:** Access Levers to Access to Medicine



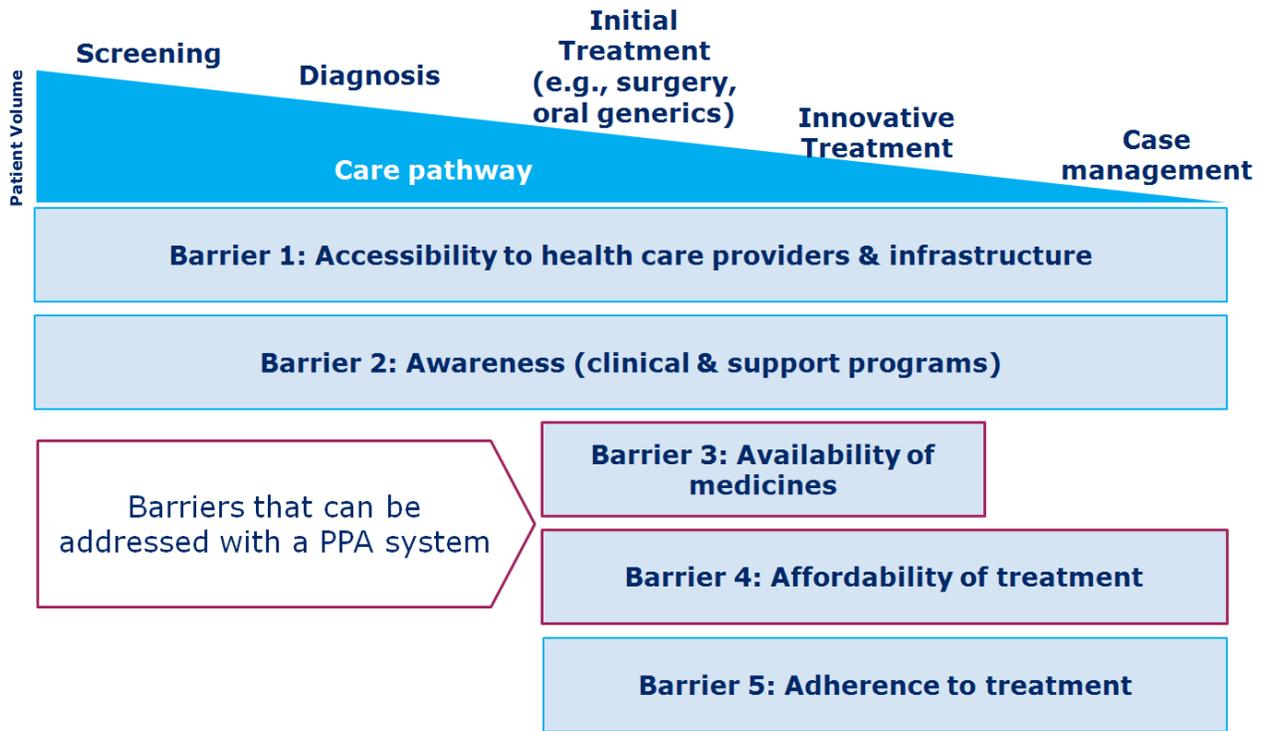
These levers represent different elements of ensuring effective access to medicines:

- **Accessibility:** Ease of access to healthcare workers and facilities
- **Awareness:** Health Care Professional (HCP) awareness of disease diagnosis and treatment protocols; and patient and caregiver awareness of health system resources available to them
- **Affordability:** Ability of patients and health systems to pay for the medicines without significant negative financial consequences

- **Availability:** Availability of medicines in the country as well as in the hospital or pharmacy close to the patient
- **Adherence:** Proper management of patients on the treatment protocols

Effective access to medicines can be hindered by a number of challenges across the patient care pathway from the process of disease screening and diagnosis through to treatment choice and disease management. To ensure effective access to medicines, it is important to address the barriers associated with each access lever occurring along such a pathway. Access barriers can stem from the demand side and/or the supply side: demand side constraints influence individuals', households' and communities' ability to use services while supply-side constraints are aspects of health services and the health sector that hinder service uptake.

**Exhibit 4:** Key Barriers Affecting Access to Medicine



An effective PPA policy framework enables a health system to prioritize medicines for reimbursement and to set appropriate price and access levels. As such, a PPA system is able to address two of the five access pillars; availability and affordability, which together constitutes the Pricing and Patient Access (PPA) framework. Further information on all the pillars can be found in the appendix. In this main report, we will focus on select availability and affordability metrics.

### **Baseline diagnostic - Availability**

The availability of generic and innovative medicines in both the public and private markets is an important indicator of access to treatment. Key parameters that affect availability are:

- Easy availability of medicine in the country
- Time before latest medicine becomes available

The availability of patented and generic medicines were analysed and the results are shown in Exhibit 5. IMS MIDAS analysis suggests that the market share of original products (patented medicines and original brands of medicines which have lost patent protection) in Thailand is low in both value (11%) and volume (2%) terms as compared to developed countries (range 38%-60% by value, 11%-20% by volume), while it is similar to that of developing countries (range 4%-25% by value, up to 4% by volume).

Most medicines under the NLEM are generics and the focus of public procurement. Therefore, market share of generics is high in Thailand as these are covered under health insurance schemes.

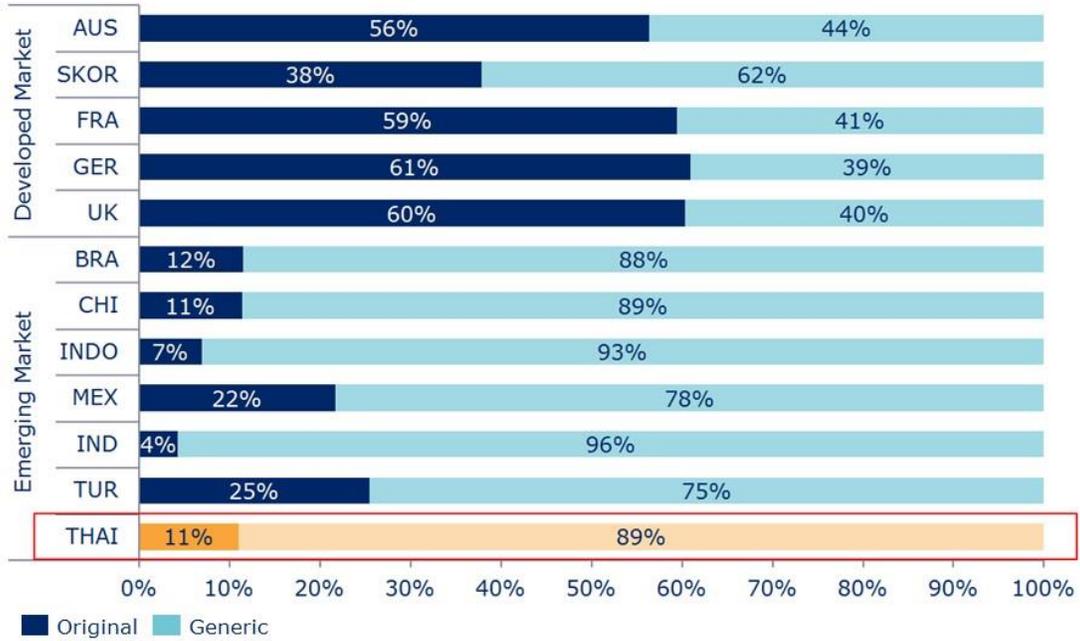
There is also substantial delay in launch of new molecules in Thailand as compared to other benchmarked developed countries (Exhibit 6) which ranges from 13 months to 48 months.<sup>10</sup> However, this delay is minimal as compared to benchmarked developing countries which ranges from 7 to >48 months. The average delay in launch of innovative molecules in Thailand is approximately 24 months from first global launch.

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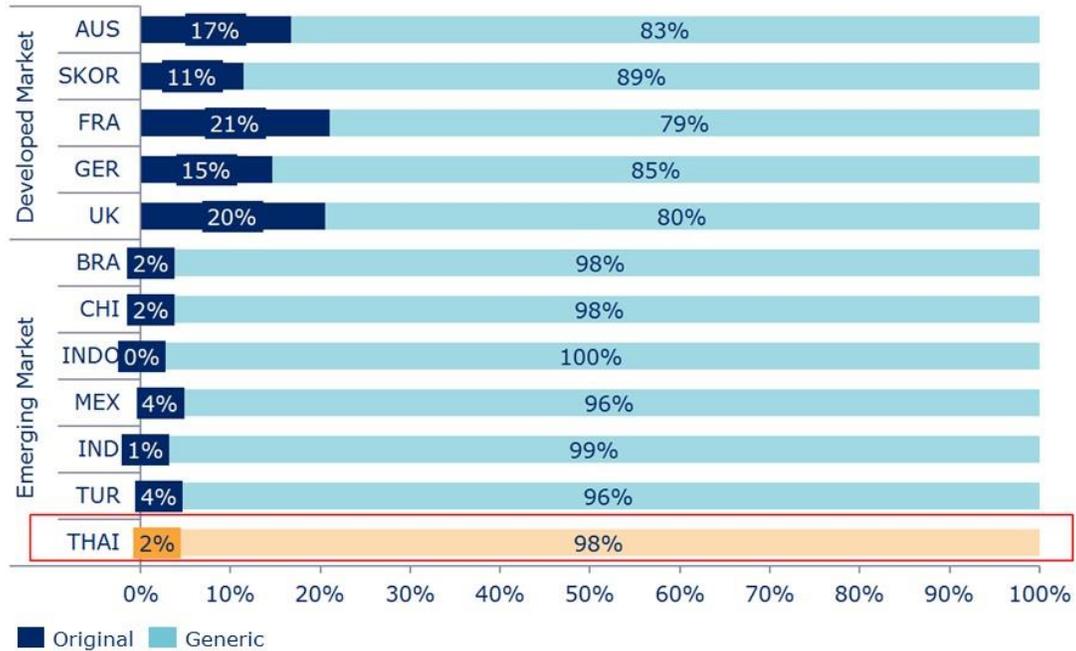
<sup>10</sup> This assessment is based on the representative products shown in Exhibit 6 across 6 therapy areas with the highest burden of disease (one product in each therapy area).

**Exhibit 5:** Market share in value (a) and volume (b) by product type<sup>11</sup>

**(a) Market share (% Value) by Product Type**



**(b) Market share (% Volume) by Product Type**



<sup>11</sup> Developed countries - AUS, Australia; SKOR, South Korea; FRA, France; GER, Germany; UK, United Kingdom. Developing countries – BRA, Brazil; CHI, China; INDO, Indonesia; MEX, Mexico; IND, India; TUR, Turkey; THAI, Thailand

**Exhibit 6: Delay in Launch of Patented Medicines**

TA	Product	First Launch Year	Time of launch compare to first launch (months)							
			0	1-6	7-12	13-18	19-24	25-36	37-48	>48
Diabetes	JANUVIA	2006								
Anti-HIV	ISENTRESS	2007								
CV	PRADAXA	2008								
Oncology	SUTENT	2006								
Anti-Inf.	MYCAMINE	2005								
Respiratory	ONBREZ	2009								

Source: IMS MIDAS Data Notes: 1) Representative product basket across TA

**Baseline diagnostic - Affordability**

Aside from the financing and reimbursement of health care, the price of medicine has an impact on its affordability. We benchmarked the price of representative patented and generic medicines in select therapy areas across several countries including Thailand. Exhibit 7 shows prices in the select countries indexed to the price in Thailand.

For most of the therapeutic areas examined, the prices of patented medicines in Thailand are roughly at the average of the rest of the benchmarked countries, with some variations by therapy area.

The list or publicly available prices of generic medicines in Thailand are marginally higher than the benchmarked developing countries. However, when we consider the discounts provided to the public hospitals (assuming this to be 30% on average), Thai prices are on the lower side. In some cases, hospitals may be getting even higher discounts on some generic versions bringing Thai public generic prices further down. However, this evidence is not available in the public domain and is based on anecdotal understanding of the market.

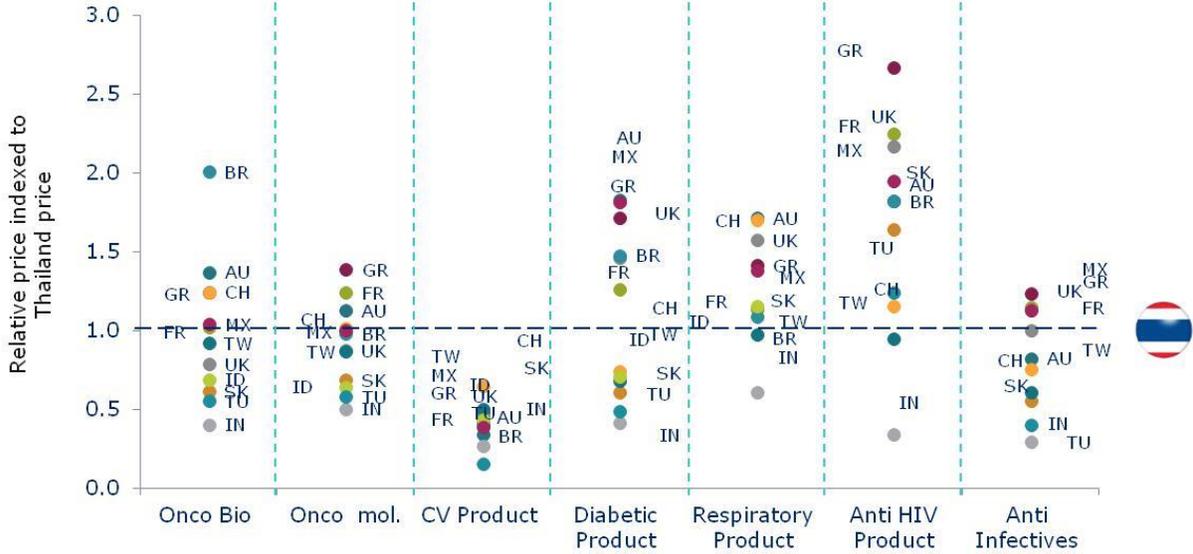
In addition to prices, we also looked at the affordability of these prices given the different income levels in the different countries. To do this we created an affordability index that is measured as the average per unit cost of product basket (shown above) divided by GDP per capita. The results are shown in Exhibit 8. Given lower GDP per capita in Thailand compared to developed countries, medicines with the same or even lower cost are comparatively less affordable in Thailand. This is true for both patented and generic medicines<sup>12</sup>.

<sup>12</sup> This analysis has been done at the list price level. For generics, if we consider net prices, the affordability in Thailand would be better than shown in the Exhibit.



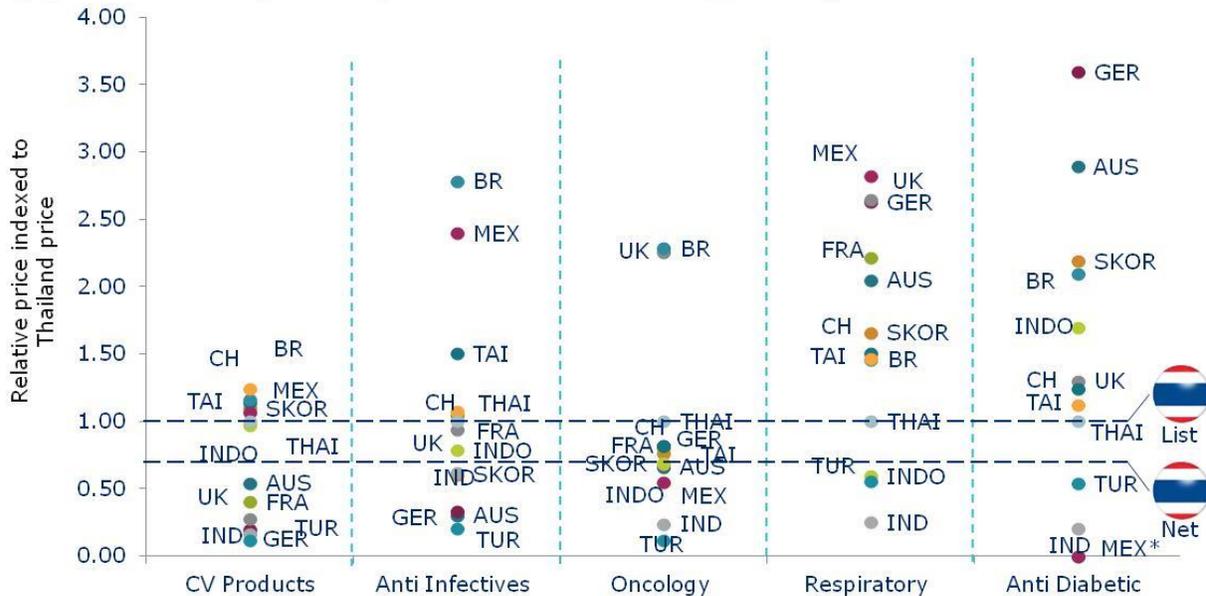
**Exhibit 7: Benchmarking of price of patented and generic and patented medicines<sup>13</sup>**

**(a) Standardized product prices of seven reference patented products across countries**



**Source:** IMS MIDAS Data, only includes retail and hospital sales – does not include tender based procurement, Based on Price to Retailer/Hospital and not list price/effective consumer price, effective price may differ given the different tax structure and trade discounts

**(b) Standardized product prices of five reference generic products across countries**

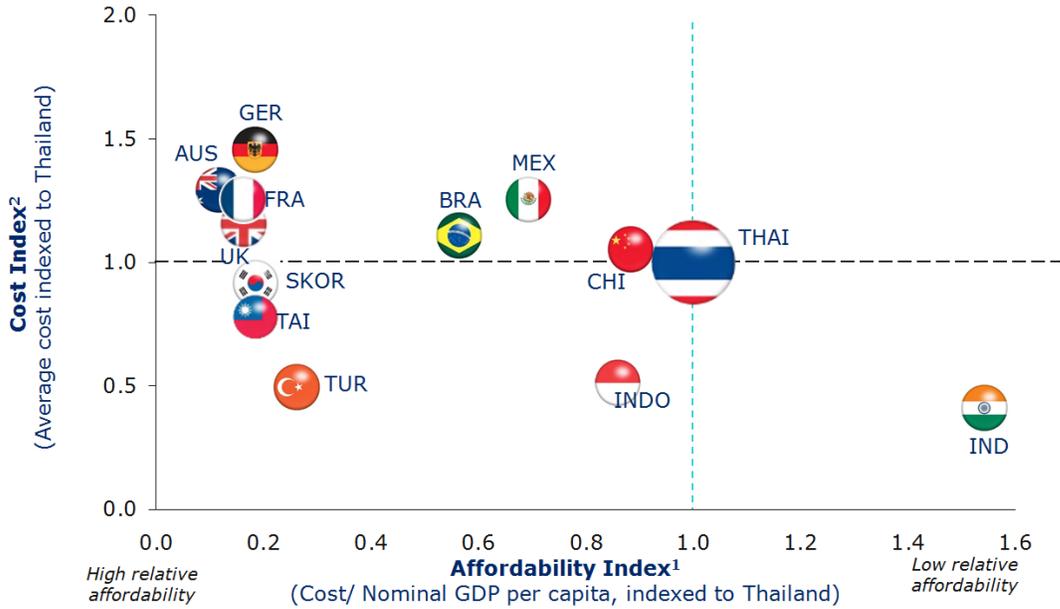


**Source:** IMS MIDAS Data, only includes retail and hospital sales – does not include tender based procurement, Based on Price to Retailer/Hospital and not list price/effective consumer price, effective price may differ given the different tax structure and trade discounts

<sup>13</sup> Net generic prices in the public system are likely to be 30-50% lower, once confidential discounts are accounted for.

**Exhibit 8: Benchmarking of affordability of patented and generic medicines**

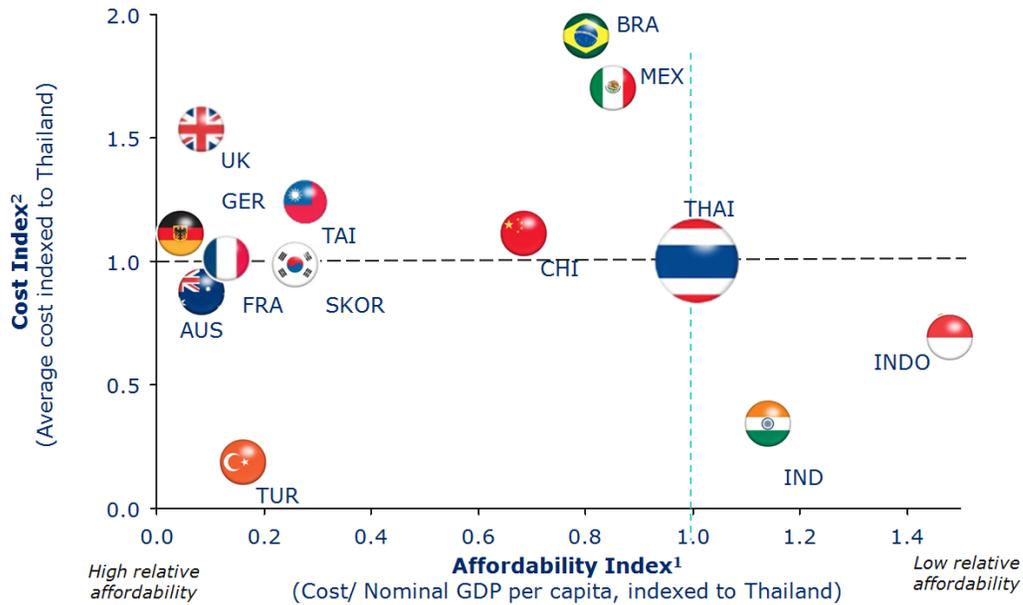
**(a) Cost vs. affordability of patented products across countries**



1. Affordability index: Average per unit cost of product basket / Nominal GDP per capita
2. Cost Index: average per unit cost of product basket
3. Product basket includes: Herceptin, Sutent, Pradaxa, Januvia, Onbrez, Isentres, Noxafil

Source: IMS MIDAS Data, only includes retail and hospital sales – does not include tender based procurement, Based on Price to Retailer/Hospital and not list price/effective consumer price, World Bank (GDP Data) – 2013, 2012

**(b) Cost vs. affordability of generic products across countries**



1. Affordability index: Average per unit cost of product basket / Nominal GDP per capita
2. Cost Index: average per unit cost of product basket
3. Product basket includes: Atorvastatin, Meropenem, Paclitaxel, Fluticasone, Pioglitazo

Source: IMS MIDAS Data, only includes retail and hospital sales – does not include tender based procurement, Based on Price to Retailer/Hospital and not list price/effective consumer price, World Bank (GDP Data) – 2013, 2012

## 3.2 Benchmarking Pricing and Patient Access Systems

### 3.2.1 Objectives of Pricing and Patient Access Systems

PPA systems evaluate new (and sometimes existing) medicines and set price and access levels for them. National, regional and local payers leverage PPA systems to achieve and balance six competing objectives (Exhibit 9):

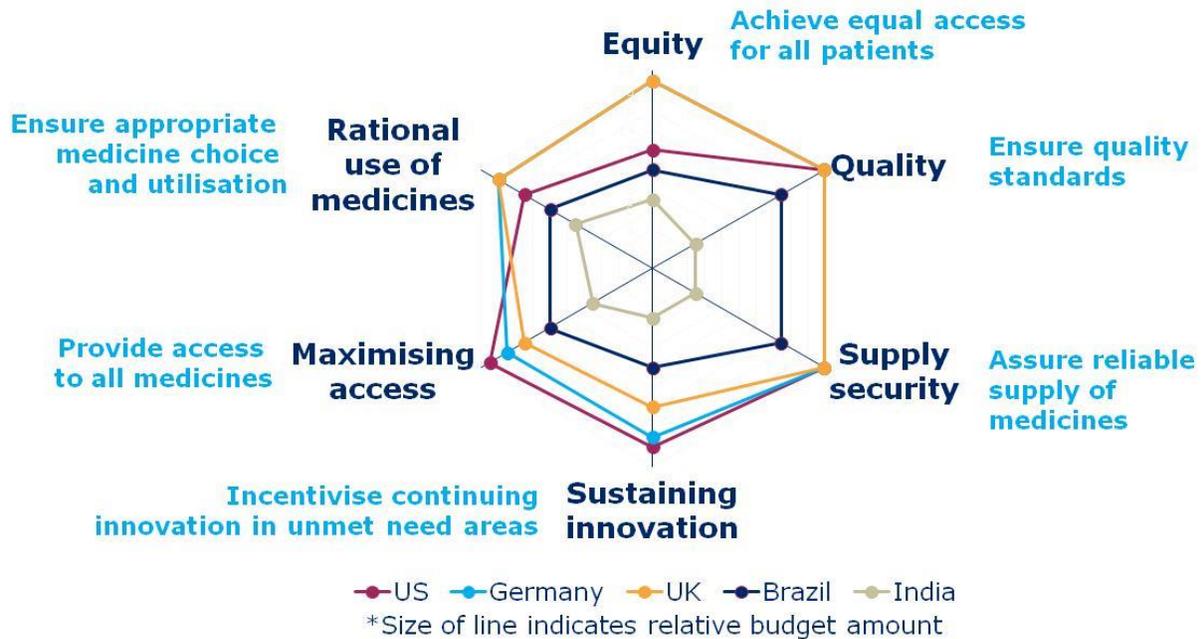
- **Equity:** Similarity or equality of access to all patients irrespective of income, demography, geography, type of disease or other differences
- **Quality:** Ensuring minimum required quality standards of medicines.
- **Supply Security:** Ensuring sufficient and secure supply of medicines.
- **Sustaining Innovation:** Incentivising manufacturers to continue to invest in research and development of novel medicines in unmet need areas.
- **Maximising Access:** Ensuring all needed medicines are reimbursed.
- **Rational Use of Medicines:** Ensuring that "patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community".

However, healthcare systems must function within a set budget with finite resources and therefore even the richest systems cannot achieve all objectives perfectly; each system must decide the right balance between its priorities. Exhibit 9 shows in a directional way how select countries manage these trade-offs<sup>14</sup>.

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<sup>14</sup> This is a directional assessment based on IMSCG expertise and knowledge of the health systems in these countries.

**Exhibit 9: Objectives of PPA System**



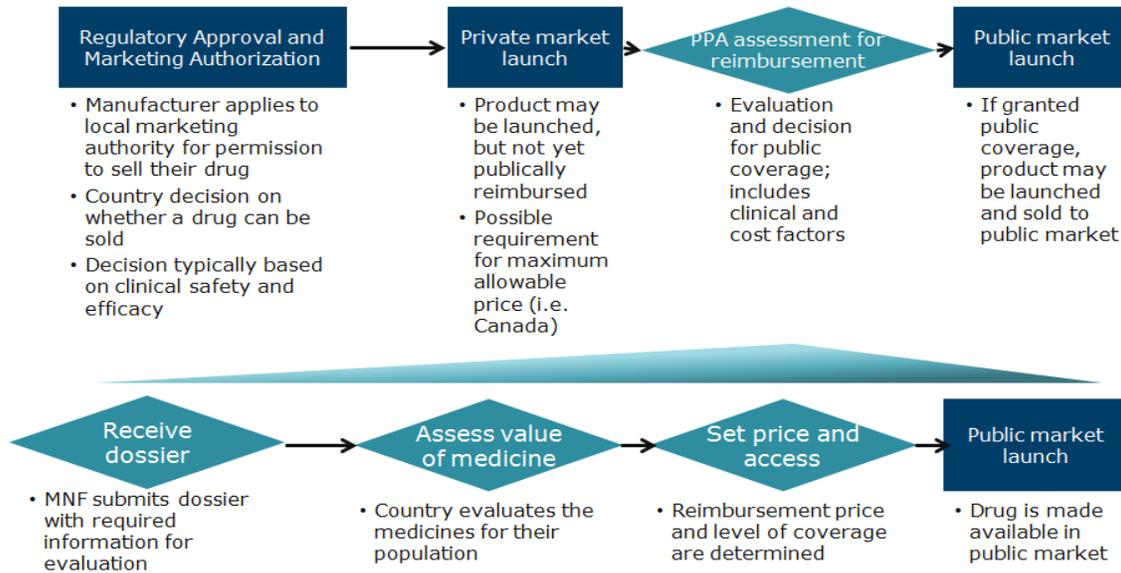
### 3.2.2 Pricing and Patient Access Framework

PPA systems help payers achieve their desired balance of objectives described above. Generally, irrespective of approach, PPA systems follow a similar approach with some common steps. Exhibits 10 and 11 show the typical steps of a new medicine launch, its evaluation and setting of price and reimbursement.

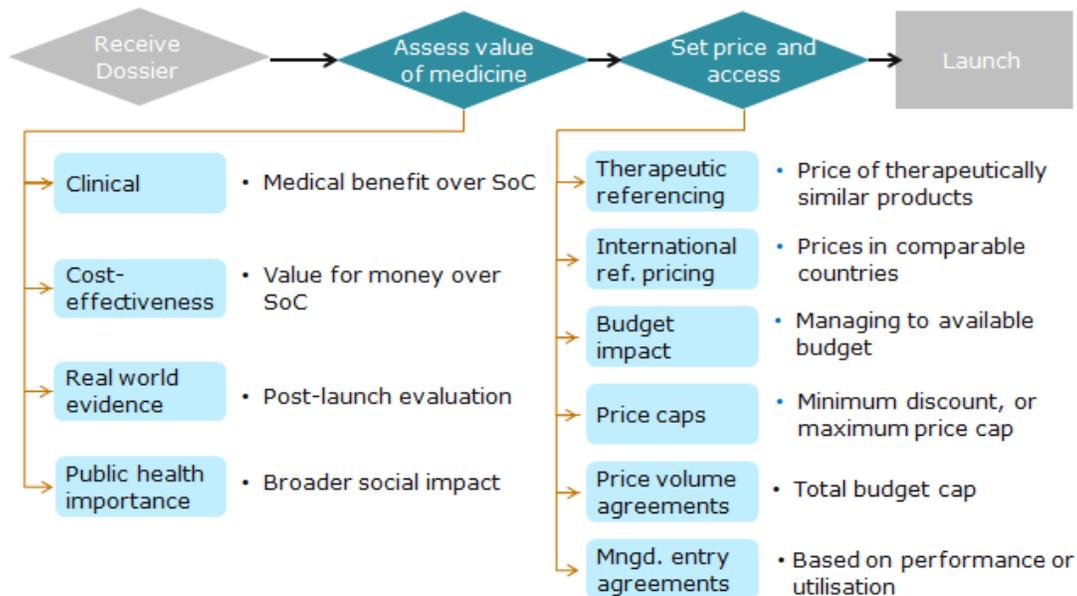
As Exhibit 10 shows, for any new product it is first mandatory to receive regulatory approval and market authorization in order to sell a product in the desired country. Once the product is approved for sale, it is typically made available first on the private market where it is paid for privately by patients out-of-pocket, or in some cases by through private insurance coverage. Typically the next step is for the manufacturer to seek public reimbursement for the product. It is at this step that the PPA system comes into play. PPA systems are used to evaluate new medicines and determine price. If the product is given a positive evaluation and a reimbursement price is decided, the product can then be listed for public reimbursement and launch in the public market.

A typical PPA system evaluates and prioritises medicines to inform pricing and access decisions, given budget constraints. A typical framework first determines value of medicine to the health system. Based on this assessment, it then helps assign a price and set the access level (all patients as per label or a subset of patients, e.g., after failure of 1<sup>st</sup> line generic treatment). Exhibit 11 shows the typical steps taken to evaluate and price new medicines using a PPA framework. To set the price and access, countries use a variety of tools, which are an integral part of the PPA system.

**Exhibit 10:** Steps for private and public market launch



**Exhibit 11:** Overview of Pricing and Access Framework Steps

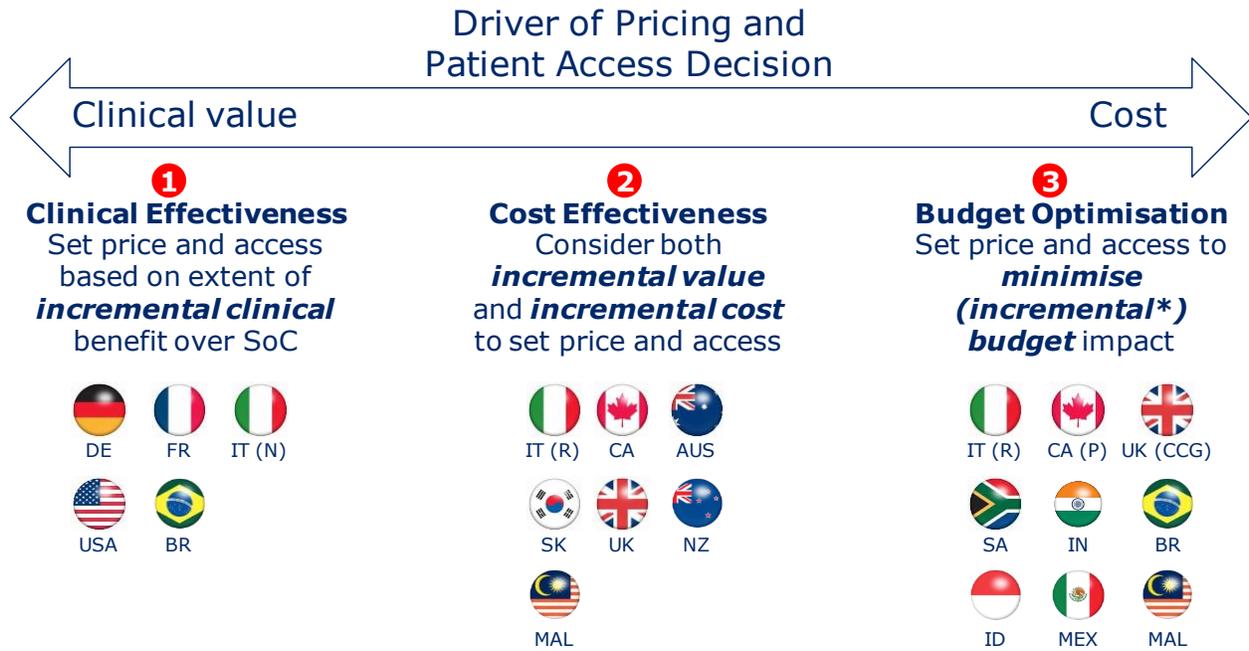


**Source:** IMS PharmaQuery, IMS Market Prognosis report & IMS analysis

While the above discussion shows the typical steps followed in most countries, not all PPA frameworks are the same, and the most suitable PPA approach depends on the product type and a country’s socio-political preferences. Countries take different approaches to defining appropriate price and patient access of medicines. Some place the highest emphasis on clinical

value, while others place the highest importance on cost, while others place emphasis on a combination of clinical value and cost. These approaches can be defined on a spectrum where one end of spectrum is “clinical value” considerations and other end is “cost/budget” considerations. Exhibit 12 illustrates this spectrum with the benchmark countries and their national and regional placed accordingly. Most countries see the use of more than one approach. Generally, national payers use either a clinical effectiveness or cost effectiveness approach, while regional and local payers are more focused on cost or budget considerations<sup>15</sup>.

**Exhibit 12: Pricing and Access Approaches<sup>16</sup>**



### 3.2.3 Pricing and Patient Access Tools

Payers use HTA and pricing tools to manage affordable patient access to needed medicines. The process of setting a price (pricing) and deciding on the level of coverage by public payers (reimbursement) are strongly interlinked. The assessment process usually includes criteria such as efficacy, effectiveness, safety, ease of use, and added therapeutic value, beside cost-effectiveness.

The selection of most suitable PPA approach and tools is also dependent upon the category of the medicines: patented and generic. For patented drugs, clinical and cost effectiveness approaches are used to set price and access based on the extent of incremental clinical benefit (Clinical Effectiveness) and incremental value and cost (Cost Effectiveness) in comparison to

<sup>15</sup> Details of the select countries’ PPA systems are provided in the Appendix.

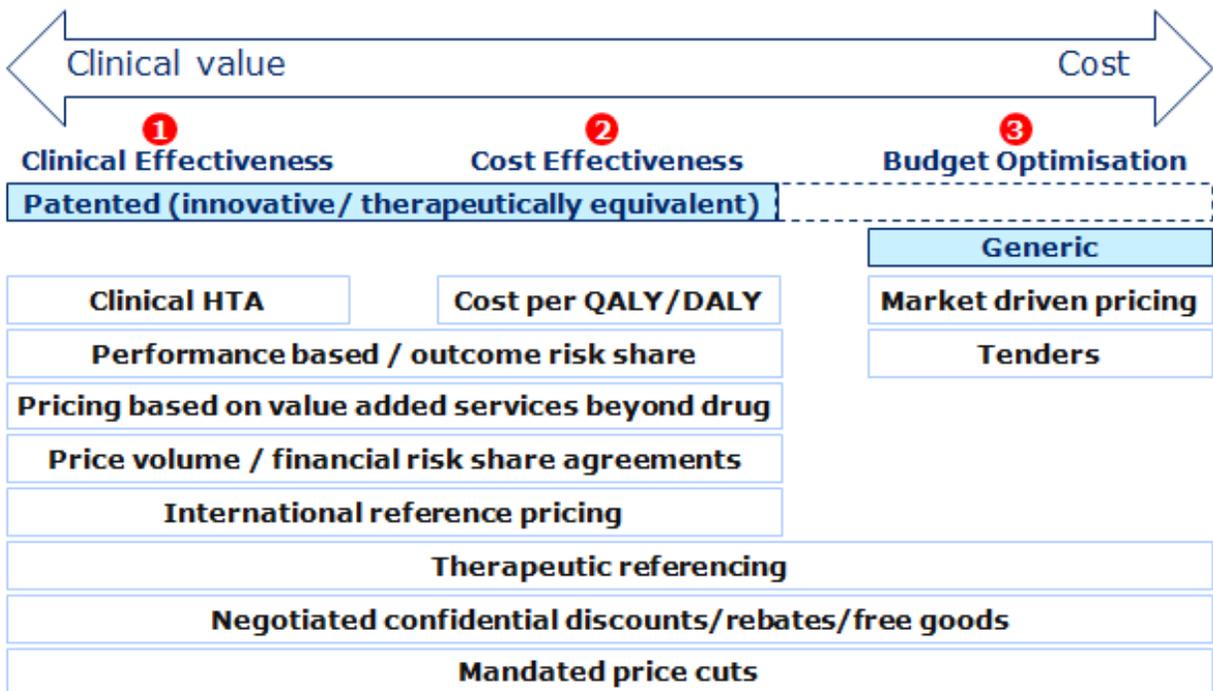
<sup>16</sup> DE: Germany; FR: France; IT: Italy; BR: Brazil; CA: Canada; AUS: Australia; SK: South Korea; UK: United Kingdom; NZ: New Zealand; MAL: Malaysia; IN: India; ID: Indonesia; MX: Mexico; (N): National payer; (P): Provincial payer; (R): Regional payer; CCG: Clinical Commissioning Groups, which are regional payers in the UK

the existing standard of care. Some payers primarily focus on minimising budget impact even for new products; however, they still indirectly consider the outcomes of HTA done by others (either national payers in their countries, or even the assessments done by HTA bodies such as NICE in other countries).

Generic drugs (high volume, low volume and low competition) have typically already undergone the health technology assessments at the time of original launch in those particular countries or other similar countries. Therefore, pricing of these drugs tend to follow different approaches based largely on competition.

The common approaches and PPA tools by product type are shown in Exhibit 13.

**Exhibit 13:** Pricing tools to control the cost of medicines



**Pricing Tools**

Setting the price of medicines can either be left to free pricing by the pharmaceutical industry and/or other stakeholder in the supply chain (wholesalers, pharmacists, hospitals) or can be performed by the government (or payer). In the case of reimbursement, payers use a wide range of pricing tools to set the price and access of medicines:

- **Clinical HTA:** Clinical HTA determines the incremental price premium over standard of care (SoC), based on the incremental or additional clinical value of the medicine. Examples of this include the innovation rating systems used by Germany, France and Italy (see appendix for details).

- **Cost per QALY or DALY:** Prices are set based on incremental QALY of DALY over existing Standard of Care (SoC) using pre-set thresholds of 1-3 times cost per QALY or DALY. Examples of this include cost-effectiveness assessments in Canada, Australia and UK (see appendix for details)
- **IRP:** International reference pricing (IRP), or external reference pricing, is a price control mechanism whereby a government considers the price of a medicine in other countries to inform or establish the price in its own country.
- **Therapeutic Referencing:** Countries use Therapeutic referencing to ensure drugs of similar therapeutic value receive similar price, thereby preventing the manufacturer from achieving premium price based on non-therapeutic attributes such as corporate brands.
- **Tenders:** Tender is a mechanism in which payers determine the price through open competition based on technical qualifying criteria and price.
- **Market Driven Pricing:** In market driven pricing, the payers reimburse the cheapest versions of the medicine available on the market; the prices can be set freely by the manufacturers.
- **Mandatory Price Cut:** The price of the medicine is reduced based on the market events such as new comparable product entry in the market, loss of the exclusivity (LoE) of the medicine or first or subsequent generic entry after LoE.
- **Performance based / Outcome risk share:** Price based on performance on pre-determined financial or clinical outcome metrics; risk is shared between manufacturer and payer
- **Value Added Services:** Price based on product and delivery of additional services such as administrative or clinical support
- **Price Volume Agreement:** Price is determined based on the volume of product sold; rebates given when volume exceeds pre-determined amount
- **Confidential Discount:** Final net price paid is discounted to the list price based on rebates that are kept confidential
- **Free Goods:** Free goods are granted to maintain list price but reduce overall cost paid for an amount of product

### Patient Access Tools

In addition to price, countries also use different access management tools to control costs. These include physician budget restrictions, patient access restrictions, prior authorization, INN Prescribing and pharmacy substitution. The application of these tools depends on the category of the medicines.

- **Physician Budget:** Germany and UK use physician budgets to control the cost of the medicines. Physicians are provided target budgets with disincentives built in if they overshoot the budget. This tool can be used for all types; innovative, me too and generic medicines.
- **Access Restrictions:** Based on the therapeutic value, some medicines are restricted to patient segments. This can be done based on severity of disease, or after failing prior cheaper treatments or other criteria. Such restrictions are generally used for more expensive patented medicines.

- **Prior Authorization:** Prior authorization helps in medical monitoring and ensures the prescription is as per the protocol. Level of use of patented products can be controlled either by the physician through prescribing decisions, or by the payer by imposing criteria for use.
- **INN Prescribing:** Restrict the physician to prescribe the medicines as per the international non-proprietary name of the medicines. This can only be used for generic medicines.
- **Pharmacy Substitution:** Generics which are interchangeable (vs. patented products which are not) can be subject to substitution at the pharmacy level for the cheapest alternative.

In the following sub-sections, we discuss different approaches to pricing patented and generic medicines and illustrate these with some specific examples.

### 3.3 Patented Pricing and Access Approaches

Patented medicines can fall under the following categories:

- **Innovative:** new patented product that typically represents unique and/or high clinical value; e.g., Sovaldi and Herceptin at time of launch.
- **Subsequent entry ('Me too'):** New patented product that is second or later to market and has a similar mechanism of action or therapeutic benefit to an existing product, e.g. anti-TNFs, DPP4s or ACEi/ARBs.

Pricing of patented drugs primarily follow clinical effectiveness or cost-effectiveness approaches. For new patented drugs, the approach maybe also depend on whether the drug is innovative or a subsequent entry ('me too') product. Pricing for subsequent entry products is made easier due to the fact that a comparable reimbursement price benchmark exists if the previous product is reimbursed. However, if the products are not completely substitutable due to differences in outcomes or relevant patient types then no easily comparable price benchmark exists.

We now discuss case examples of pricing of an innovative drug and a 'me too' drug using different approaches: cost-effectiveness and clinical effectiveness.

#### Case Study – Innovative Drug: cost effectiveness analysis of Sovaldi in UK

NICE recommended Sovaldi in its all genotypes for the treatment of Hepatitis C in the UK. In the UK, the drug costs nearly £35,000<sup>17</sup> for 12 weeks of treatment, and just under £70,000 for a 24-week course of treatment. The drug is more expensive than the existing treatments, but NICE's recommendation is based on the Sovaldi's ability to cure far more patients (up to 90 per cent) with fewer side effects and in a fraction of the time compared to older drugs (down to 12 weeks from 24 weeks). NICE used a cost effectiveness approach with pre-defined cost per QALY gained (ICER) threshold range that needed to be achieved in order to grant reimbursement under public funding. The outcomes of the assessment are summarized in Exhibit 14.

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<sup>17</sup> MIMS, UK Pricing Database

**Exhibit 14:** Cost Effectiveness analysis of Sovaldi in UK

Sofosbuvir in combination with peginterferon alfa & ribavirin				Sofosbuvir in combination with ribavirin		
Genotype	Treatment history	ICER (cost per QALY gained)	Recommendation	Treatment history	ICER (cost per QALY gained)	Recommendation
1	All	£17,500	Yes	All	£47,500	No
2	All		Not licensed for this population	Treatment-naive	£8600 (£46,300)	Only for people who are intolerant to or ineligible for interferon
				Treatment-experienced	£12,500	Yes
3	Treatment-naive	£6600 (£40,600)	Only for people with cirrhosis	Treatment-naive	£10,500 (£28,000)	Only for people with cirrhosis who are intolerant to or ineligible for interferon
	Treatment-experienced	£19,000	Yes	Treatment-experienced	£19,200 (£31,400)	Only for people with cirrhosis who are intolerant to or ineligible for interferon
4, 5, or 6	All	£20,000-£30,000 (£39,100)	Only for people with cirrhosis	All		No

**Case Study – Subsequent Entry (“Me Too”) Drug: Clinical Effectiveness Analysis of Cimzia in France**

In France, the HAS (Haute Autorité de Santé) conducted the technical assessment of Cimzia and determined no additional clinical benefit (ASMR V<sup>18</sup>) over the existing anti-TNFs (tumour necrosis factors) in the market. Therefore, the price was limited to a discount to other anti-TNF products as shown in Exhibit 15.

**Exhibit 15:** Price decrease for Cimzia in France after negotiation



<sup>18</sup> See appendix for detailed French approach and ASMR definitions.

### 3.4 Generic Pricing and Access Approaches

Generic medicines are a key instrument for payers to sustain their healthcare systems and control pharmaceutical expenditures. Generic medicines provide an opportunity to obtain similar treatments at lower costs for patients and payers, while freeing budgets to finance new innovative medicines. Pricing policies for generics are usually guided by competition or rules in regards to discounting to original/patented product and/or discounting to the first generic in the market. Approaches to increase access and promote generic medicines also include a wide range of tools such as INN prescribing.

Exhibit 16 illustrates generic pricing tools applied by developed and developing countries.

**Exhibit 16:** Pricing and access promotion approaches for generic medicines

Pricing approaches				
Pricing policies for generics are guided by rules and market forces				
<ul style="list-style-type: none"> <li>Rules are at times different for new entrant generics and branded originals post loss of exclusivity</li> </ul>				
	Generics	Branded Original	Policies for Generic Use	Tools for Generics Procurement
 FR	Enter at 60% discount	20% cut following first generic	Prescribing control, Financial rewards, Pharmacy substitution, co-payment differences	Competitive tenders by hospital groups
 UK	Free pricing provided price is below original	No pricing restrictions	Prescribing control, Financial rewards	Negotiation with suppliers, competitive tender
 DE	Reference pricing but free to reduce further	Reference pricing but free to reduce further	Prescribing control, Financial rewards, Pharmacy substitution, co-payment differences	Mandatory and voluntary discounts, contracts,
 BR	Enter at 35% discount	No pricing restrictions	INN Prescribing, Pharmacy substitution	Reverse auction tendering, negotiations by hospitals, mandatory discounts for public proc.

#### Case Study: Low Competition Generic Medicine Symbicort

For low competition generic medicines, price does not typically decrease significantly after the loss of exclusivity due to the lack of alternative competitive options. The low presence of the competitors in the market provides a favourable opportunity to the branded manufacturer to maintain the price of the product. This is typically the case where the switching cost for patients or barriers to entry are high (e.g., due to an associated device). In such cases, there are few generics manufacturers who can produce a comparable product; and even for these few, the barriers may prevent them from entering the market due to the lack of a sizeable commercial opportunity.

Exhibit 17 illustrates the example of Symbicort which was able to maintain its price following LoE, due to the supporting inhaler device which made it hard for patients to switch to a generic version and the very limited competition it faced after LoE.

**Exhibit 17:** Low Competition Generic Pricing - Symbicort

Country	Branded Price (six months before LoE* )	Branded Price (one year after LoE* )	Generic Price (one year after LoE*)	Number of Generic Products(one year after LoE )
 FR	US\$ 1.3	US\$ 1.2	US\$ 1.3	1
 UK	US\$ 1.2	US\$ 1.1	US\$ 0.9	1
 DE	US\$ ---	US\$ 1.6	US\$ 1.1	2
 MX	US\$ 0.9	US\$ 0.9	US\$ 0.4	1

\* Loss of Exclusivity/Introduction of first generic  
Price refers to price per day based on standard dosage

### Case Study: Lower Volume Generic Medicine Vancomycin

A similar effect is seen in low volume generic medicines; the branded manufacturers can keep their price on high despite having generic competitors in the market. Due to the low volume (particularly true for hospital medicines such as injectables), there is little or no incentive for a generic manufacturer to launch at a much lower price (see Exhibit 18). This may mitigate price reductions compared to large volume generics.

**Exhibit 18:** Lower Volume Generic Pricing – Vancomycin

Country	Branded Price (six months before LoE* )	Branded Price (one year after LoE* )	Generic Price (one year after LoE*)	Number of Generic Products(one year after LoE )
 FR	US\$ 0.54	US\$ 0.41	US\$ 0.20	14
 UK	US\$ 0.60	US\$ 0.59	US\$ 0.08	5
 DE	US\$ 1.10	US\$ 0.88	US\$ 0.48	34
 MX	US\$ 1.77	US\$ 2.01	US\$ 1.13	15

\* Loss of Exclusivity/Introduction of first generic  
Price refers to price per day based on standard dosage

**Case Study: High Volume Generic Medicine Escitalopram**

For high volume generic medicines, the branded products have to reduce the price of their products after loss of exclusivity due to market competition or pricing regulations set out in each country. Exhibit 19 illustrates such price changes.

**Exhibit 19:** High Volume Generic Pricing – Escitalopram

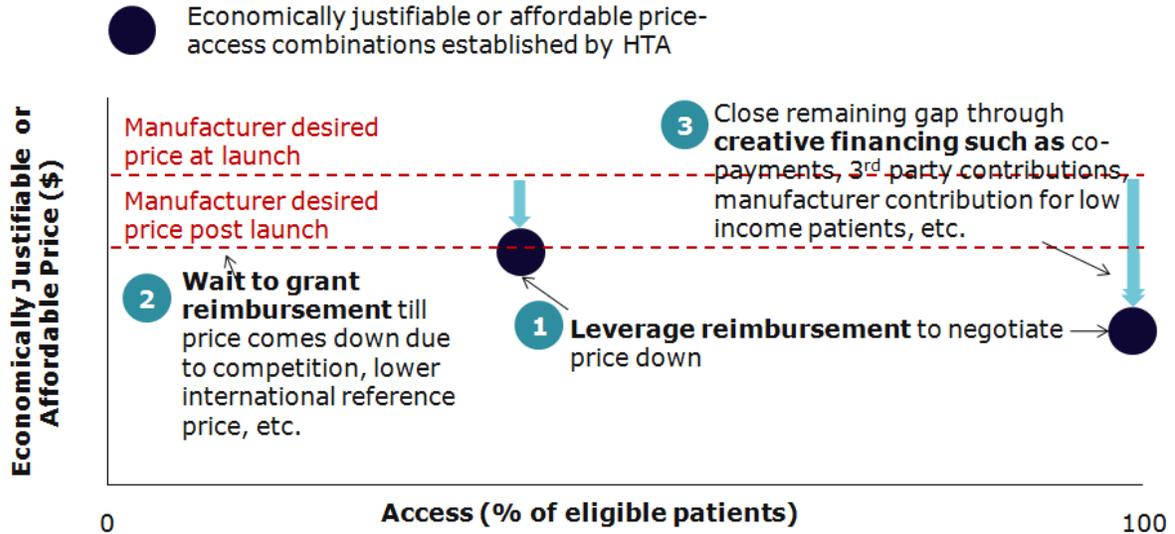
Country	Branded Price - Current	Generics Price - Current	Number of Generic Products
 FR	Discontinued	US\$ 53.1	4
 UK	US\$ 52.0	US\$ 40.7	6
 DE	Discontinued	US\$ 40.9	14
 MX	US\$ 102.9	US\$ 35.3	5

\* Loss of Exclusivity/Introduction of first generic  
Price refers to price per day based on standard dosage

### 3.5 How Effective PPA Systems Provide Tools to Improve Access

Once a PPA system has been used to establish a price and access combination, there are three powerful levers that can be used by a payer to obtain desired price and access: reimbursement decision, time to reimbursement and creative financing solutions.

**Exhibit 20:** Access levers and applications



The HTA analysis provides the economically justifiable and/or affordable price-access combinations. These prices may be lower than the manufacturer desired price at launch. However, a large payer brings large volumes. This may be sufficient for the manufacturer to agree a negotiation lower price-volume combination at a mutually acceptable level. This could be done at the list price level or through confidential rebates or tools such as price-volume agreements.

If however, no agreement is reached, the payer can decide to wait till a therapeutically competitive product enters the market and/or the manufacturer is willing to come down on price as they have launched in other countries and do not need to protect their launch prices from IRP effects. In either case, the payer and manufacturer can negotiate to a lower mutually acceptable price.

If the medicine is needed urgently, and there is a gap between the payer and manufacturer position, then other tools can be used to bridge this gap. These can include co-pays, additional financing from other 3<sup>rd</sup> parties such as charities, differential pricing for poorer patients and the provision of value added services by the manufacturer so that the payer can get more bang for the buck.

### Case Study – Negotiation for Innovative Drug Sovaldi in Brazil

Lever used: Reimbursement, Time to reimbursement

Traditionally, Brazil would have priced Sovaldi based on IRP and applied a set discount; but pricing in this way would yield a price that is too high for reimbursement. However, ANVISA was able to leverage the large eligible population, the public health need, and high revenue potential for the manufacturer, and the short time until a competitor would enter the market, to negotiate a lower price agreeable to Brazil and Gilead. At this price, it granted speedy approval was granted for Sovaldi on 30 March 2015 at a price of \$7,000 in a process that took 6 months. This is the price at which Sovaldi is available in the private market; and there is the possibility still for the public insurers at national, state and municipal levels to negotiate further discounts.

**Exhibit 21:** Decrease in price of Sovaldi in Brazil after negotiation

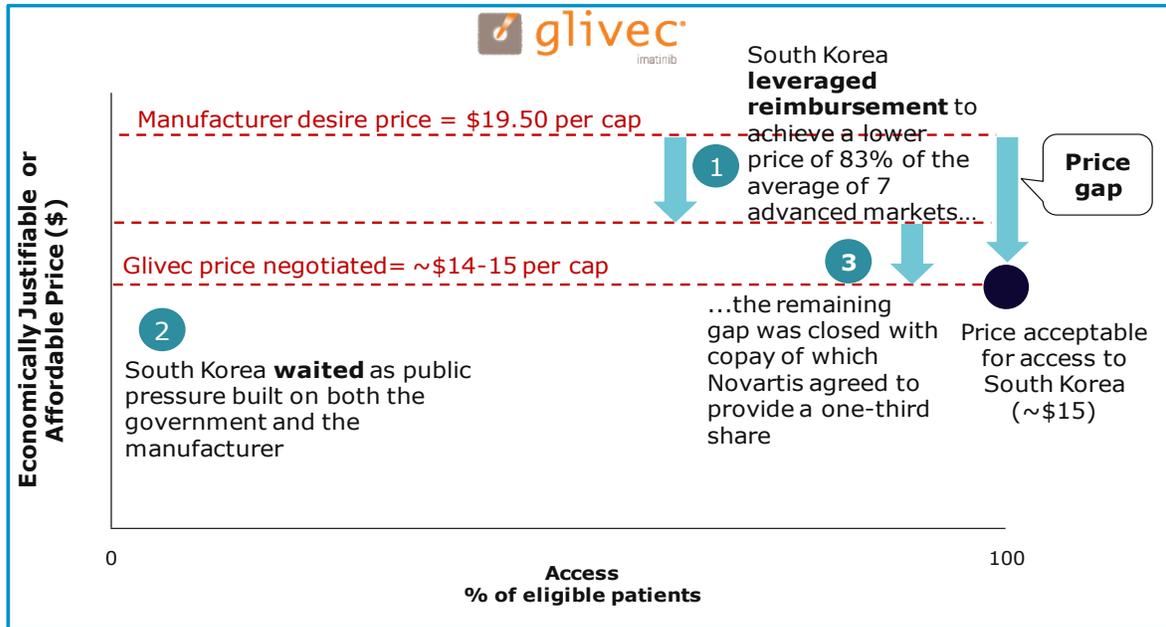


### Case Study – Access to Glivec in South Korea

Lever used: Reimbursement, Time to reimbursement, creating financing support

South Korea used all three levers to achieve a mutually acceptable price with Novartis for Glivec as Exhibit 22 shows.

**Exhibit 22:** Access to Glivec in South Korea



So far we have looked at how PPA systems work in other countries. Now we turn to the recommended PPA system for Thailand.

## 4 Recommendations for PPA Reform in Thailand

In this section we discuss the recommended PPA framework for Thailand for patented and generic medicines. The recommendations are based on:

- Current system in Thailand: We have tried to build on what exists today as this reflects the socio-political choices made by Thai stakeholders. In addition, the transition to a reformed system is easier if it builds on existing foundations.
- Benchmark analysis of other countries: We have selected ideas and aspects from other countries that work well for different types of medicines and are appropriate for Thailand based on its current system, its ability to adapt and the specific resource limitations faced.
- Input from Thai stakeholders: As mentioned in the Introduction section, the process of arriving at the recommendations involved three major workshops, where we obtained input from key Thai stakeholders – MoPH, NHSO, Thai FDA, CSMBS, other government institutions and academics. The second workshop explicitly focused on different PPA framework and pricing and access tool options, while the third workshop discussed the recommended PPA framework.

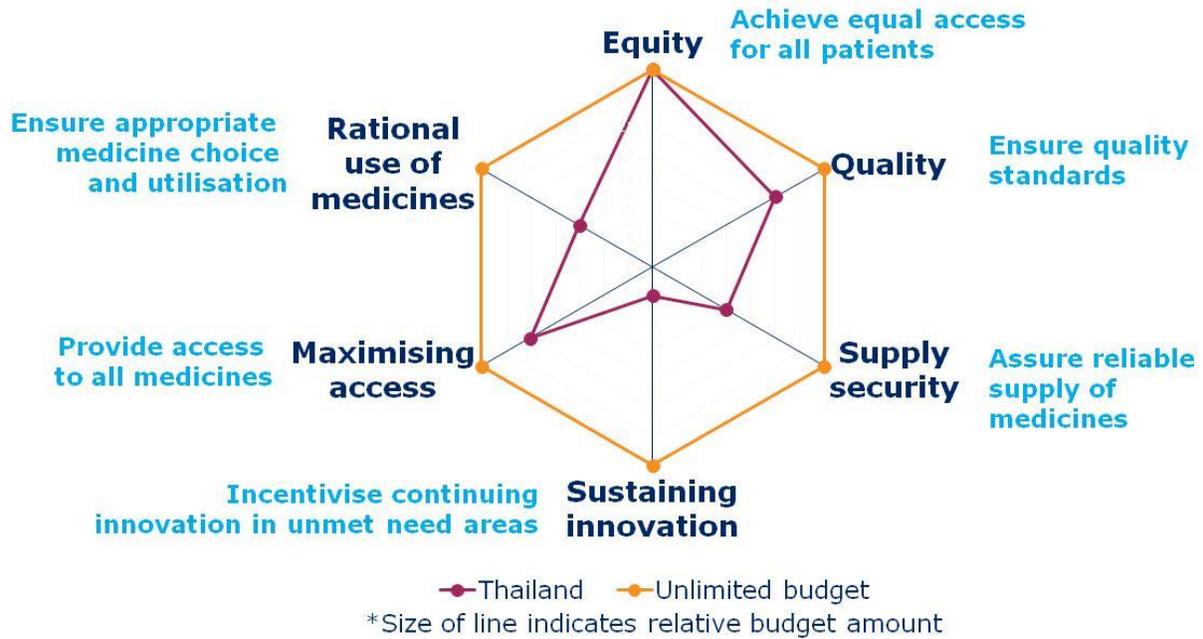
### 4.1 Objectives for the Thai PPA system

As discussed in the previous section, a PPA system must balance the trade-off between six different objectives. To understand the trade-offs that Thailand may want to make, we obtained input from the Thai stakeholders who attended the second workshop at the end of Phase 2. First, we validated the different objectives. We had started with five objectives and based on the input from the stakeholders, added an additional objective on the Rational use of medicines.

Each stakeholder was asked to provide his or her perspective on which of the six objectives were most important, and how they would prioritise resource allocation between the different objectives. After this exercise, there was a general discussion among the stakeholders on the prioritisation. Exhibit 23 shows the results of this deliberation. These are directional in nature and show the relative importance of the different objectives.

There was broad consensus that providing equitable access to medicines for the Thai population is the top priority, while maximizing access to needed medicines and ensuring quality were also highly important. These were followed by supply security and rational use of medicines. Finally, although stakeholders considered it relevant, stakeholders believed that sustaining innovation is of lower priority given the level of economic development of Thailand and the financial resources available in the health system.

**Exhibit 23:** Prioritisation of objectives for the Thai PPA system<sup>19</sup>



## 4.2 Guiding principles for the reform of the Thai PPA system

A successful and sustainable reform of the PPA system must be guided by 4 principles. These principles were also validated at the second workshop with Thai stakeholders.

1. **Transparency:** it is important to ensure that all stakeholders know the rules and processes of the PPA system. Whilst this applies to the processes in place, the end net prices achieved do not need to be confidential, as explained later in the report.
2. **Fairness:** a structured system will result in consistency across evaluations to ensure that similar medicines are assessed, valued and priced in a similar way
3. **Predictability:** the profile of a product should enable manufacturers and other stakeholders to know what the likely outcome is following the PPA process
4. **Ease of implementation:** buy-in from key stakeholders is imperative to ensure adopt of the PPA framework and the ease of implementation can be aided by ensuring that it is practical and builds on existing structures and capabilities.

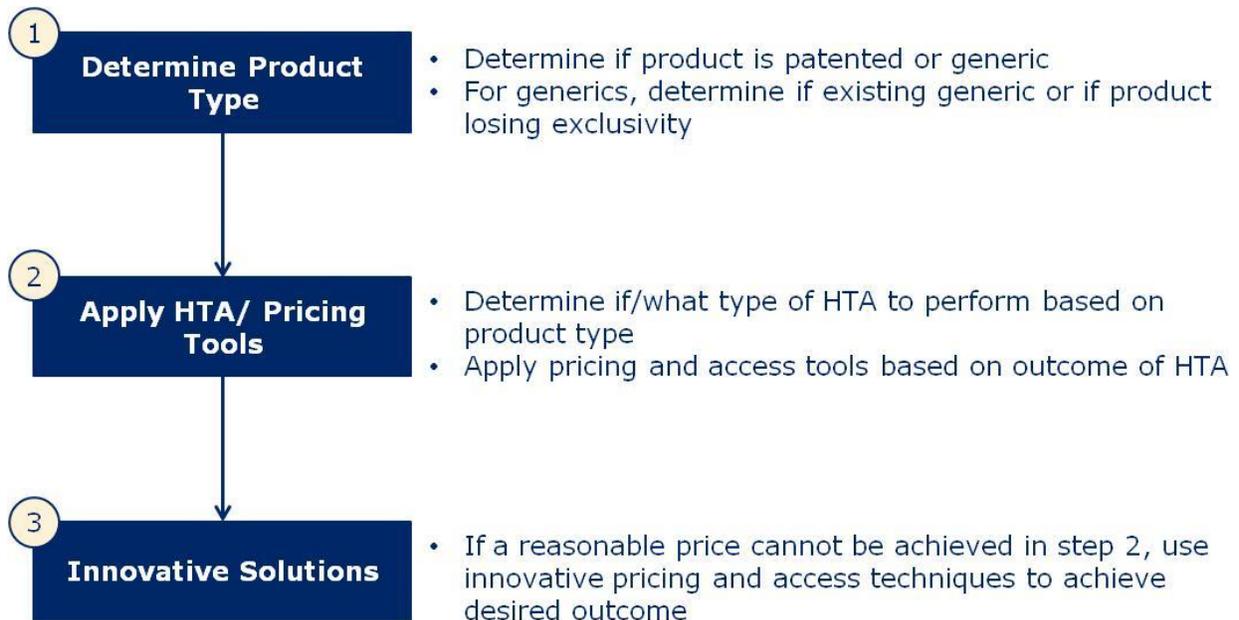
<sup>19</sup> This prioritisation is based on the stakeholders who attended the second workshop who mainly represent government and academic stakeholders. The perspectives of other stakeholders such as industry or patient associations are not included in this assessment.

### 4.3 Recommended PPA Framework

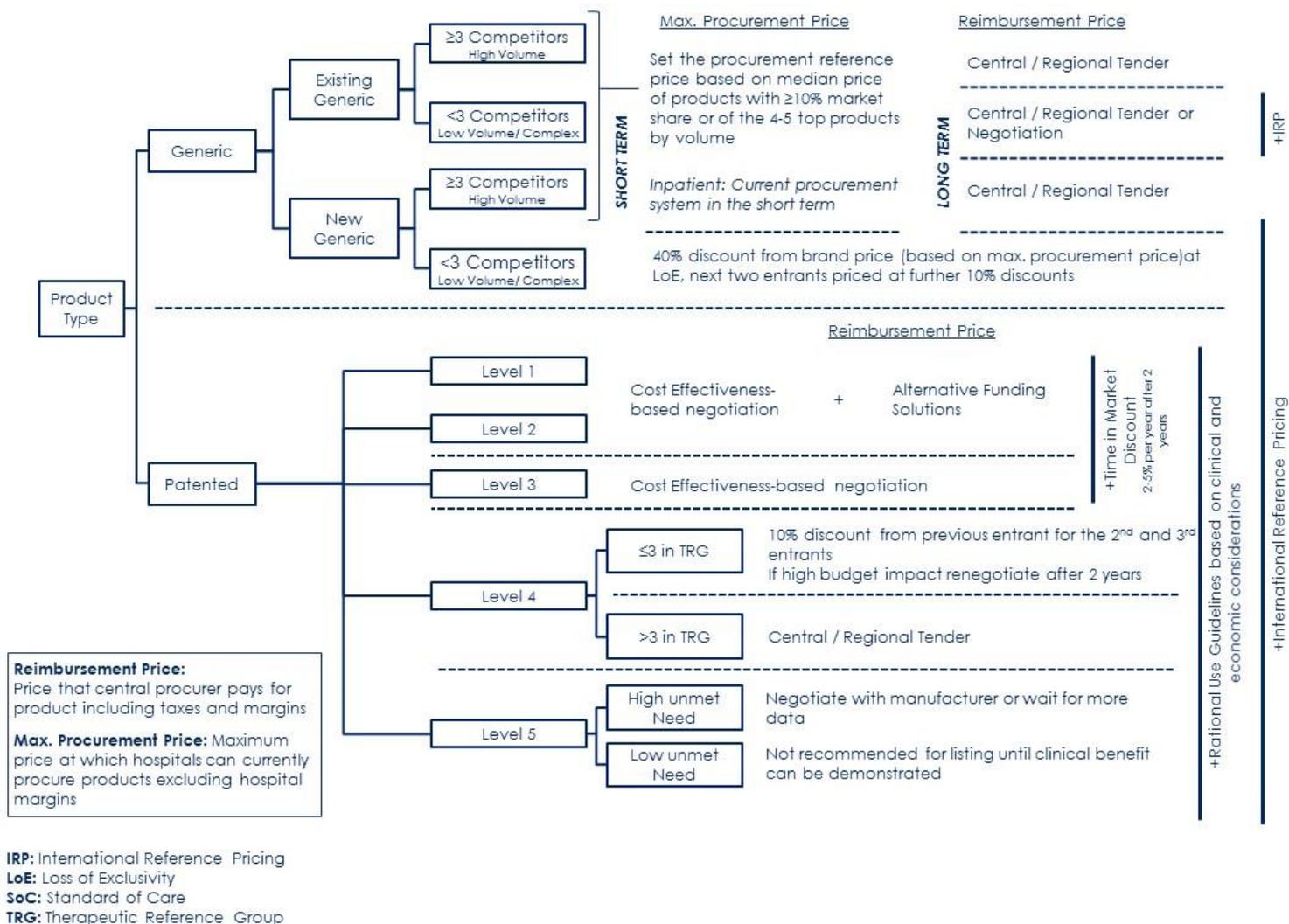
The recommended PPA framework provides a three-step approach to set medicine price and access levels as illustrated in Exhibit 24. The first step classifies medicines into patented and generic categories. The second step determines the type of HTA and pricing tools that would apply to each category of medicine to set price and access levels. If price and access cannot be agreed in Step 2, the next step provides for innovative approaches to setting price and access in exceptional cases where the medicine is of sufficient value to be reimbursed for Thai patients.

The recommended framework is based on the prioritised objectives, namely ensuring equitable access as well as maximised access to drugs. Following these guiding principles, we recommend moving from a procurement price system to one where there is a centrally determined reimbursement price and net discounts or innovative funding solutions are applied at a central level, for both generic and patented products. Moving towards central procurement ensures equity amongst hospital stakeholders, allowing all hospitals and care providers to purchase drugs at the same price.

**Exhibit 24:** Recommended PPA Approach for Thailand



**Exhibit 25:** Recommended PPA Approach per Product Type (applies to both inpatient and outpatient medicines)



**Exhibit 25** shows the decision flow for which pricing methodology is recommended, based on product type. The methodology for generic pricing is further split into short- and long-term in order to accommodate the current system, whilst also laying out the recommendation for future reform, which includes moving from the procurement price-setting system towards a reimbursement price.

### 4.3.1 Step 1: Determine Product Type

This first step of the PPA framework is simple yet crucial. Patented and generic products need different pricing and patient access tools. Generics have multiple alternative alternatives on the market with established prices. Patented medicines are more likely to be unique with no clear price comparators on the market. Further, it is easier to use competition to set prices for generics than for patented medicines.

Within the generic category, we need to distinguish between existing generics and a situation when a currently patented product will lose exclusivity and therefore will have generic competitors. These two sets of generic categories need different PPA approaches.

Regarding inpatient and outpatient differences, the recommended framework applies to both. In the short-term, the current system should be applied for generic medicines, until regional or central tenders can be applied.

### 4.3.2 Step 2: Applying HTA and Pricing Tools – Generic Medicines

Generic pricing has to balance four competing objectives:

- Achieving the lowest price
- Ensuring quality
- Ensuring adequate supply and security of that supply
- Ensuring appropriate utilization for optimal patient outcomes

The current system is able to address the first objective well, however in doing so the quality and supply security of medicines can sometimes be compromised. The suggested reforms will ensure that the remaining objectives are also addressed.

For generic medicines there are two situations which require different approaches:

- There are existing generics on the market
- The loss of exclusivity of the original patented brand followed by new generic entry

The following reforms are recommended in the short term to mid-term. These build on the current approaches used by Thailand to set prices of generic medicines. Longer term reforms to address all generic pricing objectives will need more radical change.

#### 1. Existing generics on the market

For high volume generics:

- **Procurement Reference Pricing<sup>20</sup>:** Reference prices can be set using median pricing based on basket of products which have at least 10% of market share, including outliers, or containing top 4-6 products by volume share. We recommend limiting the products in the median price reference basket due to the following reasons:
  - Only manufacturers with sufficient scale to ensure minimum quality standards and supply security are included
  - It is logistically easier to collect and model price information

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<sup>20</sup> The current median price.

The procurement reference price is the maximum hospital procurement price for reimbursed drugs.

- **Procurement Reference Price Review:** Reference prices should be reviewed every 2 years and they can be increased or decreased to accommodate market changes such as prescription patterns, inflation and market prices. Reviewing price at set intervals preserves price for a period of time allowing manufacturers to have financial predictability. Allowing both price increases and decreases provides flexibility to get competitive prices without leading to a price 'race to the bottom' that can compromise quality and supply security.

For low volume generics:

- **Procurement Reference Pricing:** As above
- **International Reference Pricing (IRP)<sup>21</sup>:** Use IRP to validate reference price determined from median. Low volume generics have typically fewer options available in the market and therefore are not subject to the same competitive price pressures as high volume generics. As such, IRP can be used to ensure prices are in line with international prices.

## 2. Patented drugs LoE

When a branded product loses patent, the price of first generic as well as the originator brand are recommended to be set at 40% discount to the original brand price prior to loss of exclusivity mirroring what is done in several European countries such as France, Italy and Spain<sup>22</sup>. Subsequent generics should be priced at 10% discount to the first generic; once there are >3 generics on the market, median pricing can be used to set a reference price. Thailand may choose to favour locally manufactured generics by adjusting the level of required discount if desired, subject to Thai international trade agreements. However, this is more of an industrial policy rather than a PPA policy.

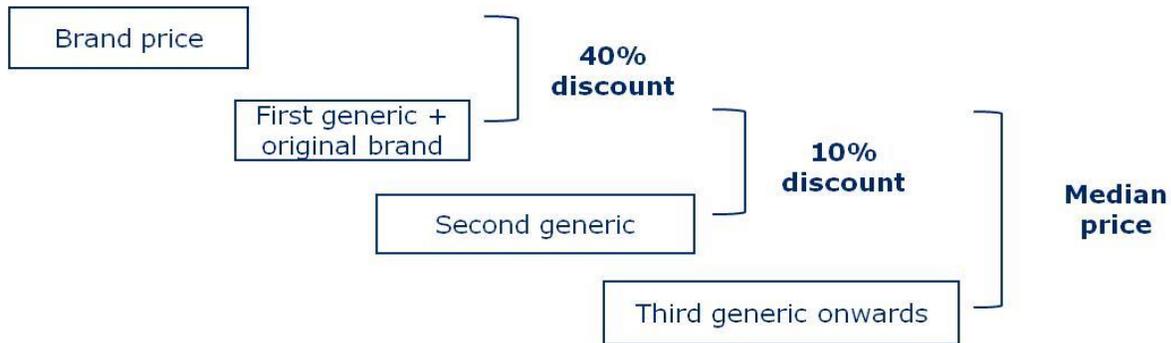
In order to employ this pricing method it is important to be clear regarding which products are patented and which are not. For example, branded products that have lost exclusivity but remain branded would be considered to be generic, not patented. To implement this properly, the price setting body needs to work with the relevant authorities in Thailand that determine the patented status of a medicine in Thailand.

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<sup>21</sup> The recommended IRP system is described in detail later in this section.

<sup>22</sup> In France, after LoE, the original brand price is cut 20%, while the first generic has to provide 60% discount to the original brand price. After 18 months, the original brand faces a further discount of 12.5%, while the generics has to provide an additional 7% discount. In Italy, there are no price cuts on the original brand, but price discounts varying from 30% to 75% are mandatory for generics. In Spain, original brands face 15% discount if no generic brands available, but no discount if generic brands available. The generics have to be at 40% discount of the original. With multiple generics, prices can go even lower due to competition.

**Exhibit 26:** Mandatory Price Reductions for Patented Drugs with LoE



### Longer term reform of generic pricing

In the long term further reform to set price and access for generics within Thailand can be considered. This can be done through two mechanisms:

- **Further system reform**

- Implement median pricing for generics along with minimum quality assurance

*Rationale:* Current median pricing rules of continually re-referencing prices can result in a race to the bottom and compromises quality. Applying a requirement for quality assurance may result in slightly higher prices, but overall outcomes will improve due to quality of medicines

- Ensure quality of medicine with added monetary incentive for hospitals with good patient outcomes

*Rationale:* Rewarding hospitals based on patient outcomes can incentivise appropriate use of medicines and avoid hospital underuse of medicines for financial reasons.

- **Centralized procurement (tenders)**

High volume generics:

- Implement national or regional tenders for generics facilitated by NHSO; hospital groups or Ministry of Public Health may also conduct large-scale tenders
- Tenders should be based on lowest price with guarantees for quality and supply security
- Tenders should be for 2 to 3 products for each molecule (INN) to allow broad access (large volume) with supply security
- Tenders should be for a set period of time (1-2 years) to allow manufacturers financial predictability and minimize administrative costs

Small volume generics:

- Centralised procurement by direct negotiations with manufacturers can be conducted. Larger national or regional volumes may lead to lower price than the volumes provided at a hospital by hospital price setting
- Guarantee price for set period of time with adjustments for major market changes such as high inflation

*Rationale:* Centralized tenders can provide for uniform and lower medicine prices nationally, leading to a more equitable system.

These long terms reforms will replace the median pricing or procurement reference pricing system with a pricing system that only focuses on reimbursement price<sup>23</sup>. However, such long term reform will need to be accompanied by reforms to how hospitals are financed. Today, hospitals often make money from medicines as they can procure below the median price. They use this to finance other health services. If Thailand moves to a central procurement system, hospitals will need to be compensated financially so health services do not suffer.

### **4.3.3 Step 2: Applying HTA/ Pricing Tools – Patented Medicines**

#### **Applying HTA**

It is recommended that pricing and access for patented drugs are determined based on the value of the drug to the Thai population. Three metrics can be used to determine such value: level of clinical benefit over the existing standard of care (SoC), the level of unmet need of the patient, and the degree to which the treatment is important to the public health of Thailand. Using these three metrics, patented medicines can be classified into one of five levels as outlined in Exhibit 27, which can then be used to inform pricing and patient access decisions. In this way, HTA need only be applied to drugs with a high budget impact, or drugs which are Level 1-3, which reduces the burden on the HTA bodies.

#### **1. Incremental benefit over standard of care**

This metric is determined based on the extent of additional clinical benefit over standard of care. Influencing elements include the extent of benefit such as efficacy and safety and the strength of the evidence based on the trial design.

The grades of incremental benefit over SoC are defined as follows:

- **Very Substantial**
  - Treatment is curative or preventive
  - Evidence from large head-to-head trials with long duration
- **Substantial**
  - Treatment has high additional impact on patient health
  - Evidence from head-to-head trials with moderate duration

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<sup>23</sup> Price paid by insurance schemes including ex-man price, any discounts (confidential or otherwise), and any applicable margins or taxes.

- **Limited or None**
  - Treatment has no or small additional clinical benefit over SoC
  - Evidence from placebo trials
- **Unquantifiable**
  - Level of clinical benefit cannot be determined by available evidence

**Exhibit 27:** Level of Clinical Benefit Based on Three Factors

	① Incremental Benefit over SoC	② Level of unmet need	③ Public health importance	Example
	<b>Level 1</b> Very Substantial	High - Very High	High - Very High	Prevenar
	<b>Level 2</b> Substantial - Very Substantial	High - Very High	High	Sovaldi
	<b>Level 3</b> Substantial	Moderate - High	Moderate - High	Zytiga
	<b>Level 4</b> Slight or Same	N/A	N/A	Tradjenta
	<b>Level 5</b> Unquantifiable	High or Low	High or Low	Bosulif/Glybera

## 2. Level of unmet need

Unmet need is a function of the impact of disease on the patient and caregiver and the availability or lack thereof of treatment alternatives. Influencing elements include mortality, morbidity, Quality of Life (QoL), patient economic and social impact, caregiver burden and the number and quality of available alternative treatments.

The grades of level of unmet need are defined as follows:

- **Very High**
  - High mortality and high impact on most influencing elements
  - No available alternatives
- **High**
  - High impact on most influencing elements

- Imperfect alternative; alternative exists but doesn't fully address patient need
- **Moderate**
  - High impact on some or medium impact on most elements
  - Some alternatives that partially address patient needs
- **None**
  - Limited or no unmet need given current treatments

### 3. Public health importance

This is determined by the extent of benefit to the broader population and health system in Thailand. Influencing elements include the number of people directly and indirectly affected by the condition, total health system resources consumed, economic burden to society and the preventative effect.

- **Very High**
  - Impacts high population proportion
  - High health system and economic impact
- **High**
  - Impacts a sizeable population proportion
  - Moderate health system and economic impact
- **Moderate**
  - Impacts smaller proportion of the population
  - Low health system and economic impact
- **None**
  - Very small population affected

The specific details on how the above measures would apply to different disease areas will need to be worked out by clinical and HTA experts in Thailand. In order to carry out the clinical benefit assessment and to determine the levels under which the products fall, Thailand can build on its existing frameworks and institutional capabilities to ensure full integration into the healthcare system:

- **ISaFe** – leverage current iSaFe methodology to evaluate clinical efficacy, safety, quality of life, and public health importance
- **HTA Bodies**– utilize HITAP cost-effectiveness analysis to inform value for money
- **NLEM** – continue to evaluate new medicines and make listing decisions based on the determined product level
- **Ministry of Public Health** – provide information and data across hospitals to inform setting of reference price
- **NHSO** – continue to set reference price and procure selected therapies

In addition, HTA assessment processes can be leveraged from other markets to inform the clinical benefit rating process and determine which level of benefit is appropriate for the product.

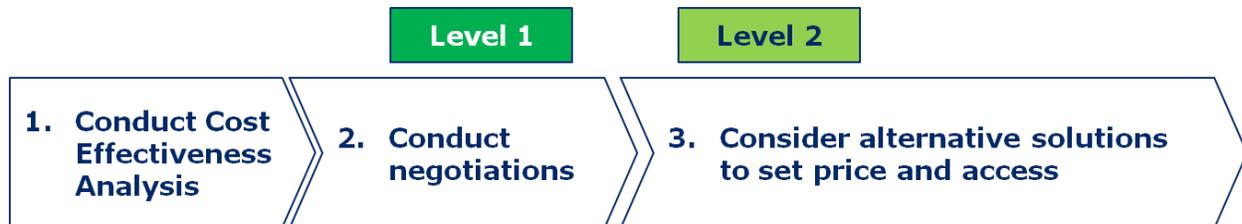
The clinical and cost effectiveness assessments should be separate and subsequent from one another as the clinical outcome should inform the cost analysis rather than the other way around. This system is seen in both France and Italy.<sup>24</sup> They can be carried out within the same agency, however should involve separate processes which also increases the transparency of the review procedure.

Clinical assessment reference countries should represent those with high standards and potentially include:

- Clinical effectiveness: - 'Commission de Transparence' in France, 'Gemeinsamer Bundesausschuss' in Germany
- Cost effectiveness – 'NICE' or 'Scottish Medicines Consortium' in UK, 'Health Insurance and Review Assessment Service' in South Korea
- Other markets' HTAs can be referenced on an ad hoc basis as needed – Canada, Sweden, Taiwan, Australia, Japan

## Pricing and Access Tools

### Level 1 and Level 2 Products:



For products with a benefit of level 1 or 2, or level 5 where relevant, follow the below process to determine price and patient access (full details of pricing tools can be found in the appendix):

#### 1. Conduct Cost Effectiveness Analysis

- Using existing methodology, HTA bodies can conduct a cost effectiveness analysis
- Use the pre-determined cost effectiveness threshold for listing decisions on the NLEM
- *List on NLEM*: products which meet the cost effectiveness threshold
- If price higher than threshold, go to the next step in the process below.

<sup>24</sup> In France the Commission de Transparence determine the clinical benefit and Le comité économique des produits de santé negotiate the price based on this assessment; in Italy AIFA determines whether the product is deemed 'innovative' and further negotiates based on this assessment.

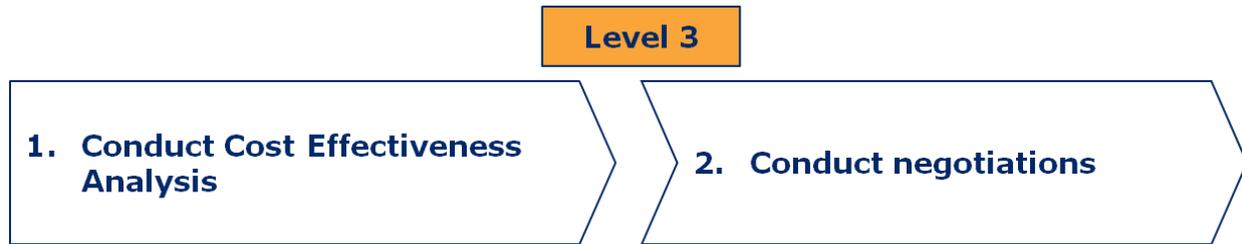
## **2. Conduct negotiations**

- Negotiate with the manufacturer to lower the net price to below the cost effectiveness threshold
- Strategies such as confidential price-volume agreements, risk-sharing, and discounts/ rebates can be used to facilitate this, with the caveat that they require strong legal and contractual basis for implementation and execution
- *List on NLEM*: products where an agreement is reached that lower the net price to the cost effectiveness threshold
- If agreement not reached, then go to the next step in the process below.

## **3. Consider alternative solutions to set price and access**

- Alternative solutions such as restricting access to sub-populations where price is cost-effective can be considered
- 'Time in market' discounts, as in Japan, could be considered in the future if no 'me-too' products enter the market within 5 years. This would mandate a price drop of 10-20%
- Furthermore, if a product was the launch in a new indication, the price should be re-negotiated with the manufacturer based on the fact that the patient population will expand
- Other solutions such as innovative funding through a high-value, high-cost drugs fund, additional funding sources, co-payments and other ways for MNF to increase value of the treatment (e.g., through value added services) can be used to negotiate price and access
- Finally, the cost effectiveness threshold can be increased as another course of action if other solutions are not possible to provide access to high cost products. However, this should be a last resort and done only on an exceptional basis (e.g., for end of life care or for orphan drugs) to avoid the new threshold becoming the norm.

**Level 3 Products:**



The following process can be used to evaluate level 3 medicines:

**1. Conduct Cost Effectiveness Analysis**

- Using existing methodology, HTA bodies can conduct a cost effectiveness analysis
- Use the pre-determined cost effectiveness threshold for listing decisions on the NLEM
- *List on NLEM:* products which meet the cost effectiveness threshold
- If price higher than threshold, go to the next step in the process below.

**2. Conduct negotiations**

- Negotiate with the manufacturer to lower the net price to below the cost effectiveness threshold
- Strategies such as confidential price-volume agreements, risk-sharing, and discounts/ rebates can be used to facilitate this, with the caveat that they require strong legal and contractual basis for implementation and execution
- *List on NLEM:* products where an agreement is reached that lower the net price to the cost effectiveness threshold

Products classified as level 3 are deemed less important to Thailand than levels 1 and 2, and therefore reimbursement for these products through innovative agreements is not recommended. If negotiations fail, the health schemes in Thailand can wait till the price comes down to list the product.

As for Level 1 & 2 products, Level 3 products could also apply 'time in market' discounts to revise the drug price as well as re-negotiating the price upon drug entry into a new indication.

**Level 4 Products:**



All products at this level can be listed on the NLEM but at price based on therapeutically equivalent medicines

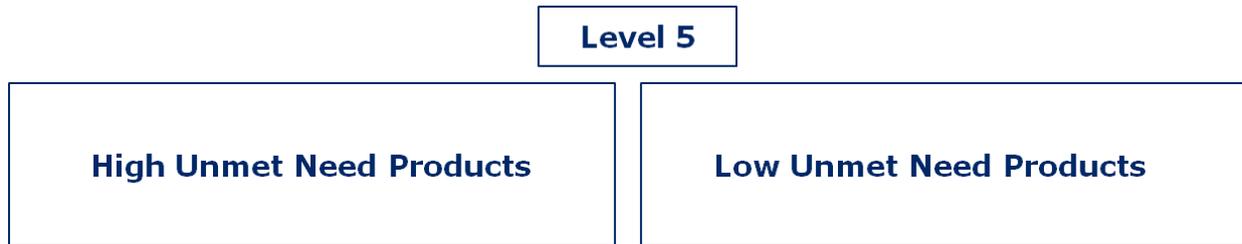
**For therapeutic groups with three or fewer medicines:**

- A level 4 product in a Therapeutic Reference Group would likely be a 'me-too' product with similar benefit to the SoC. So the second and third products in the group should be priced at a fixed discount of 10% to the previous entrant.
- In product groups which have high budget impact and there are 3 or fewer products, after 2 years, prices can be renegotiated with the manufacturer

**For therapeutic groups with more than three medicines:**

- Once there are more than 3 products in a therapeutic reference group, central or regional tenders should be conducted for preferred product listing

**Level 5 Products:**



For medicines with an unquantifiable additional benefit and high unmet need:

- These products can be listed if there is a high unmet need
- NHSO can negotiate with the manufacturer OR;
- NHSO can wait to see if more data will become available before making a reimbursement decision

For medicines with an unquantifiable additional benefit and low unmet need:

- Products for which there is a low unmet are not recommended to be listed on the NLEM until the clinical benefit can be re-evaluated and determined

For all of the levels described, hospitals would purchase the drugs at a centrally reimbursed level, meaning that there would equitable access to medicines across hospital types. However, this system necessitates guidelines for product use to ensure appropriate use of medicines.

Furthermore, where discounts to the list price are given by manufacturers to ensure inclusion on the NLEM, it benefits both parties to keep the net price confidential. Manufacturers are able to offer both access and better prices in the knowledge that steep discounts, in whatever form, are confidential and cannot be formally referenced by other countries, meaning that whilst the process is transparent and predictable, the final price paid for products should be kept confidential. This may or may not require a legal change if the price setter is also the procurer of drugs.

#### **4.3.4 Step 3: Innovative Solutions for High Importance Drugs**

In cases where an acceptable price for high-value high-cost drugs cannot be achieved, innovative methods may be used to improve access especially for patients who need these drugs. One of the prevalent methods is to create a separate fund for drugs addressing a particular high morbidity and/or mortality disease.

Drugs categorised under the benefit rating in Thailand as level 1 or level 2 which have high clinical value, but are too expensive to meet the cost-effectiveness or cost per QALY threshold in Thailand can be reimbursed by creating a separate funding mechanism such as a high-

value, high-cost drugs fund. Eligible medicines can be priced using selected pricing tools and access can be strictly managed for patients meeting set criteria and prior authorizations.

Several countries with varying levels of wealth also implement similar programs which Thailand can look to for reference. Some such examples include:

- **Cancer Drug Fund, UK<sup>25</sup>:** The Cancer Drugs Fund (CDF) is money the Government has set aside to pay for cancer drugs that haven't been approved by the National Institute for Health and Care Excellence (NICE) and aren't available within the NHS in England. It is currently undergoing reform due to over-spending, illustrating the potential pitfalls of such programmes. Whilst at the time of writing the new structure has not been fully disclosed, it seems that the CDF is moving towards a system which will give manufacturers a set period of time to generate better evidence for a product, if their price is not covered by the current cost per QALY threshold, however inclusion in the reformed CDF is likely to be stricter, time restricted and mandate greater confidential discounts than previously seen.
- **Expensive Disease Program, Russia:** In the year 2008, DLO earmarked money for the seven rare expensive diseases – haemophilia, cystic fibrosis, hypophysial nanism, Gaucher's disease, myeloleukemia and other hemoblastosis, disseminated sclerosis, post transplantation treatments. This program covers 17 most expensive drugs in the market
- **APAC Tariff, Brazil:** The government of Brazil reimbursed for high cost medicines for outpatient treatment including cancer drugs though APAC tariffs
- **T2A Exclusion List, France:** If a drug is deemed clinically effective (ASMR III or higher) but is too expensive to be funded through the usual DRG routes for inpatients it is placed on the T2A Exclusion List, meaning that there is central funding and the full cost of the drug is reimbursed.
- **NUB & ZE Codes, Germany:** If a drug is not covered to inpatients via the usual DRG system, hospitals can apply to sick funds each year for additional funding via NUB (at launch) and ZE (once established) codes. DRGs are further revised each year to ensure they cover the average costs associated with treating a patient.

Further, in addition to, or as an alternative to such additional innovative funding programs other innovative methods can also be explored in Thailand. For example:

- **Individual patient funding:** funding requests for individual patients to receive a specific treatment can be made, as seen in the UK for products not covered by other innovative funding mechanisms, or in another indication. The problem with this system is that it may not be the fairest way of distributing treatment, as deciding who deserves innovative drugs is a subjective decision
- **Patient co-pay:** patients contribute towards a proportion of drug treatment costs, however there is always a concern that this may exclude a section of the population from treatment. To address equity concerns, the co-pay can be means-tested based on income, with poor patients or older retired patients with low incomes not paying

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<sup>25</sup> NHS England, Cancer Drugs Fund Consultation 2016

co-pays. In addition, co-pays can be capped so that chronic patients do not face an undue financial burden.<sup>26</sup>

- **NGO funding:** non-governmental organisations or charities can supplement funding for some patients
- **Innovative pricing agreements with manufacturers:** Arguably the fairest and most equitable method, innovative pricing agreements which include stipulations such as value added services, which provide complementary broader care management services to achieve more value for money, or managed entry based on future evidence generation, or risk-sharing or patient number caps can help ease the cost and risk of access to innovative drugs.
  - These pricing methods are particularly pertinent for oncology therapies which enter the market after Phase I/II trials, with limited data and high uncertainty
  - Their clinical effectiveness cost effectiveness assessments will also have to account for their unique position as they would not be found to be acceptable using usual thresholds. They should be evaluated in a separate framework or at least with different expectations

#### 4.3.5 International Reference Pricing

Complementary to the above recommended approach, IRP can be implemented as a tool to validate the prices of patented medicines, irrespective of level of clinical benefit, and small volume generics in Thailand. High volume generic prices are generally well regulated through competition and median pricing, and therefore, do not require IRP. Additionally, limiting IRP to patented medicines and small volume generics limits the administrative burden to run the system.

Whilst the tools described above for each HTA bracket should ensure appropriate pricing levels, IRP can be an *additional* safeguard to achieve a fair price and can be applied to new drugs and drugs already on the market alike. However, the IRP specifics should be adapted to the country it functions in; in Thailand it must include a mix of developed and developing countries as references in order to ensure that the price is not too high, such that it remains unaffordable, or too low, such that quality is compromised. A set pricing formula, based on a formal basket of referenced countries should determine the ceiling reimbursement price in Thailand. IRP can be implemented in the following steps.

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<sup>26</sup> Such means-testing and caps exist in other countries. For example, in the UK, poorer segments as well as retired people are exempted from co-pays, as are those that have chronic diseases.

**a. Select reference basket**

Choose basket of countries to reference based on:

- A faster time to launch in comparison to Thailand,
- The presence of rigorous HTA in the country to evaluate new drugs
- The existence of significant public markets
- Different income levels including countries similar to Thailand

Based on the above, and an analysis of a broader group of countries, we recommend a basket of 13 countries as shown in Exhibit 28. There is no standard practice regarding the number of countries in IRP baskets. With too few countries one runs the risk of only including 'high-price' countries which are more likely to have products launched earlier. On the other hand, with too many countries, tracking prices becomes a harder task and potentially redundant especially if the basket is of reasonable size and includes a representative selection of countries based on the above criteria. Therefore, we recommend a basket of 13 countries. We believe the countries recommended below provide a good mix and tread the line between too few and too many well.

**Exhibit 28:** Criteria for Reference Basket selection and recommended countries

Country	Rigorous HTA Assessment	Early Launch	Significant Public Markets	Similar Income Level
Australia	++	+	++	-
Brazil	+	+	+	++
Canada	++	+	++	-
France	++	++	++	-
Germany	++	++	++	-
Italy	+	+	++	-
Japan	+	+	+	-
Mexico	+	-	+	++
Spain	+	+	++	-
S. Korea	++	+	++	-
Taiwan	+	-	+	-
UK	++	++	++	-
US	++	++	+	-

\*Value for Taiwan not available

**Key:**

	-	+	++
<b>Rigorous HTA Assessment</b>	No HTA	Limited use of HTA	Sophisticated HTA
<b>Early Launch</b>	Launch usually >3yrs after 1 <sup>st</sup> launch	Launch usually 1-3yrs after 1 <sup>st</sup> launch	Launch usually within 1yr of 1 <sup>st</sup> launch
<b>Significant Public Markets</b>	<50% population with reimbursement	50-70% population with reimbursement	70-100% population with reimbursement
<b>Similar Income Level to Thailand</b>	GNI (PPP) >30,000	18,000< GNI (PPP) ≤30,000	10,000< GNI (PPP) ≤18,000

**b. Select price to reference**

- i. Ex-manufacturer list price should be referenced as unlike other price points, this is the one that is comparable across countries (see Exhibit 29) as neither discounts nor additional charges are included in it. This is the price to be used in the formal IRP formula below.
- ii. The price taken per drug should take into account how it is used. In most cases the price per defined daily dose (DDD) is the best method to compare the drug prices across the countries. However, in some cases where treatment occurs over a set time period, the cost for a course of treatment is perhaps a better comparative tool. Furthermore, prices may need to be further adjusted based on local assumptions; for example the average daily dosing in USA, if based on average weight, may not be the same as that in Thailand for certain oncology medicines.

**Exhibit 29:** Top Level View of Price Build-up



**c. Set price ceiling depending on product type**

**i. Marketed Patented Medicines and Low Volume Generics**

For currently marketed patented medicines and low volume generics, we recommend taking the lowest ex-manufacturer list price from the reference countries to set the ceiling reimbursement price. In the case of generics, if there is more than one manufacturer supplying the generic, then use the price of the highest selling brand by volume to determine the ceiling reimbursement price.

**ii. New Patented Medicines (All Levels)**

Depending on launch timing we suggest two different approaches:

- i. If the product is launched after Brazil, Mexico, South Korea and Taiwan take the lowest price of all of the referenced markets; this is because prices in

those countries listed are generally lower and closer to the expectation in Thailand.

- ii. If the product is launched in Thailand before any of Brazil, Mexico, South Korea or Taiwan, take the lowest price in the set of 9 countries below and apply a GNI (PPP) discount. The method for this is outlined below<sup>27</sup>.

The logic of using a discount based on GNI (PPP) is to achieve a fair price based on overall country affordability relative to other countries referenced. This same method is employed for IRP in Brazil, where it is referred to as CAP. This is the **minimum** discount rate applied to the lowest price from the list of reference countries that Brazil uses.

Therefore, the lowest ex-manufacturer list price minus discount provides the ceiling price for the product. Thailand can apply non-IRP tools to negotiate further discounts below this ceiling price, which will define the net price of the product. These further discounts can be confidential and done at the net level. For example, France also uses IRP, but then negotiates further net discounts based on price volume agreements. Similarly, Italy applies further confidential discounts at national and regional level. The method is outlined below.

- a. Take the lowest ex-manufacturer list price from the reference countries, excluding Brazil, Mexico, South Korea and Taiwan<sup>28</sup>
- b. Apply discount based on weighted average of GNI PPP per capita, weighted by the GNI of the selected countries<sup>29</sup>:

Country	GNI (PPP) per capita	GNI (PPP)
	US\$, 2014	US\$, 2014
Australia	42,880	1,007,360,995,516
Canada	43,400	1,542,426,582,642
France	39,720	2,629,540,954,789
Germany	46,840	3,789,008,295,598
Italy	34,710	2,128,949,072,773
Japan	37,920	4,821,127,879,640
Spain*	32,860	1,532,120,506,305
UK	38,370	2,475,105,345,805
US	55,860	17,812,700,000,000
<i>Thailand</i>	<i>13,840</i>	<i>937,629,871,573</i>

<sup>27</sup> This is based on the system used in Brazil today; see Camara de Regulacao do mercado de medicamentos, Secretari-Executiva, Resolução nº 3, de 2 de março de 2011

<sup>28</sup> We exclude these countries as they are closer in income level to Thailand and have some of the lowest prices. Given this, a further discount may not be needed or justified based on income levels. Further, manufacturers may not agree to visible discounts below prices in these markets due to fear of Thai price being referenced by other countries. Therefore, further discounts are best negotiated at confidential levels based on the overall PPA approaches described in this section.

<sup>29</sup> Source: The World Bank; \*Spain GNI is for 2013

$$Discount = \sum_{i=1}^9 \frac{\left[1 - \left(\frac{IR_{Thailand}}{IR_i}\right)\right] \times 100 \times GDP(PPP)_i}{\sum_{j=1}^9 GDP(PPP)_j}$$

Where:

GDP (PPP) = Gross Domestic Product at Purchasing Power Parity in US\$

IR<sub>i</sub> = Per capita income index of country i:

$$IR_i = \frac{\ln \frac{GNI(PPP)}{capita}_i - \ln \frac{GNI(PPP)}{capita}_{MIN}}{\ln \frac{GNI(PPP)}{capita}_{MAX} - \ln \frac{GNI(PPP)}{capita}_{MIN}}$$

Where:

GNI (PPP)/capita = Gross National Income per capita at Purchasing Power Parity

GNI (PPP)/capita<sub>MAX</sub> = Maximum Gross National Income per capita at Purchasing Power Parity, based on the maximum value the Human Development Index uses (\$75,000)

GNI (PPP)/capita<sub>MIN</sub> = Minimum Gross National Income per capita at Purchasing Power Parity, based on the minimum value the Human Development Index uses (\$100)

Based on the formula and data above, the discount to the lowest ex-man list price in Thailand should be **19.7%**.

**IRP Example 1: Patented Medicine: Sovaldi**

- a) Sovaldi is reimbursed, or will shortly be reimbursed in 8/11 of the reference countries: Canada, France, Germany, Italy, Japan, Spain and UK
- b) Based on the price for a DDD of 400mg/day (or 1 tablet/ day) we can calculate the cost for a standard 12-week course of treatment in the following countries where ex-man prices are public:

Country	Ex-man price/ course of Tx <sup>30</sup>
France	€41,001.00
Germany	€43,562,52
Italy	€45,000.00
UK	€48,886.32*
US	€76273.50**

<sup>30</sup> \*UK Price is £11660.9 per pack, used exchange rate of £1=€1.40 (02/11/15); \*\*US Price is \$84000 per pack, used exchange rate of \$1=€0.91(02/11/15)

- c) Considering that none of Brazil, Mexico, South Korea and Taiwan has publicly available ex-man list prices for Sovaldi, we will apply the discount method.

The lowest known price is €41,001 per course of treatment, in France.

Therefore, based on IRP methodology described above, the ceiling price per 12-week course of treatment in Thailand should be:

$$€41,001 - 19.7\% = \underline{€32,923.80}$$

While this price may still be high for Thailand, it can negotiate further confidential discounts below this price using other PPA tools described in this section. Further, it can wait to see what the reimbursed prices in the other 4 countries are when they become available and then use the lowest of these prices as the ceiling price if it is lower than the above number.<sup>31</sup>

### Example 2: Patented Medicine: Trajenta

- a) At the time of the first sale of Trajenta in Thailand, December 2012, Trajenta had launched in 8 of the IRP bucket countries: Australia, Brazil, Canada, Japan, Mexico, Spain, Taiwan and UK. Ex-man price at the time of Trajenta’s launch in Thailand can be calculated based on IMS MIDAS Sales Data:

Country	Ex-man price/ DDD (US\$)
Australia	\$2.66
Brazil	\$1.82
Canada	\$2.52
Japan	\$2.05
Mexico	\$1.74
Spain	\$1.68
South Korea	\$0.65
Taiwan	\$0.95
UK	\$1.68
US	\$6.81

**Source:** IMS MIDAS Sales Data

The price of Trajenta in Thailand at launch in December 2015 was \$1.25

<sup>31</sup> Brazil price is likely to be lower once reimbursement has been negotiated. The private price negotiated with ANVISA for regulatory approval is ~\$7K; this applies to the out of pocket market only at this point.

- b) Considering both Trajenta launched after Brazil, Mexico and Taiwan, we can use the lowest known price as the ceiling, which was \$0.65 in South Korea, significantly lower than the price achieved in Thailand at the time.

**Example 3: Low Volume Generic: Vancomycin**

For low prices generics, the product in each country with the highest market share (by units sold) at time of launch in Thailand is referenced.

- a) Vancomycin is a generic product available in every country referenced, however without any recent sales in Brazil, which is therefore not included in the IRP.
- b) Considering a generic wanting to enter the Thai market in the present day, we can use current pricing data and the WHO DDD of 2mg to ascertain its IRP.

<b>Country</b>	<b>Product with highest market share</b>	<b>Ex-man price/ DDD (US\$)</b>
Australia	Vancomycin, Sandoz	\$0.005
Canada	Vancomycin, Jamp Pharma	\$0.05
France	Vancomycin, Mylan	\$0.01
Germany	Vancomycin, Hikma Pharma	\$0.02
Italy	Vancomycin, Hikma Pharma	\$0.02
Japan	Vancomycin, Meiji Seika	\$0.03
Mexico	Vancocin, Sandoz	\$0.10
Spain	Vancomycin, Normon	\$0.01
South Korea	Vancocin, Korea United Pharm.	\$0.02
Taiwan	Vancomycin, C.C.P.C	\$0.01
UK	Vancomycin L.U.	\$0.04
US	Vancomycin, Hospira	\$0.02

**Source:** IMS MIDAS Sales Data

The price per DDD of the Vancomycin generic with the highest market share, Edicin (manufactured by Sandoz), in Thailand is currently \$0.01.

- c) The IRP is the lowest price from the bucket of countries above; \$0.005 per DDD in Australia, which is lower than the current price for the generic with the highest market share in Thailand.

## **d. Implementation of International Reference Pricing**

### **Sourcing Prices**

An IRP system requires a reliable source of ex-manufacturer pricing information; these can be availed from multiple sources of ex-manufacturer list price data, for example:

- Request from manufacturer
- From payers in reference countries, where possible (e.g., Lauer Taxe in Germany, MIMS in UK)
- From IMS data
- From other public databases such as the Austrian Health Institute, which provides EU drug prices for a fee

Furthermore, the success of IRP as a tool requires a maintained price database, updated on an annual basis which requires a small team to manage and keep up to date.

### **Prioritisation**

In order to best utilise resources, all existing, in market medicines need not be subjected to IRP, unless they have a high budget impact. For example, the five products with the highest budget impact each year could be re-referenced, as well as any for which a reimbursed price could not previously be agreed. However, any new patented or low volume generic products entering the market can have the tool applied.

### **Re-referencing**

We do not recommend re-referencing products after a set period of time for two reasons, mainly due to the high administrative burden, but also because it may be the case that discounts greater than the price ceiling set by IRP have been negotiated, in which case re-referencing may jeopardise these.

The only case where re-referencing products routinely may be beneficial is in exceptional circumstances where a product has high budget impact.

## 5 Implementation of PPA Reform in Thailand

This final section of this report assesses how the recommended PPA system can be successfully implemented in Thailand to ensure improved access and pricing of medicines.

### 5.1 Guidance for Implementation

A successful PPA system relies on effective implementation which can be facilitated with buy-in from key stakeholders based on building awareness to educate on the need to enforce institutional change. Once buy-in has been obtained the appropriate capabilities can be developed to ensure that the people responsible for implementing the PPA process have the right skills and knowledge to do so.

Four key areas need to be addressed in order to facilitate a smooth and successful transition to the new PPA system in Thailand:

#### 1. Awareness Building

Currently, stakeholders are only partially aware of the pricing and patient access tools that are being used when reviewing new products in Thailand. In order to ensure institutions are aligned on the need for change to the system, stakeholders should be educated about the objective for change as well as the different possible approaches to pricing and patient access that can be applied in Thailand.

Through the development of this report, stakeholders are gradually becoming more aware of the objectives and constraints of the existing system in Thailand for evaluating and pricing drugs. They are also becoming more aware of the variety of tools that can be utilized to set price and patient access in any system. Thailand should continue to build on this knowledge and continue to educate the various stakeholders on different PPA systems and tools through seminars, courses, and meetings regionally, nationally and with other countries in the ASEAN region. National education can build local awareness and capabilities. International initiatives can help Thailand become a regional leader in PPA systems, providing lessons to other developing countries in Asia and beyond.

#### 2. Institutional Change

Thailand should build on its existing PPA methodologies used by the existing stakeholder groups. However, these institutions have existing interests that are not fully aligned with the recommended PPA strategy. In some cases, misalignments can be addressed by setting up new institutions or changing focus of existing ones. It is recommended that:

- **NHSO:** should take the lead in communicating the recommended PPA framework, getting buy-in and leading implementation of reform. The NHSO should also invest in specific resources, skills and capabilities for the implementation
- **HTA Bodies** such as HITAP should continue to conduct cost effectiveness analyses to inform decision making for the NLEM for levels 1-3 medicines

- **NLEM Committee** should continue to make listing decisions on the NLEM. However, it may need to adapt methodology based on a new PPA system
- **Expert Committee:** an expert committee for determining pricing and patient access for new drugs can be set-up to ensure alignment of decision making across the NHSO representing the UCS, the CMSBS and SSS schemes, as well as the MOPH and hospitals.
- **Ministry of Commerce:** should continue to monitor drug prices in the private market, however, the Ministry of Public Health and its constituent bodies as well as the insurance schemes should be responsible for the PPA system.

These adjustments to the current structure aim to build into the system a streamlined clinical effectiveness procedure followed by a cost effectiveness analysis by the correct bodies for patented drugs classified under Levels 1-3. This recommendation follows the French example where the 'Commission de la Transparence', commonly known as the 'CT' carries out a clinical effectiveness assessment<sup>32</sup>, assigning an ASMR of I-V. This assessment feeds into the cost effectiveness assessment and ultimately negotiation with manufacturer carried out by the 'Comité Economique des Produits de Santé', commonly known as 'CEPS'. In the French case, these procedures are undertaken by separate organisations; however this structure is not a prerequisite for a functioning system. It is, however, advisable that a certain division of labour exists and separate committees undertake the separate clinical and cost effectiveness analyses in Thailand to avoid feedback from one affecting the other.

**Exhibit 30: Key Stakeholders in the PPA System**



### 3. Stakeholder Buy-in

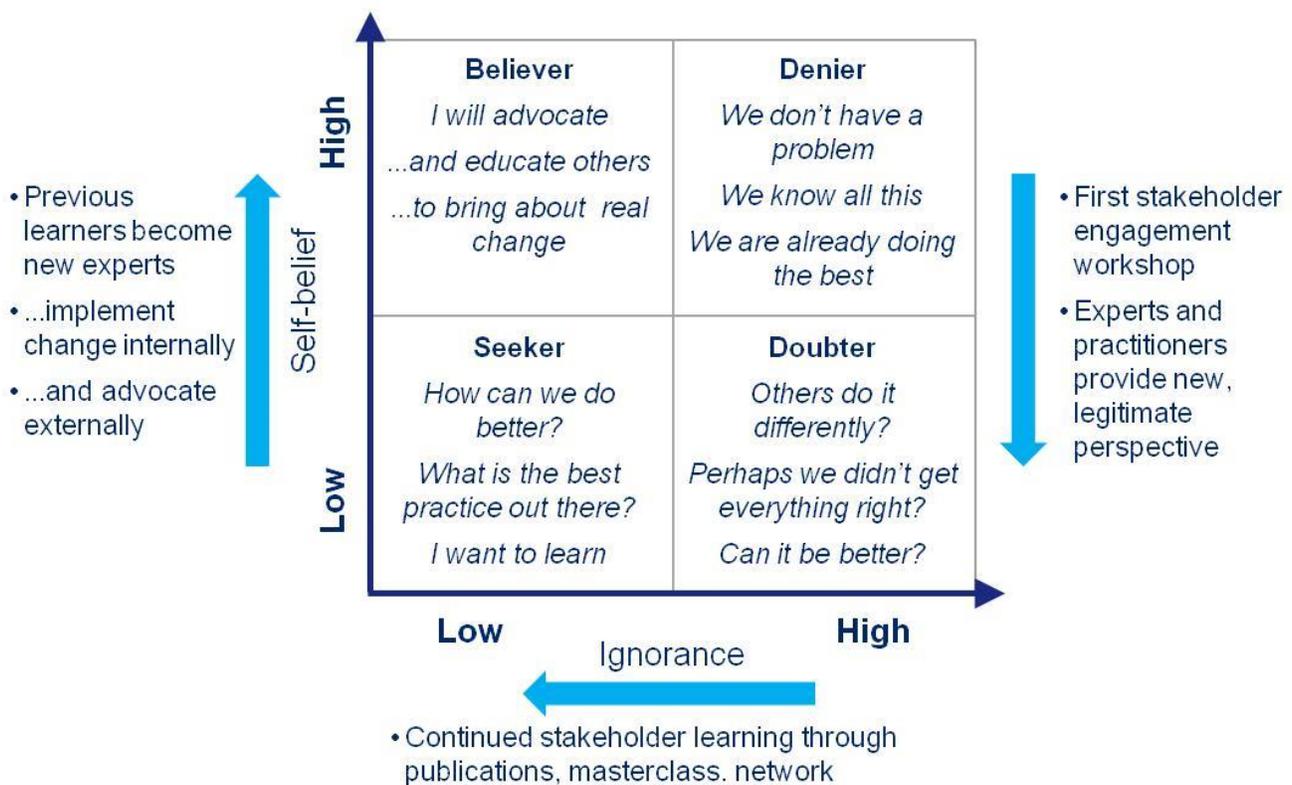
Stakeholders involved in the PPA system will need to agree with or buy-in to the proposed reforms. This will ensure that a system with broad consensus among government, civil

<sup>32</sup> French ASMR rating system described in Appendix

society and industry is implemented, thereby leading to a new system that is likely to be effective and sustainable.

There are four stages that must be traversed before true realization and acceptance can be achieved by stakeholders, as illustrated in Exhibit 31. Initially, stakeholders will be deniers of change and engagement workshops with experts can help to create awareness of the need to change. Next, continued learning through publications and courses can educate and inform stakeholders nudging them to take interest in the changes. Finally, previous learners become new experts and help to implement change internally as well as advocate this externally.

**Exhibit 31: Perception Change Map**



#### 4. Capability Building

A new PPA team will need to be set up in order to promote the implementation of the new system. The number of staff for the PPA setting will need to be increased and appropriate training provided to give staff key knowledge and skills on the PPA framework, HTA and negotiation. Additionally, the IT (information technology) capability should be enhanced to create a database on price and utilization information within Thailand as well as information on international prices for medicines for which IRP will be used.

## **6 Appendix**

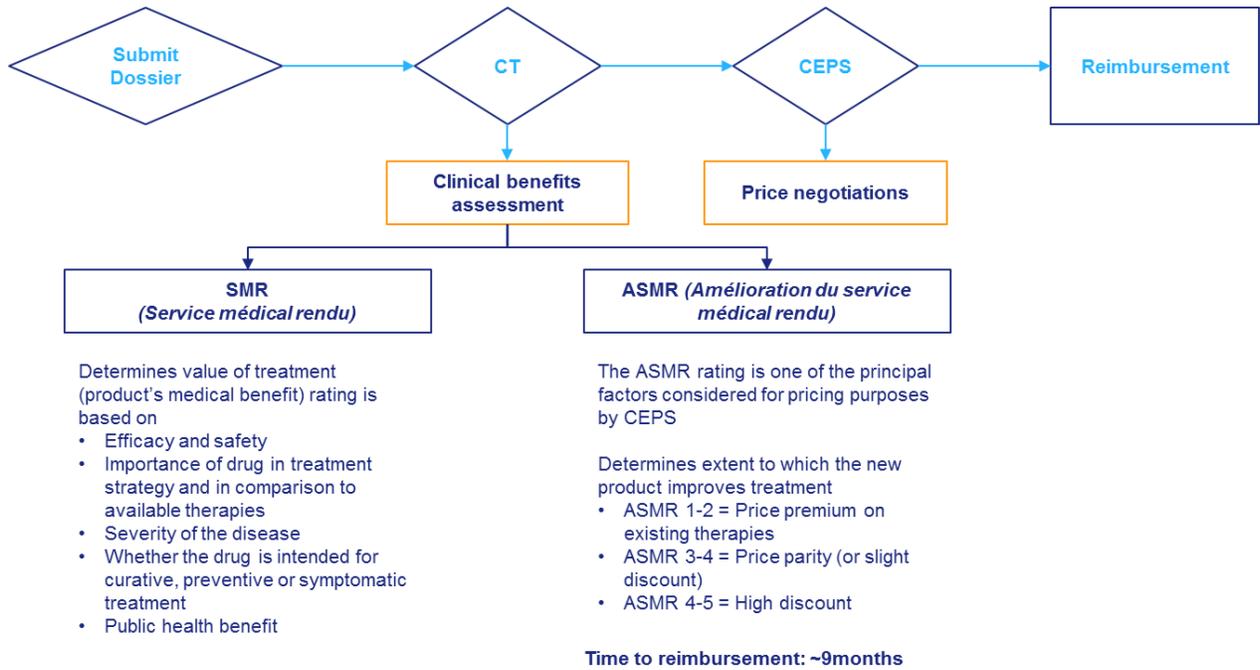
### **6.1 PPA Frameworks in Benchmark Countries**

#### **6.1.1 France**

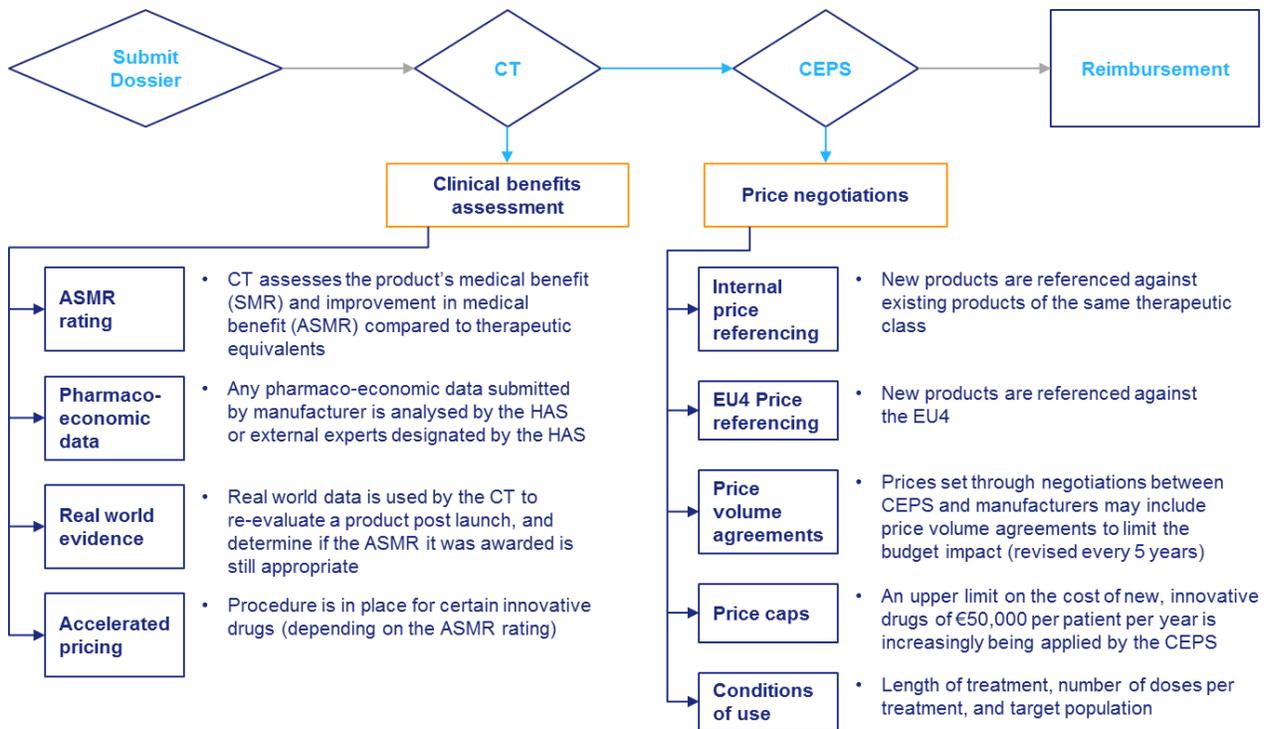
In France, clinical benefit assessment is first conducted by the CT which strongly influences subsequent price setting by CEPS. CT and CEPS utilize a number of tools such as ASMR, pharmacoeconomic data, and real world evidence to assess clinical benefits and negotiate price with manufacturers.

The price of the new product is referenced against the price of existing product of the TAs, with price in EU4 and negotiation between CEPS and pharmaceutical manufacturers. In case the product is considered to be innovative: (1) it is allowed to have an accelerated pricing procedure; (2) it benefits from the “five-year European guarantee”, meaning that during that five years the price will be no lower than the lowest among the 4 reference countries (Germany, Italy, Spain, and the UK).

**Exhibit 32a: Overview of PPA system in France (1/2)**



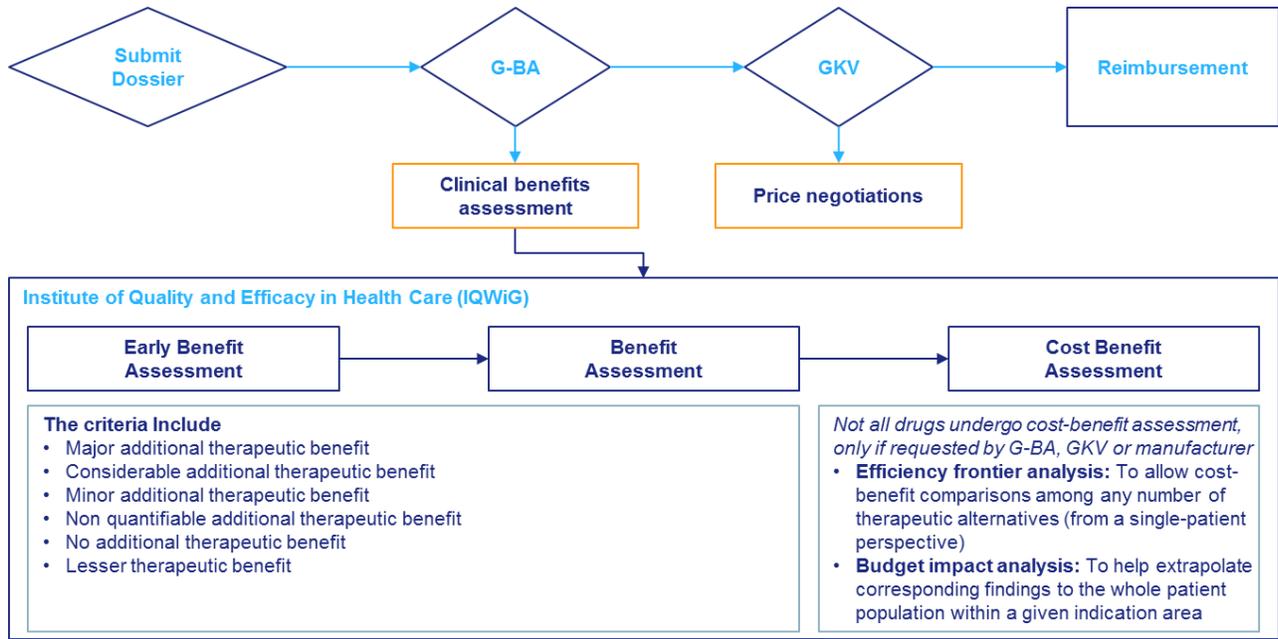
**Exhibit 32b: Overview of PPA system in France (2/2)**



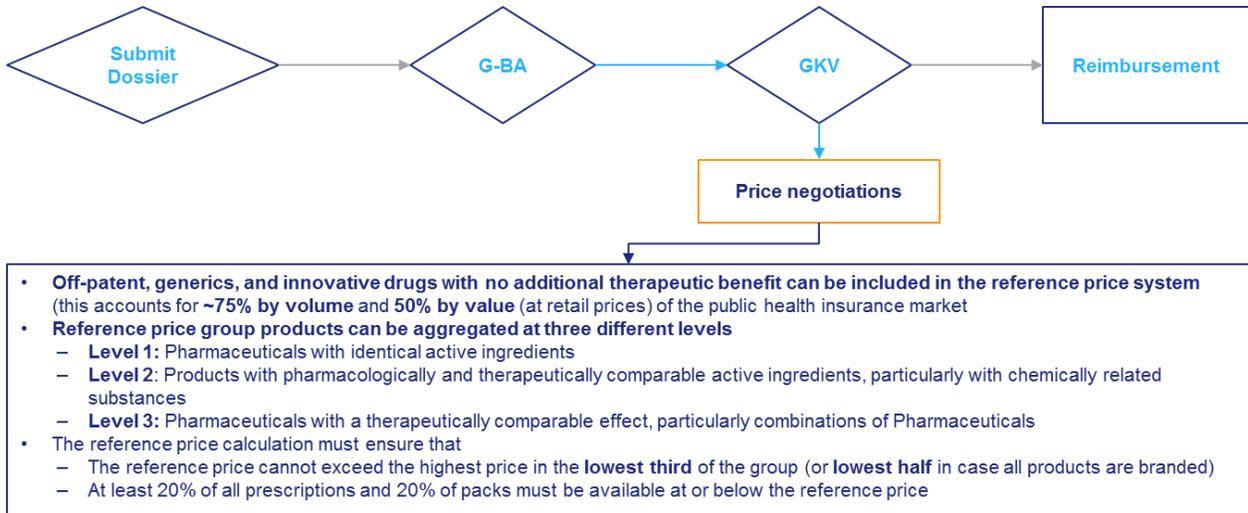
### 6.1.2 Germany

In Germany, the manufacturer of new medicine submits a benefit dossier to the Federal Joint Committee (*Germeinsamer Bundesausschuss*; G-BA) at product launch. Institute conducts the preliminary assessment of the drug for Quality and Efficiency in Healthcare (IQWiG), within the three months of product launch. All types of reimbursed drugs – patented drugs, off patented original generics, and reimbursed non-prescription drugs can be added to the active ingredient and therapeutic reference price reimbursement system. Once included, reference priced drugs are only reimbursed up to the reference price. The G-BA forms separate reference price groups for drugs with the same route of administration, method of administration and formulation.

**Exhibit 33a:** Overview of PPA system in Germany (1/2)



**Exhibit 33b:** Overview of PPA system in Germany (2/2)

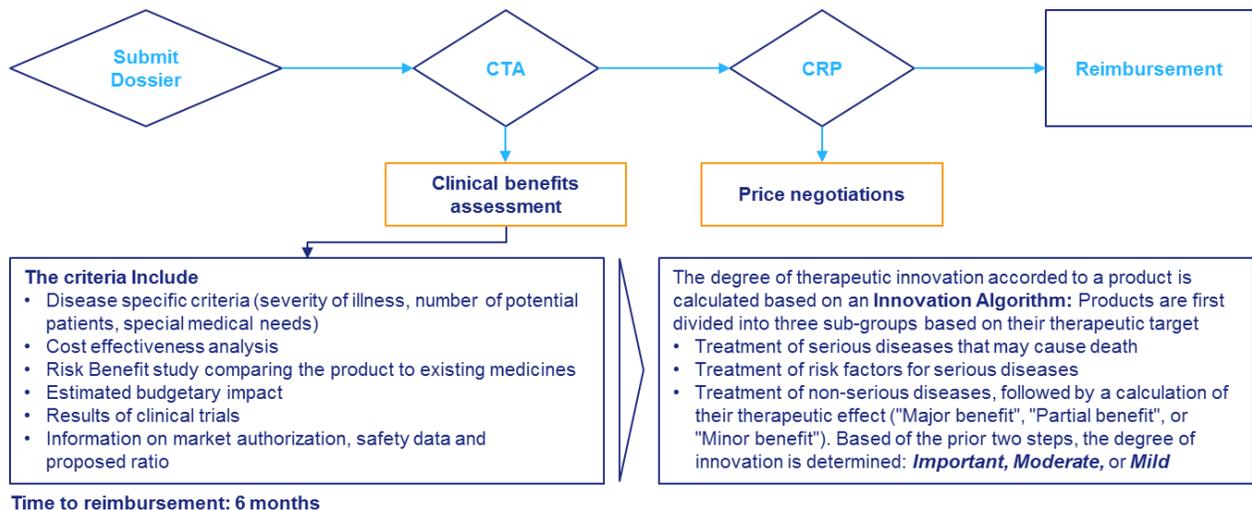


### 6.1.3 Italy

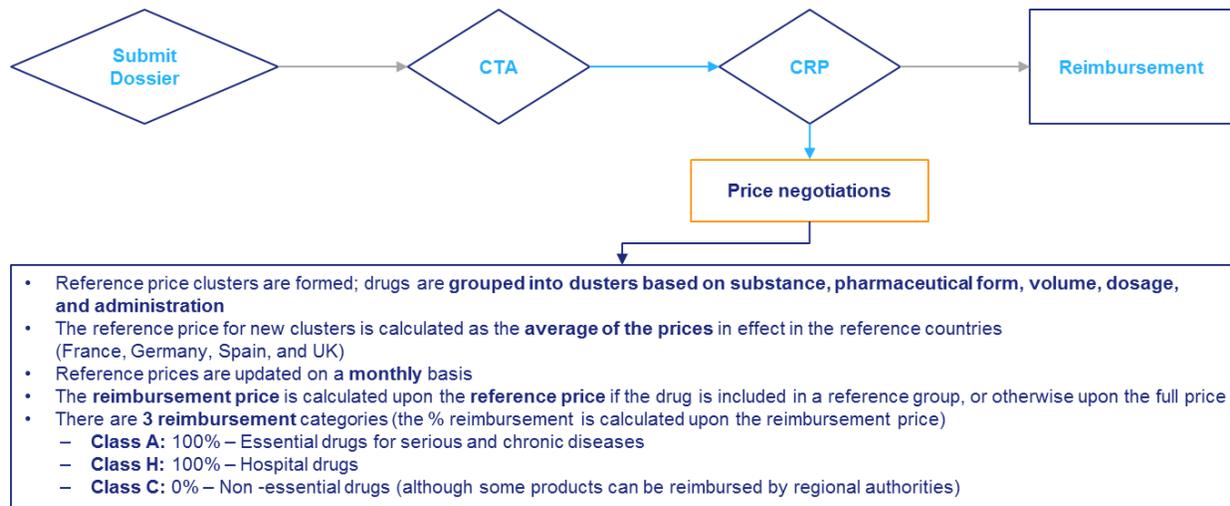
Responsibility for pricing and reimbursement decisions rests with the Italian Medicines Agency (*Agenzia Italiana del Farmaco*, AIFA). Manufacturers seeking reimbursed status for their products negotiate a manufacturer’s selling price (MSP) with AIFA, which comprehends two relevant committees: the Technical-Scientific Commission (CTS), which assesses the therapeutic value of a product and advises on its reimbursement status, and the Pricing and Reimbursement Committee (CPR), and conducts price negotiations with the manufacturer.

When deciding on a drug’s price, the CPR takes into account the drug’s therapeutic value (as assessed by the CTS) and its cost-effectiveness. Prices are compared with those in other European Union (EU) countries and with similar drugs already included on the national reimbursement list (*Prontuario Farmaceutico Nazionale*, PFN). Drug prices are usually aligned with the lowest EU prices (often within the lowest quartile).

**Exhibit 34a: Overview of PPA system in Italy (1/2)**



**Exhibit 34b: Overview of PPA system in Italy (2/2)**

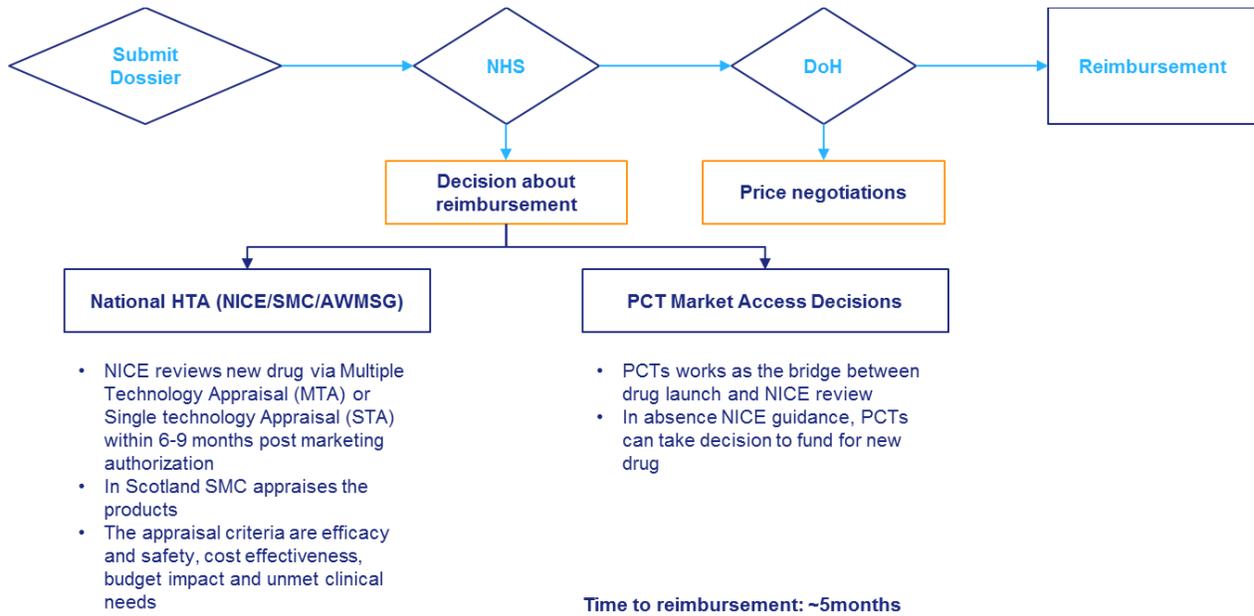


### 6.1.4 UK

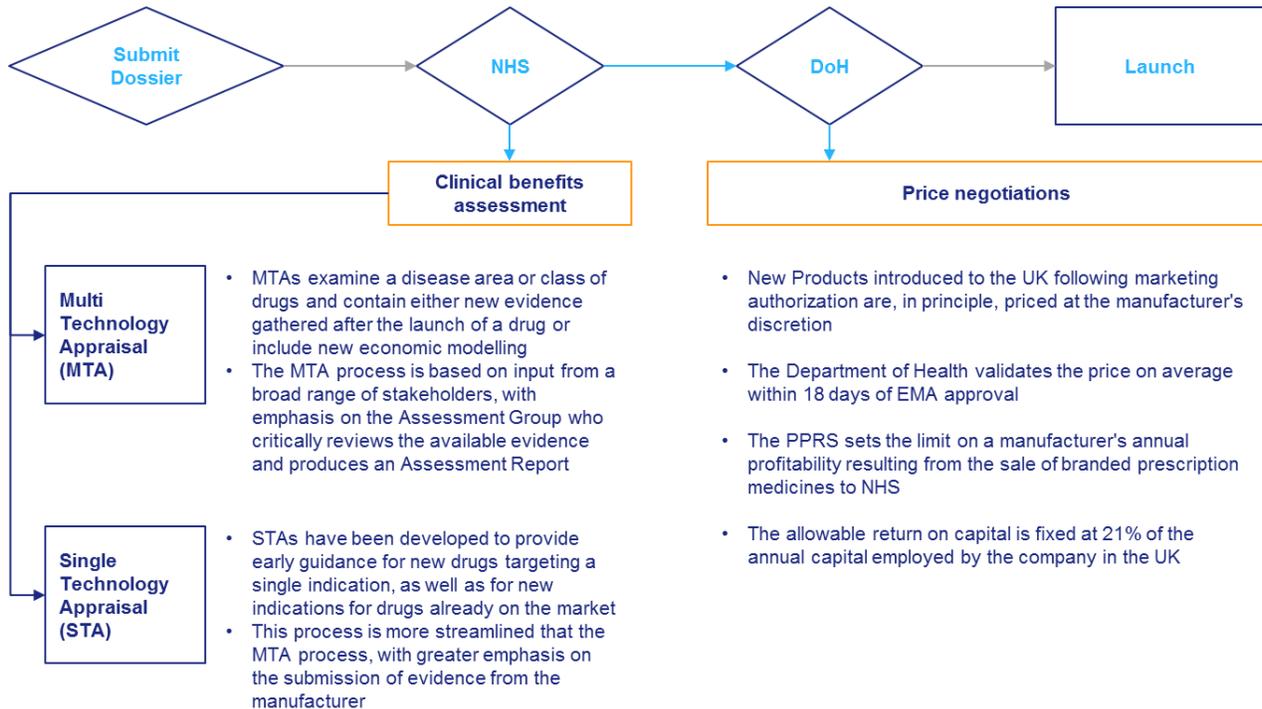
In UK the clinical benefit of new drug is conducted by HTA agencies like National Institute for Health and Clinical Excellence (NICE), Scottish Medicine Consortium (SMC), All Wales Medicine Strategy Group (AWMSG) etc. They use a variety of tools such as Multiple Technology Appraisal (MTA) and Single Technology Appraisal (STA) to evaluate the clinical effectiveness and efficacy of the new drug.

The decision regarding pricing is taken by Department of Health (DoH) through Pharmaceutical Price Regulation Scheme (PPRS). Once the drug is approved through HTA agencies and PPRS, the DoH included it in reimbursement list.

**Exhibit 35a: Overview of PPA system in UK (1/2)**



**Exhibit 35b: Overview of PPA system in UK (2/2)**



### 6.1.5 Australia

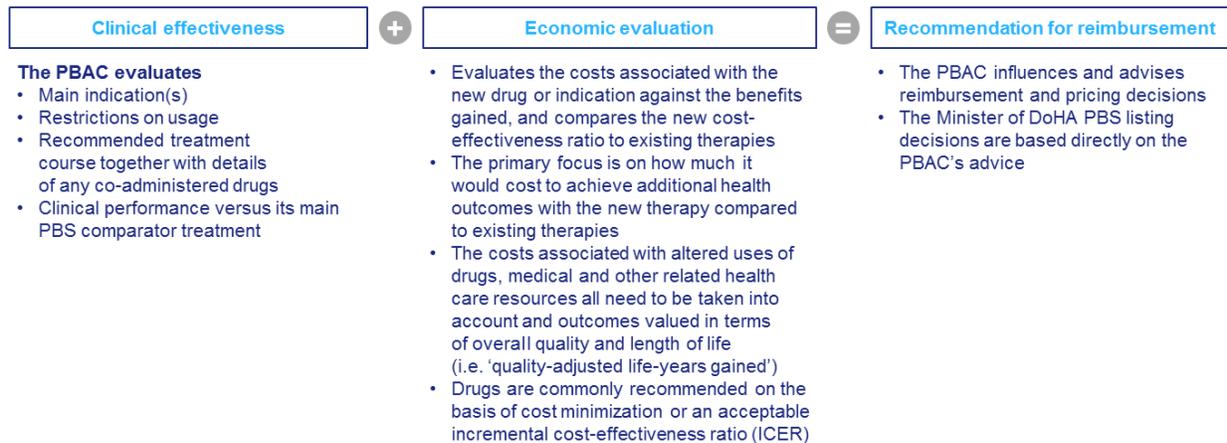
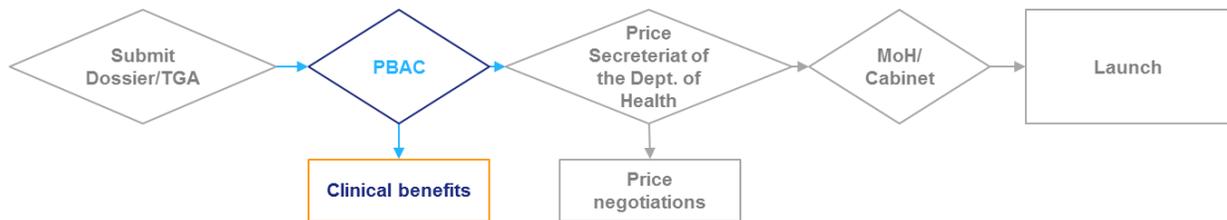
Pricing and patient access decisions in Australia involve multiple tools. First, the therapeutic goods association approves new drugs and products for marketing. Then the Price Secretariat of the Department of Health (DH) advises on whether to reimburse or not. Then the manufacturer must propose an ex-manufacturer price to the Price Secretariat of the Department of Health and Aging which is followed by confidential pricing negotiations. Before listing for reimbursement, the product must be further approved by the Minister of Health, whereas for any medicine costing \$20m or more in the first four years of listing, the cabinet must also approve the drug. While taking the decision on access and reimbursement, PBAC uses an HTA process which considers clinical effectiveness and an economic evaluation.

Apart from using above mentioned system, Australia conducts regular pricing reviews and engages manufacturers in innovative agreements, especially for high cost agents.

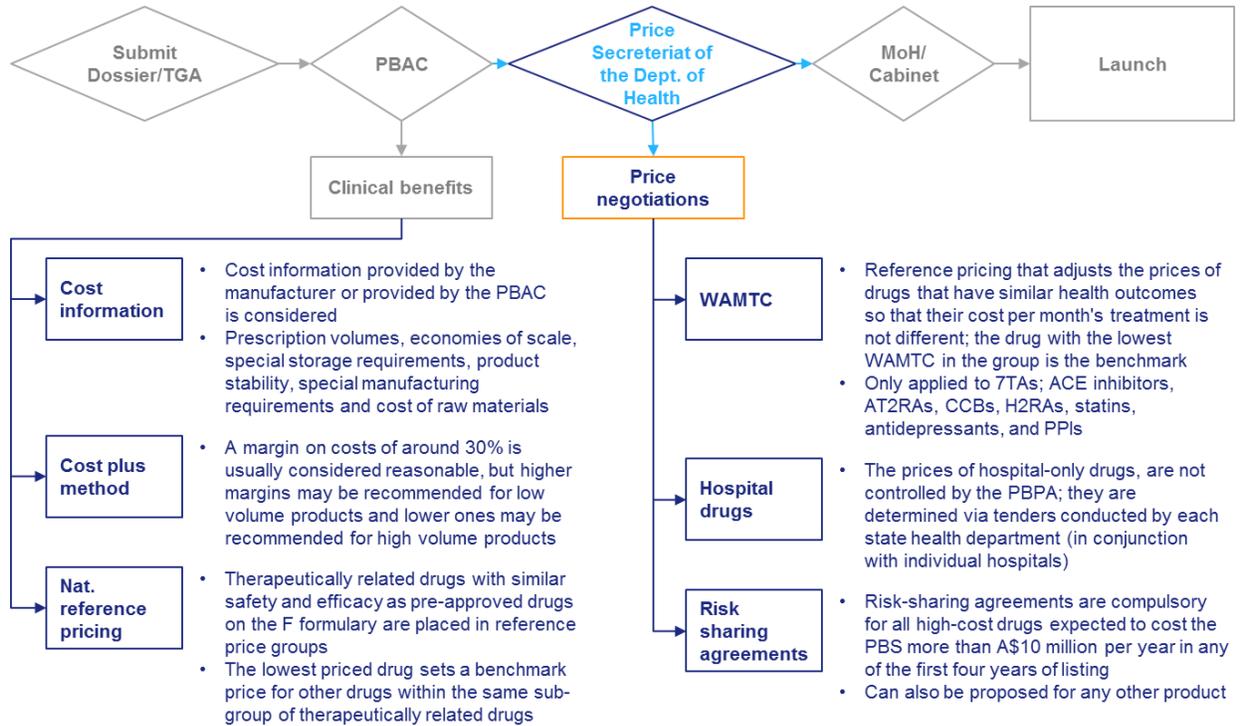
Price of all drugs covered under pharmaceutical reimbursement system (PBS), are reviewed annually. The prices of generic, off-patent and therapeutically interchangeable patented drugs on the F2 formulary are controlled via statutory price reductions (2% a year over 2008, 2009, 2010, and 2011)

Government also engages in innovative agreements for high priced medicines. Such arrangements may be suggested or requested by the PBAC, the PBPA, the manufacturer, or be required should the drug require Cabinet consideration. For new drugs requiring risk-sharing agreements, the most common arrangements are rebates where the manufacturer offers to cover the cost of increased expenditure over set annual subsidization thresholds.

**Exhibit 36a:** Overview of PPA system in Australia (1/2)



**Exhibit 36b:** Overview of PPA system in Australia (2/2)

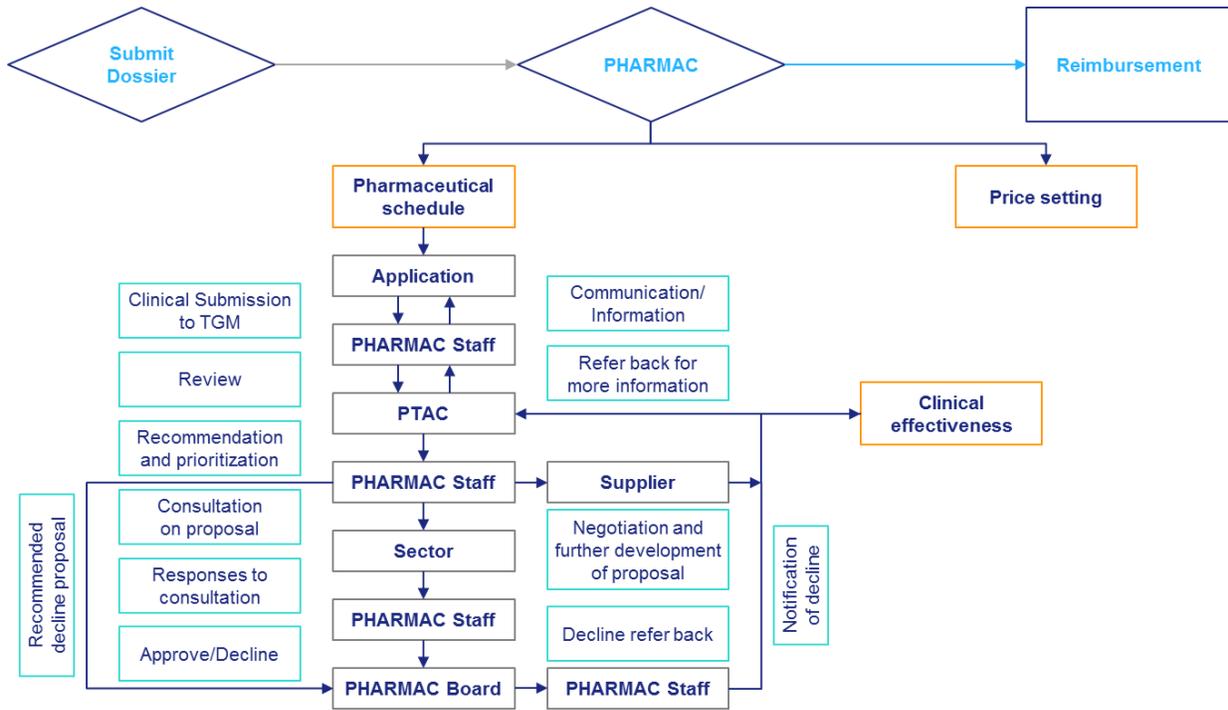


### 6.1.6 New Zealand

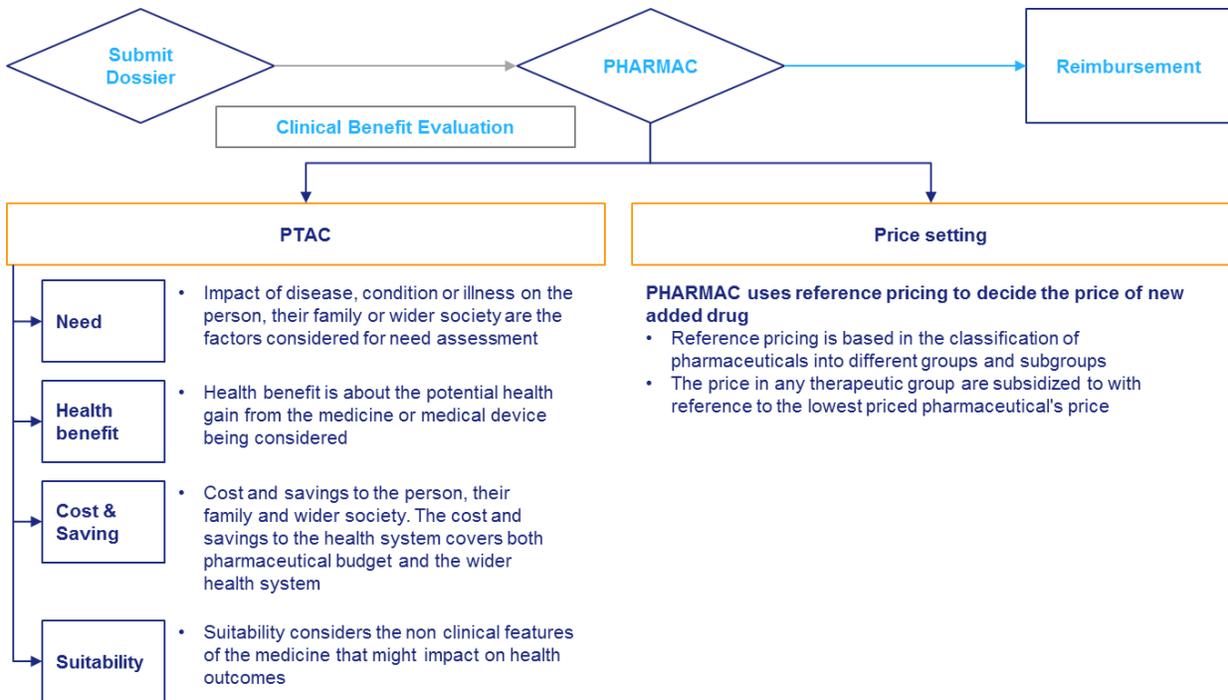
Pharmaceutical Management Agency (PHARMAC) is responsible for taking decision on pricing and reimbursement related decision in New Zealand. Pharmaceutical manufacturers are required to submit the drug information in prescribed format to PHARMAC for their review. Pharmacology and Therapeutic Advisory Committee (PTAC), a subcommittee of PHARMAC, is responsible for evaluating the medicines for their clinical effectiveness and benefit.

PTAC uses several parameters such as need, health benefit, cost and savings and suitability of the medicines to evaluate its effectiveness. Once after clinical evaluation of the medicine, PHARMAC sets the price of the medicines for reimbursement using reference-pricing mechanism. The lowest priced product in any therapeutic group is considered as the reference price for that particular group.

**Exhibit 37a:** Overview of PPA system in New Zealand (1/2)



**Exhibit 37b:** Overview of PPA system in New Zealand (2/2)



### **6.1.7 Canada**

In Canadian system prices of patented drugs are regulated by patented medicine review board (PMPRB) while generics/off patented drugs are freely priced. PMPRB establishes the patented drug's level of therapeutic improvement (LTI) vs. comparators and calculates the drug's maximum average potential prices based on the LTI.

Canadian Agency for Drugs and Technology in Health's (CADTH) Common Drug Review (CDR) provides advice and evidence-based information regarding drug effectiveness and health technologies to provinces, whereas the CADTH's pan-Canadian Oncology Drug Review (pCODR) deals with oncology specifically.

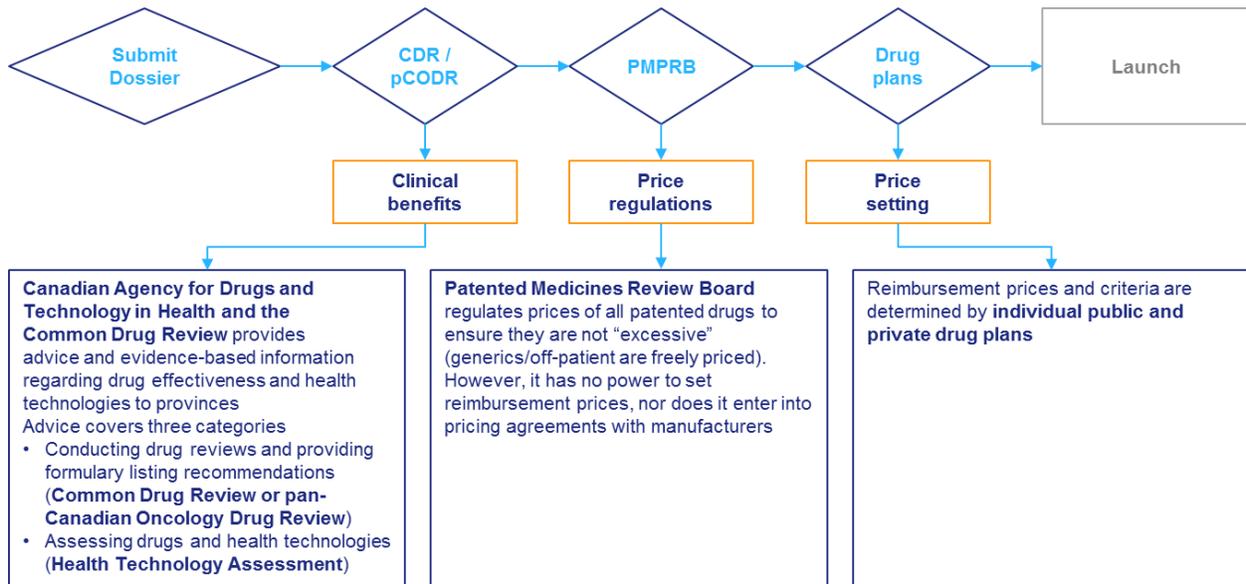
The CDR and pCODR conduct clinical and cost-effectiveness evaluations of products for listing recommendation to publicly funded formularies (excluding Quebec), however recommendations are not binding and some provinces/ territories/ drug plans also conduct some of their own assessments. It also supports provincial drug plan decisions by providing access to evidence and expert advice. They have to decide whether new drug is better than alternatives, which patient segments will it benefit, and is it cost effective?

CDR is supported by the Canadian Drug Expert Committee (CDEC), an Independent advisory body composed of individuals with expertise in drug therapy and drug evaluation. CDEC reviews clinical studies demonstrating safety & efficacy in appropriate patient populations, therapeutic advantages and disadvantages relative to accepted therapy, and cost-effectiveness (CE) of drug relative to accepted therapy.

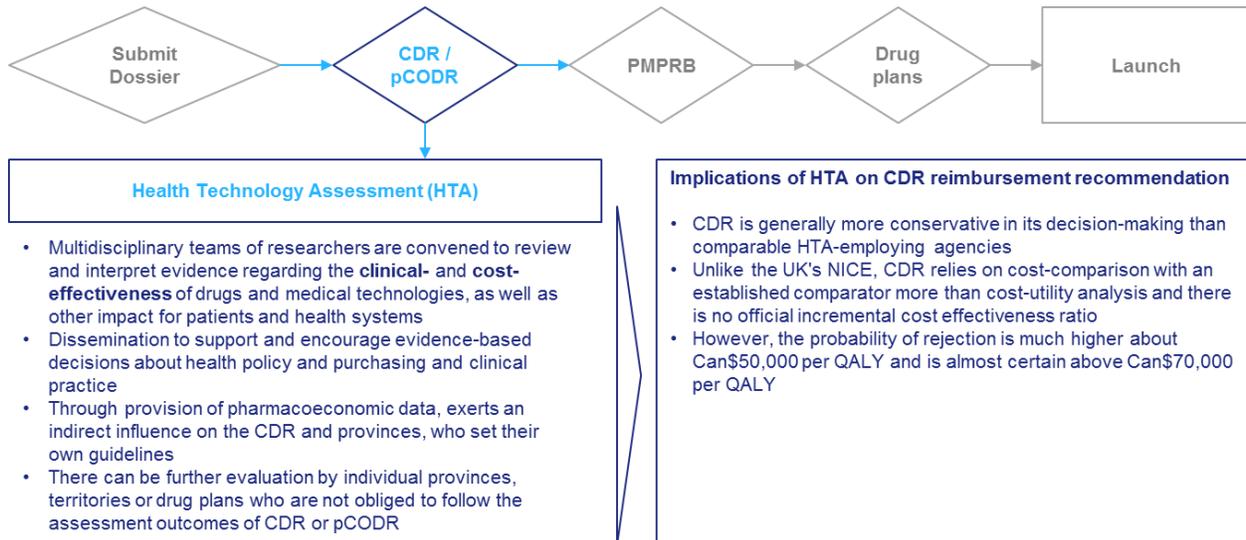
After getting feedback and listing recommendation from CDR, PMPRB regulates prices of patented medicine. It sets up maximum average potential price (MAPP) in consideration with international reference prices.

MAPP of a new patented drug is dependent of its level of therapeutic improvement, thus a breakthrough innovative drug gets maximum price premium while a 'me too' drug gets minimum price premium.

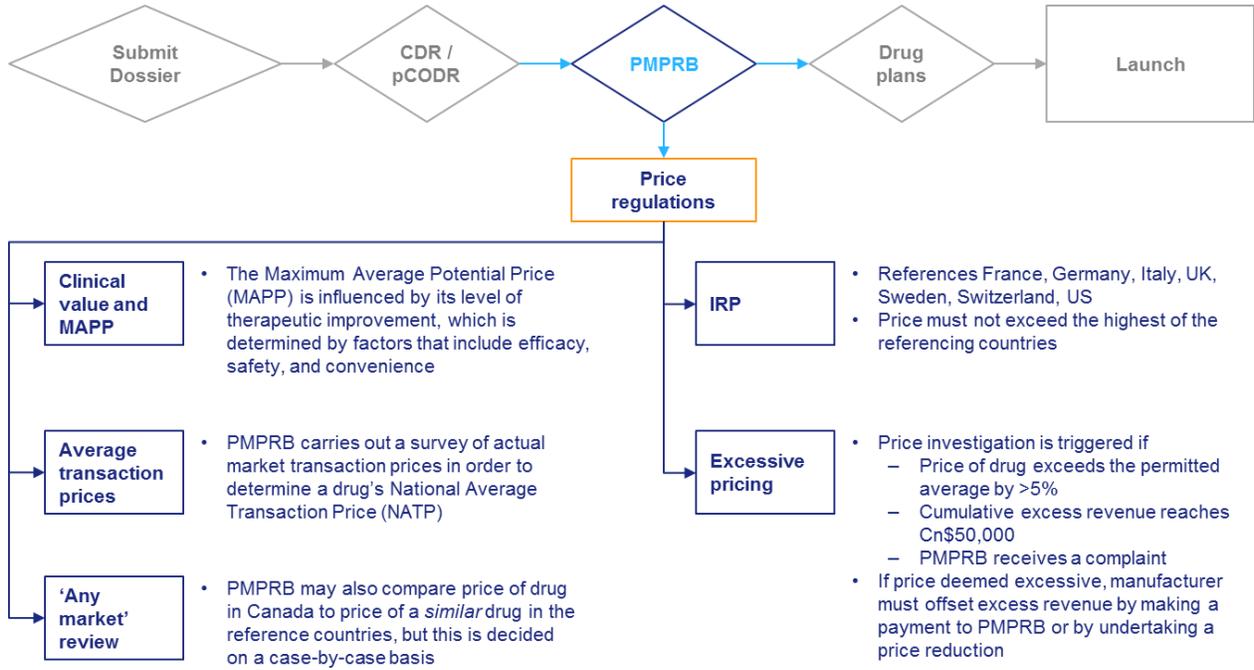
**Exhibit 38a: Overview of PPA system in Canada (1/4)**



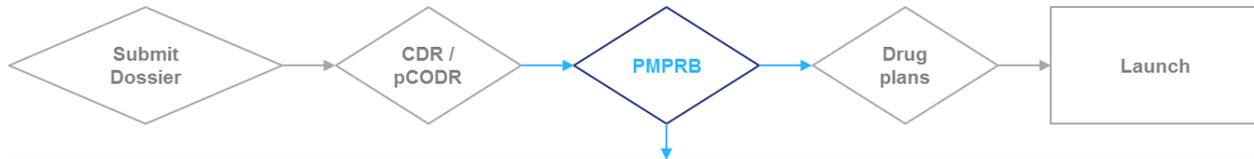
**Exhibit 38b: Overview of PPA system in Canada (2/4)**



**Exhibit 38c: Overview of PPA system in Canada (3/4)**



**Exhibit 38d: Overview of PPA system in Canada (4/4)**



Level of Therapeutic Improvement and associated pricing		
Level	Definition of level	Price limit
<b>Breakthrough</b>	The first to treat an illness or address an indication effectively	Median ex-factory price of the same product (strength & dosage) in the 7 reference countries (must be sold in 5)
<b>Substantial Improvement</b>	Provides substantial improvement in therapeutic effects relative to other products	The higher of <ul style="list-style-type: none"> <li>Lower public price of the highest-price comparable product with the same indication</li> <li>Median reference country price</li> </ul>
<b>Moderate Improvement</b>	Provides moderate improvement in therapeutic effects relative to other products	The higher of <ul style="list-style-type: none"> <li>Mid-point between highest priced comparable product with the same approved indication and the median international price</li> <li>Lowest public price of the highest-priced comparable product with the same indication</li> </ul>
<b>Slight or no Improvement (includes line extensions)</b>	Provides slight or no improvement in therapeutic effects relative to other products	<ul style="list-style-type: none"> <li>Lowest public price of the highest-priced comparable product with the same approved indication</li> <li>For new presentations (same indication, same/comparable dosage form and same dosage regimen), strength per unit and price versus the highest priced original product is reviewed</li> </ul>

**6.1.8 South Korea**

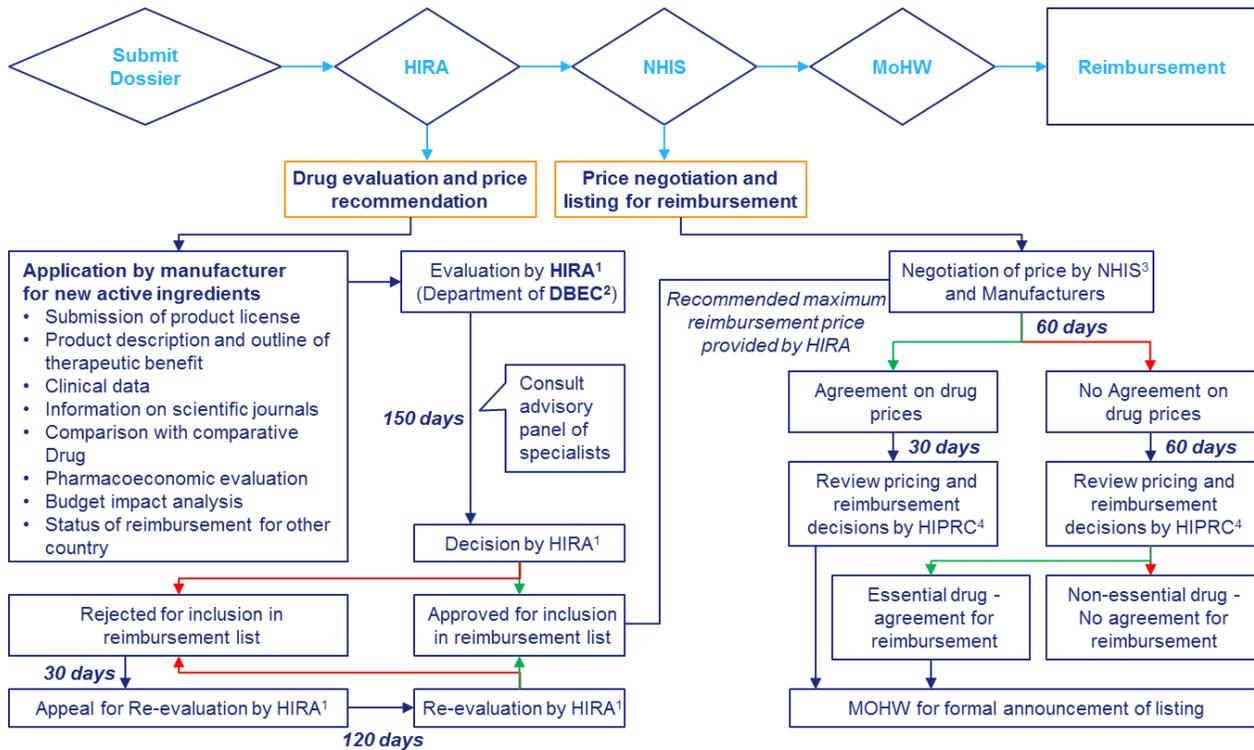
In South Korean system, the National Health Insurance Service (NHIS) sets up reimbursement price after considering HTA evaluation done by the Health Insurance Review

and Assessment Services (HIRA) Drug Benefit Evaluation Committee (DBEC). DEBC decision making follows a process that is similar to those employed in the UK (NICE) and Australia (PBAC), with an emphasis on cost-effectiveness, clinical value and reimbursement in OECD countries.

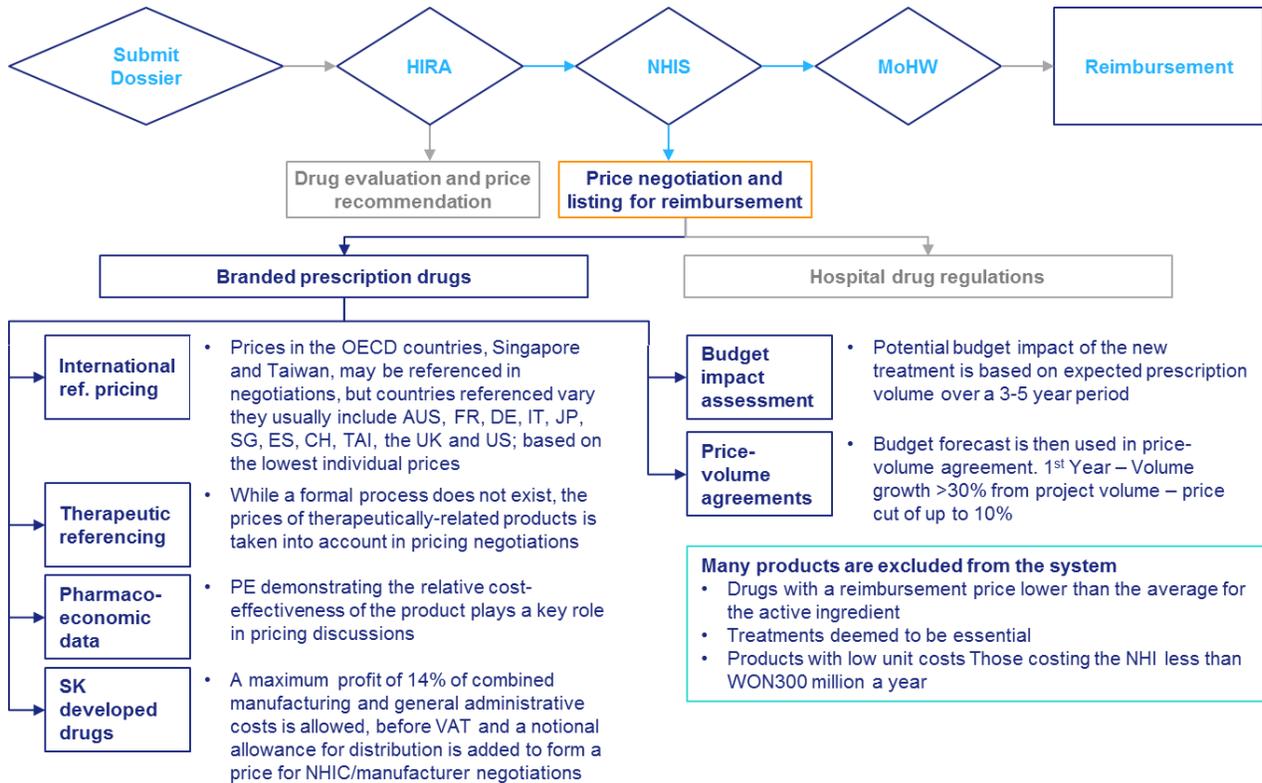
Following DEBC recommendations, the NHIS utilises a number of tools in negotiating price with manufacturers. Though many products are excluded from the system:

- Drugs with a reimbursement price lower than the average for the active ingredient
- Treatments deemed to be essential
- Products with low unit costs
- Those costing the NHI less than WON300 million a year

**Exhibit 39a:** Overview of PPA system in South Korea (1/2)



**Exhibit 39b: Overview of PPA system in South Korea (2/2)**



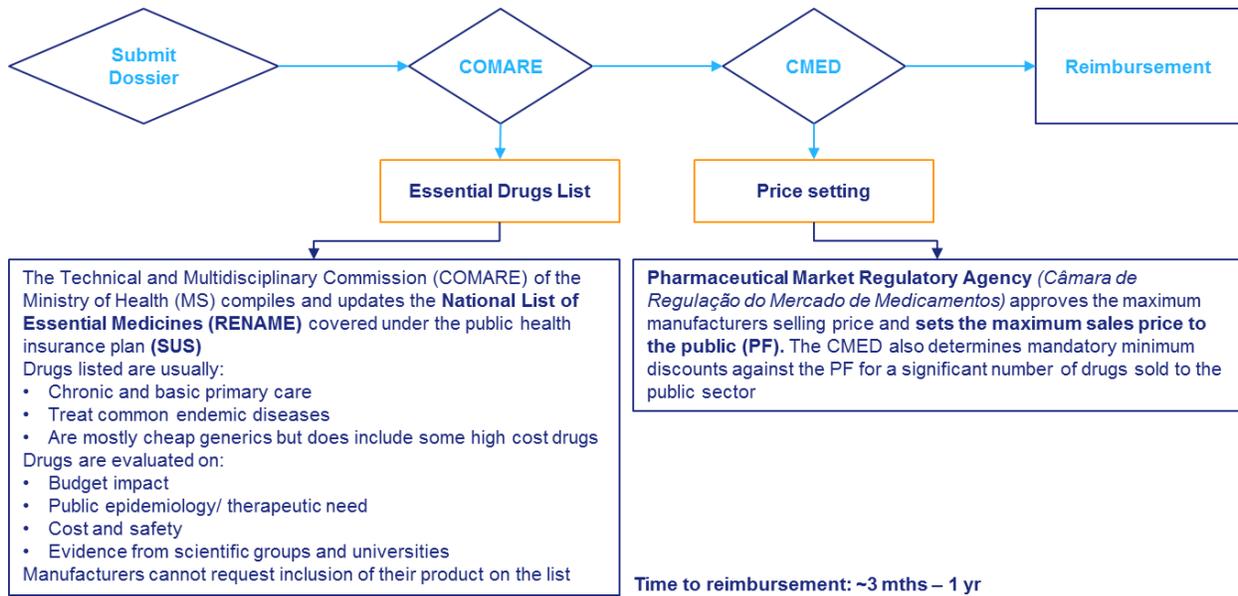
### 6.1.9 Brazil

The Technical and Multidisciplinary Commission (*Comissão Técnica e Multidisciplinar de Atualização da Relação Nacional de Medicamentos Essenciais*, COMARE) of the Ministry of Health (MS) compiles and updates the National List of Essential Medicines (RENAME) covered under the public health insurance plan (SUS). Pharmaceutical Market Regulatory Agency (*Câmara de Regulação do Mercado de Medicamentos*) approves the maximum manufacturer's selling price and sets the maximum sales price to the public (PF).

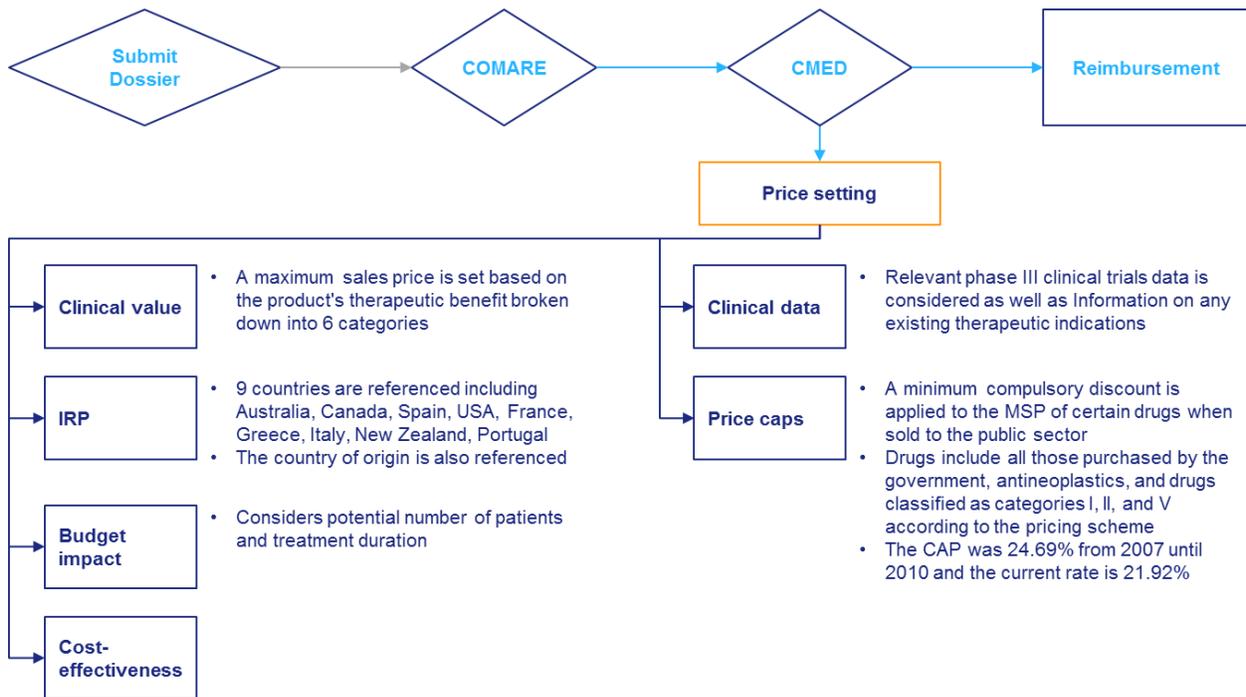
Pricing decision is based on international reference prices, which takes prices in 9 countries into account. Clinical effectiveness, cost effectiveness and budget impact are also considered.

Different drug's category is considered while setting maximum sales price like generic or innovative. Both national and international reference prices are used to determine maximum sales price.

**Exhibit 40a: Overview of PPA system in Brazil (1/3)**



**Exhibit 40b: Overview of PPA system in Brazil (2/3)**



**Exhibit 40c: Overview of PPA system in Brazil (3/3)**



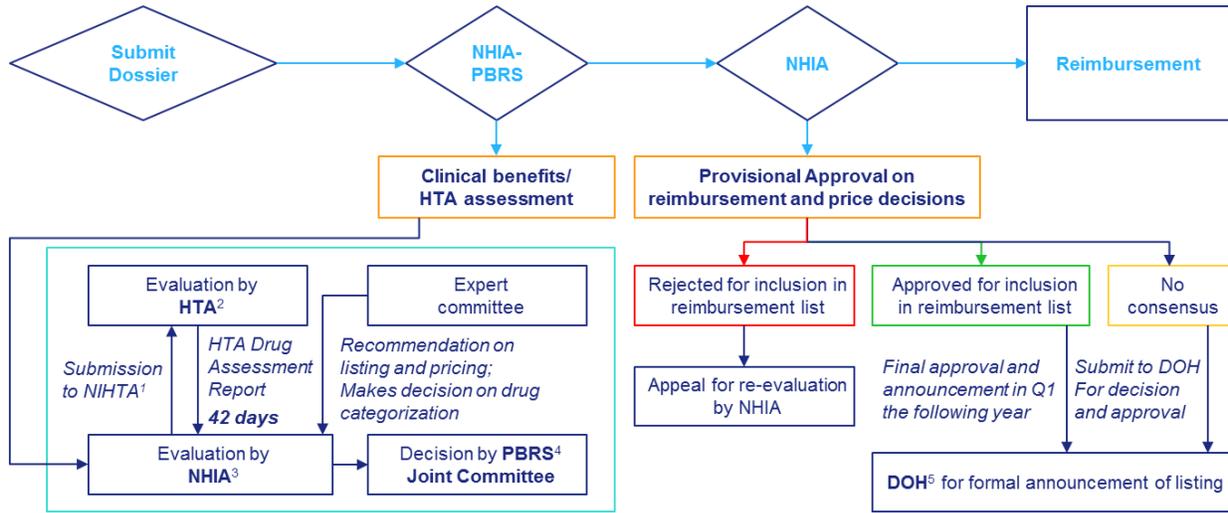
**6.1.10 Taiwan**

In Taiwan the National Health Insurance Administration (NHIA) and Patient Benefit Reimbursement Scheme (PBRs) decides about the reimbursement and pricing of new drug. The PBRs evaluates the dossier submitted by pharmaceutical manufacturer for its comparative effectiveness, cost effectiveness and budget impact parameters. Based on the results of the evaluation, the PBRs joint committee makes decision on drug listing and categorization.

The pharmaceutical manufacturer receives a provisional approval after the PBRs evaluation for the applied drug.

The NHIA is responsible for deciding the prices of new drugs for reimbursement. Pricing decision is based on the median price of IRP in A10 countries. The efficacy, safety and convenient of dosing is also considered during deciding the prices

**Exhibit 41a: Overview of PPA system in Taiwan (1/3)**



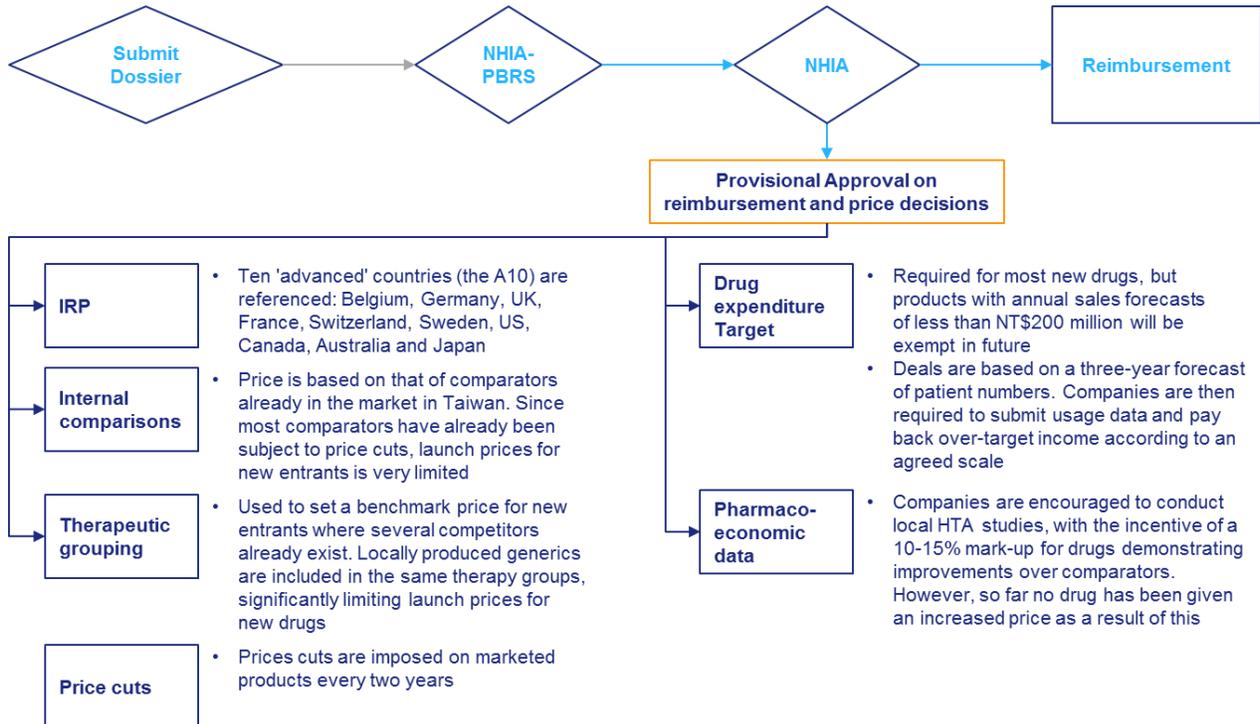
**PBRS considerations**

- PBRS Joint Committee consists of representatives from the NHIA (insurer), relevant government agencies, experts, patients, employers, and medical providers
- Appraise HTA reports for decision making
- Can invite drug company, relevant experts, patients to express opinions for re-submit cases

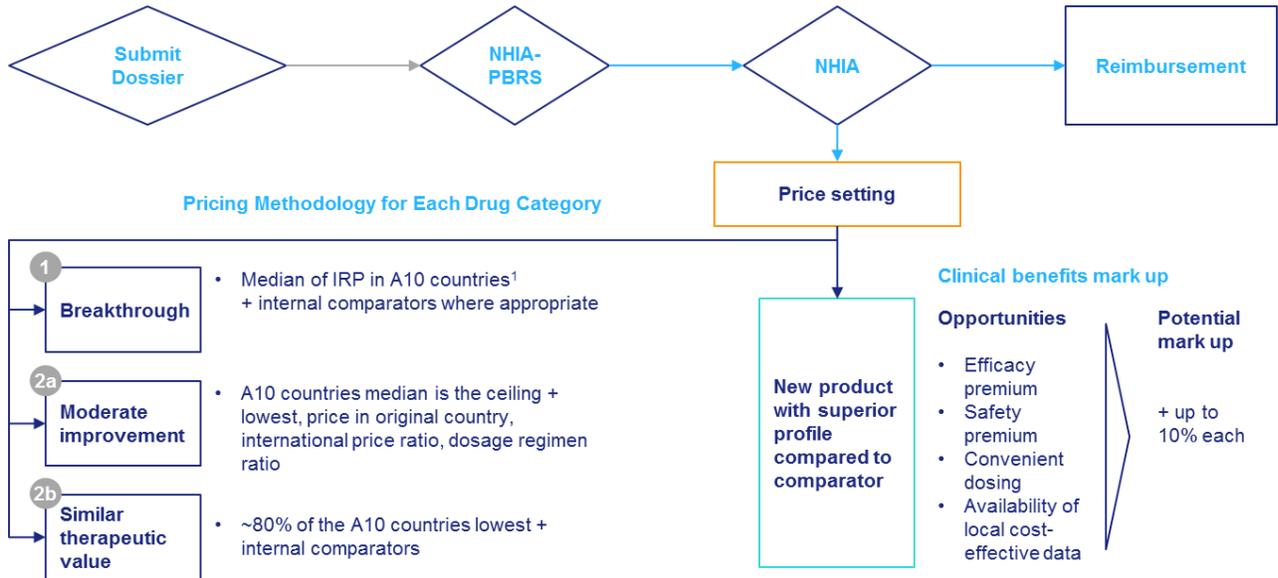
**Time to reimbursement: 12-18 months**

<sup>1</sup>NIHTA: National Institute of Health Technology Assessment; <sup>2</sup>HTA: Health Technology Assessment; <sup>3</sup>NHIA: National Health Insurance Administration  
<sup>4</sup>PBRS: Pharmaceutical Benefits and Reimbursement Scheme (managed by the NHIA); <sup>5</sup>DOH: Department of Health

**Exhibit 41b: Overview of PPA system in Taiwan (2/3)**



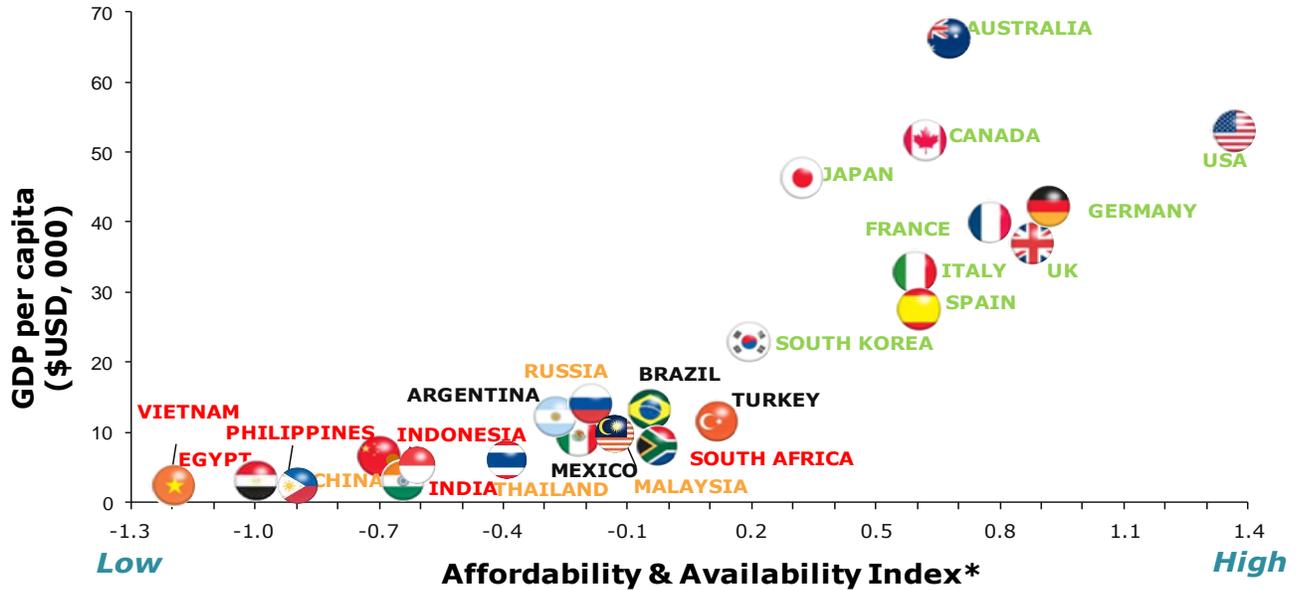
**Exhibit 41c: Overview of PPA system in Taiwan (3/3)**



## 6.2 Impact of PPA system on Access to Medicine

The development of a pricing and patient access (PPA) framework positively affects a country’s access to innovative medicines. Analysing different countries on access to medicine performance index and GDP per capita (illustrated in Exhibit 42), reveals that even controlling for income, countries with more developed PPA system achieve better access to innovative medicines.

**Exhibit 42:** Impact of PPA systems on access to medicine



\*Affordability & Availability index was calculated as the average of standard deviations from the mean of Affordability parameters (“level of public coverage”, “Insurance coverage”, “OOP as % of GDP”, “relative affordability of generic and patented medicines”) and Availability parameters (“total generic molecules launched, total patented molecules launched, “Innovative drug time to launch from regulatory approval”).

**PPA system:** Well developed, Moderately developed, Developing, Weak or non-existent

The broad criteria for categorization of PPA systems are on the basis of structure, transparency and reliability. Description of each category are shown in Exhibit 43.

**Exhibit 43: Learning from Developed and Developing Countries PPA System** <sup>33</sup>

	Description	Countries
<b>Well-developed PPA system</b>	<ul style="list-style-type: none"> <li>Structured and transparent</li> <li>Sophisticated HTA that bases price and access on relative value of medicine across all TAs</li> </ul>	Australia, Canada, France, Germany, UK, South Korea
<b>Moderately developed PPA system</b>	<ul style="list-style-type: none"> <li>Prioritises TAs and medicines based on public health need</li> <li>Some use of HTA to inform price/ access</li> </ul>	Brazil, Mexico, Turkey, US
<b>Rudimentary but developing PPA system</b>	<ul style="list-style-type: none"> <li>Focus on public health priority</li> <li>PPA system under development</li> <li>New HTA systems, but limited impact on price and access</li> </ul>	China, Russia
<b>Weak or non-existent PPA system</b>	<ul style="list-style-type: none"> <li>No systematic assessment of medicine cost-benefit</li> <li>Blunt or absent tools to manage price and access</li> </ul>	South Africa, India, Indonesia

## 6.3 Benchmarking Access to Medicines Across Developed and Developing Countries

### 6.3.1 Methodology

Benchmarking of PPA systems, including Thailand, consisted of following activities:

#### I. Leverage secondary research, discussion with key local stakeholders and IMS internal P&A experts:

We conducted secondary research, literature review, interview / discussion with local key stakeholders and our internal pricing and access experts to get better understanding of existing system in Thailand, draw out their perspective on PPA policy framework and for their inputs on benchmarking countries and indicators

#### II. Identification of Benchmarking Countries

To benchmark the existing system of pricing and patient access framework in Thailand we selected a mix of developed and developing countries. The guiding principle for selection of countries for benchmarking is based on the following criteria:

<sup>33</sup> Source: IMS PharmaQuery , Market Prognosis & IMS expertise

Countries	Rationale	Identified Countries
Developed	<ul style="list-style-type: none"> <li>Represents different insurance systems</li> <li>Have structured and transparent PPA system</li> <li>Represent spectrum of methodologies regarding evaluation of drugs based on clinical and cost effectiveness</li> <li>Provides learning opportunities regarding some of the best practices of PPA system</li> <li>Provide insights about what has worked and what not</li> </ul>	<ul style="list-style-type: none"> <li>Australia</li> <li>South Korea</li> <li>France</li> <li>Germany</li> <li>United Kingdom</li> <li>Taiwan</li> </ul>
Develop	<ul style="list-style-type: none"> <li>Size and growth of pharma market</li> <li>Challenges faced with respect to improving access</li> <li>Commonalities and differences in approaches to expanding access to healthcare</li> <li>Represent different approaches to pricing and access policies with some common elements</li> <li>Insights about challenges implementation of a PPA system in a low and middle income country</li> </ul>	<ul style="list-style-type: none"> <li>Brazil</li> <li>China</li> <li>Indonesia</li> <li>Mexico</li> <li>India</li> <li>Turkey</li> </ul>

### III. Selection of Benchmarking Metrics of pricing and patients access in developed and developing countries:

We selected metrics to benchmark the Pricing and Patient Access in Thailand with other developed and developing market countries. In order to get the insights for pricing and affordability of medicines, we compared the price of representative product baskets of identified therapeutic areas across the benchmark countries.

Access Pillar	Benchmarking Metric	Rationale / Definition	Data Source
Accessibility	Healthcare spend per capita	Sum of public and private health expenditures/Total population	WHO data base
	Hospital bed per 1000 population	Total number of hospital beds (inpatient beds available in public, private, general, and specialized hospitals and rehabilitation centres)/1000	WHO data base

	Physician per 1000 population	Total number of physicians (include generalist and specialist medical practitioners)/1000	WHO data base
<b>Awareness</b>	Diabetes guidelines awareness	A summative index of diabetes awareness among the population represented in a four category Likert scale	WHO data base
	National awareness scheme for NCD	A summative index of diabetes awareness among the population represented in a seven category Likert scale	WHO data base
	Tuberculosis case detection rate	Number of cases notified divided by the number of cases estimated for that year, expressed as a percentage.	WHO data base
<b>Availability</b>	Number of new molecules launches	Number of Innovator Drugs launched in market over a certain period of time	IMS MIDAS data
	Delay in new molecules in Thailand vs. other countries	Total delay in launch of Innovator Drug in Thailand from its first global launch	IMS MIDAS data
	Market share by product type (original vs. generics) by value and volume	<b>Original</b> includes protected and no longer protected drugs  <b>Generic</b> includes branded/unbranded/ and unlicensed products	IMS MIDAS data
<b>Affordability</b>	Population coverage of private and public reimbursement	Total population covered under public and private insurance schemes	IMS Prognosis
	Extent of diseases covered	Diseases (NCDs, Chronic etc.) covered under the health insurance scheme	IMS Prognosis
	Out of pocket spend	Household out-of-pocket expenditure on health comprises cost-sharing, self-medication and other expenditure paid directly by private households, irrespective of whether the contact with the healthcare system was established on referral or on the patient's own initiative.	World Bank
	Cost index for generic and patented drugs	Cost index is the average per mg cost of drug (Indexed to Thailand)	IMS MIDAS

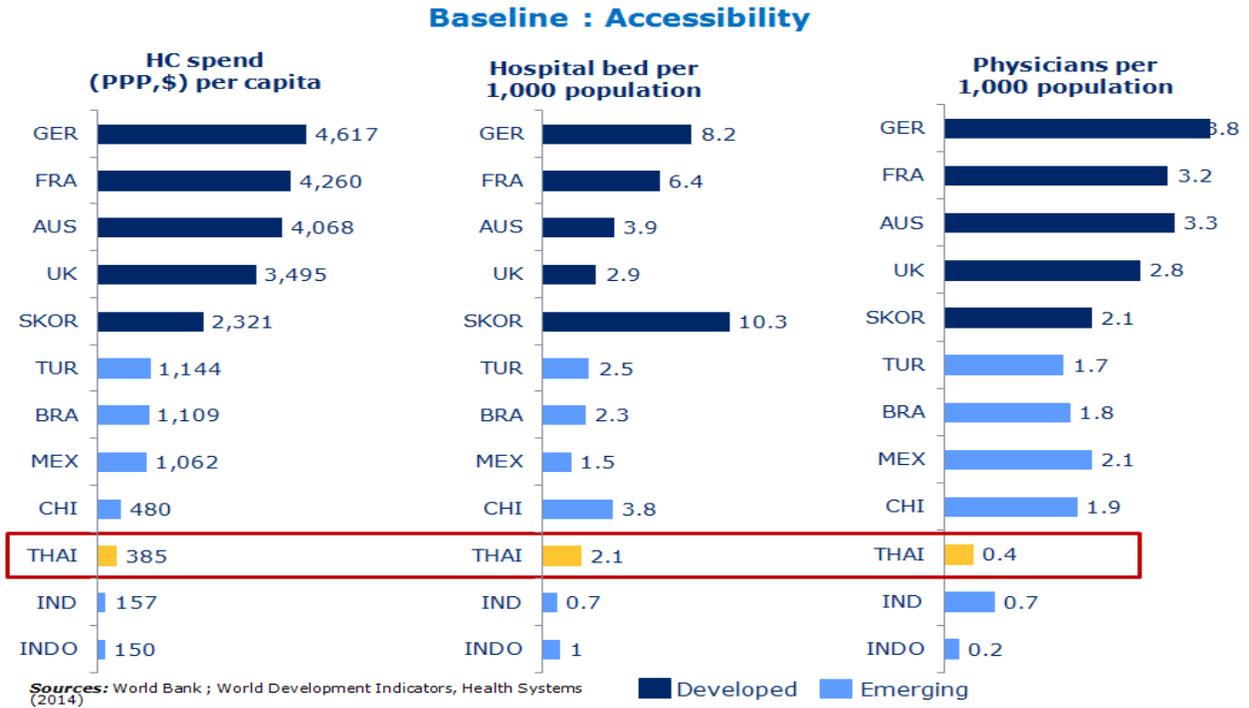
		Drugs with highest market share in Thailand (by value) in particular TA were selected for benchmarking	
	Affordability index for generic and patented drugs	Affordability index: Average per mg cost of drug / Nominal GDP per capita  Drugs with highest market share in Thailand (by value) in particular TA were selected for benchmarking	IMS MIDAS, World Bank
<b>Adherence</b>	Avoidable cost due to non-adherence	Percentage of total health expenditure that can be avoided by taking the complete drug regimen	IMS Institute – Responsible use of Medicines
	Avoidable cost due to antibiotic misuse	Percentage of total health expenditure that can be avoid by appropriate use of antibiotic	IMS Institute – Responsible use of Medicines
	Avoidable cost due to suboptimal use of generic	Percentage of total health expenditure that can be avoided by using the best available generic medicines	IMS Institute – Responsible use of Medicines
	Avoidable cost due to delayed medicine use	Percentage of total health expenditure that can be avoided by taking medicines without any delay	IMS Institute – Responsible use of Medicines

**Data Sources used:** Various secondary sources and previous studies by IMS Health were referenced to conduct diagnostic assessment of the current patient access situation in Thailand and other benchmark countries. IMS data assets such as IMS Local Market Audit and IMS MIDAS database were used to conduct pricing related analysis. IMS Prognosis reports and the IMS PharmaQuery database were used to understand the PPA framework of benchmark countries.

### 6.3.2 Baseline Diagnostic – Accessibility

Access to basic healthcare infrastructure such as healthcare workers, diagnostic facilities, and primary/secondary care facilities is a pre requisite for providing effective access to medicine. Several factors such as healthcare spending, availability of hospitals and health workforce play a critical role in determining the access to basic healthcare facilities.

**Exhibit 44: Benchmarking of accessibility parameters**



**Thailand has lower access to health facilities than developed countries and most developing countries**

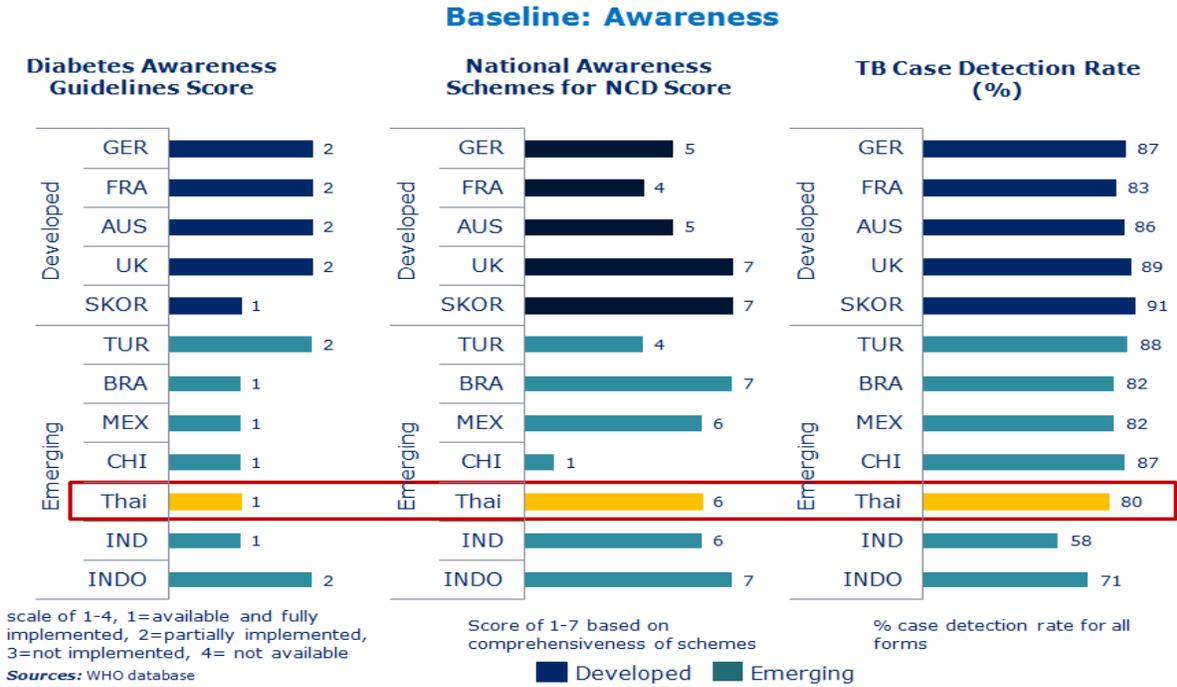
Thailand lags behind most developed and developing countries in regards to accessibility parameters. Thailand’s hospital bed density per 1,000 population is lower than in developed countries but in a similar range as developing countries. With comparison to the average per capita healthcare spending (US \$385) and physician density (~0.4), Thailand falls into the bottom third of the benchmarked countries. Thailand’s healthcare reform brought massive funding for the healthcare of the population, and has certainly influenced today’s access parameters in Thailand. Overall, accessibility remains a concern for Thailand and can act as a barrier for the population in realising effective healthcare services and outcomes.

**6.3.3 Baseline Diagnostic – Awareness**

Awareness about the available healthcare services, benefits, and drug treatments among both healthcare providers and patients is an important aspect for effective use of medicine.

We compared Thailand with other benchmarked countries on awareness parameters such as awareness about diabetes, non-communicable diseases and case detection rate of tuberculosis.

**Exhibit 45: Benchmarking of awareness parameters**



**Thailand’s health system gives a level of awareness that is comparable to most developed countries**

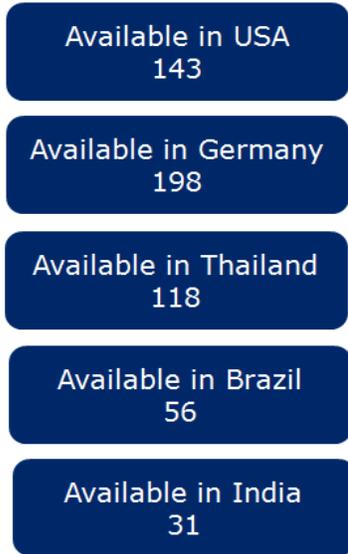
Thailand’s awareness indicators are comparable to most developed countries and better than most developing countries.

**6.3.4 Baseline Diagnostic – Availability**

In terms of availability of patented medicines, Thailand has better availability than other developing countries such as Brazil and India. Data from the IMS MIDAS database suggests that 373 new medicines have been launched worldwide since 2006, out of which 118 are available in Thailand. In developed market like Germany and the USA, 198 and 143 molecules are available respectively.

**Exhibit 46:** Availability of patented medicines in Thailand

**Total Molecules Launched Since 2006 – 373**



**Availability of new molecules across TAs**

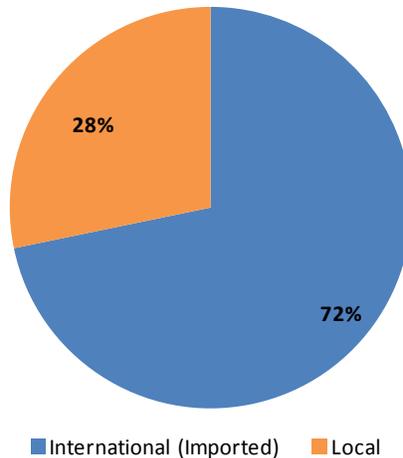
TA	# of molecules launched worldwide	# of molecules launched in Thailand
Oncology & Immunomodulating	155	45
Cardio-vascular	91	30
Anti-infective	84	28
Respiratory	43	15

*Source: IMS MIDAS database Notes: 1) Based on patented drugs listed in IMS MIDAS database*

**Availability of patented medicines in Thailand is better than other developing countries although somewhat lower than developed countries**

Another critical area for addressing barriers to availability is to ensure there is no overdependence on imports for meeting pharmaceutical/healthcare needs of the country.

**Exhibit 47:** Imported vs. Locally Manufactured Share of Pharmaceuticals Sold in Thailand



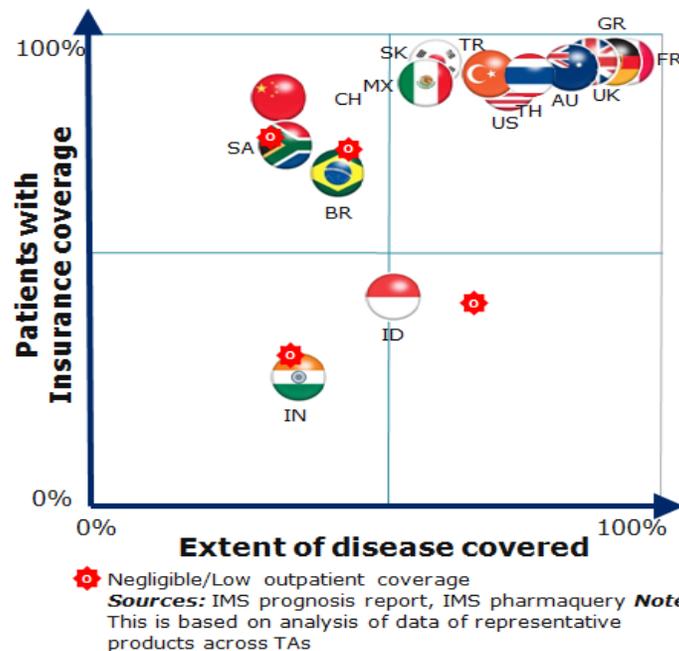
In Thailand, 3/4<sup>th</sup> of medicines sold in hospitals and retail drug stores are imported. Importation applies not only to patented medicines; 15% generic drugs sold in Thailand are also imported from various international markets.

### 6.3.5 Baseline Diagnostic – Affordability

#### Healthcare Coverage

Disease coverage is an important component of patient affordability as it removes the out-of-pocket cost burden giving patients access to products that would otherwise be unaffordable. In most developed markets, the insurance coverage for most diseases is high, including both in-patient and out-patient expenses. Although many emerging markets have a high population coverage through national or regional schemes, medicine coverage is often limited to low cost and generic products, with little access to new high value innovative medicines.

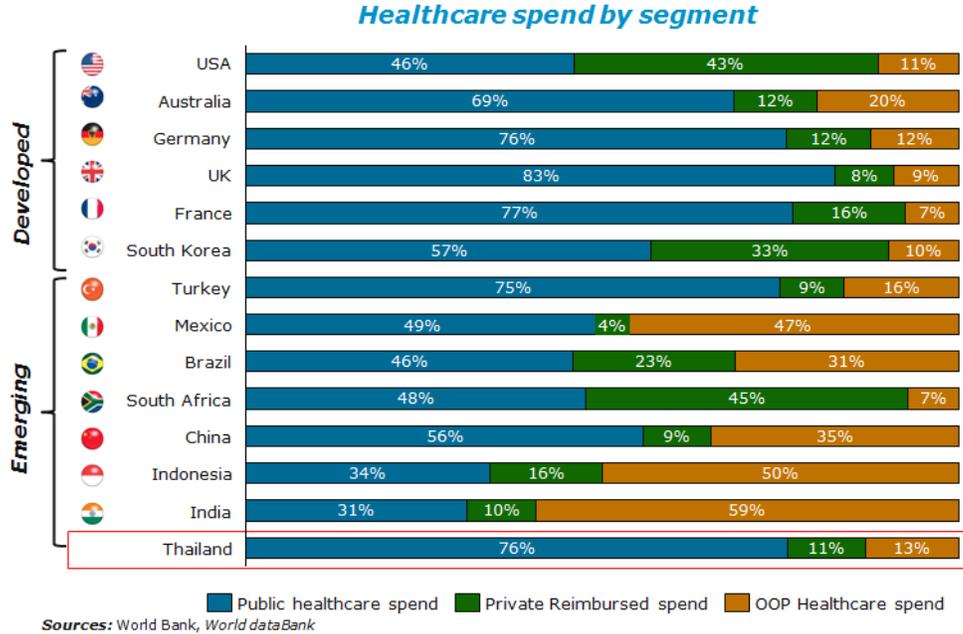
**Exhibit 48:** Disease Coverage of Benchmark Markets



In 2002, Thailand introduced the Universal Coverage Scheme (UCS) after the elected government initiated the “30-Baht for All Diseases Policy” in 2001. It was based on the country’s constitutional law, which was thought to enable the entire population with access healthcare services. As a result, in Thailand approximately 99% of the total population is covered under one of the two government sponsored health insurance schemes (UCS and CSMBS) or private employer based scheme (SSS). The coverage of diseases in Thailand is also very high compared to other emerging markets such as India, Indonesia, and Brazil.

Because of high population and disease coverage, Thailand has a considerable public healthcare spend, which is causing a high economic burden on the government. Thailand’s Government share of overall spending on healthcare is ~ 76%, which is higher than in many developed market countries. As the result of high public spending on healthcare, the patient out-of-pocket is expenditure is lower than most benchmark countries at 13%.

**Exhibit 49:** Cost coverage of benchmark markets



### Cost of Medicines

Cost is an important aspect for access of medicines as it directly influences the affordability of medicines to the mass population. In order to compare the price and affordability of generic medicines a representative product basket across therapeutic areas was selected. Price comparison was done across the product type by measuring relative price indexed to Thailand price. Affordability index was measured as average per unit cost of product basket / GDP per capita.

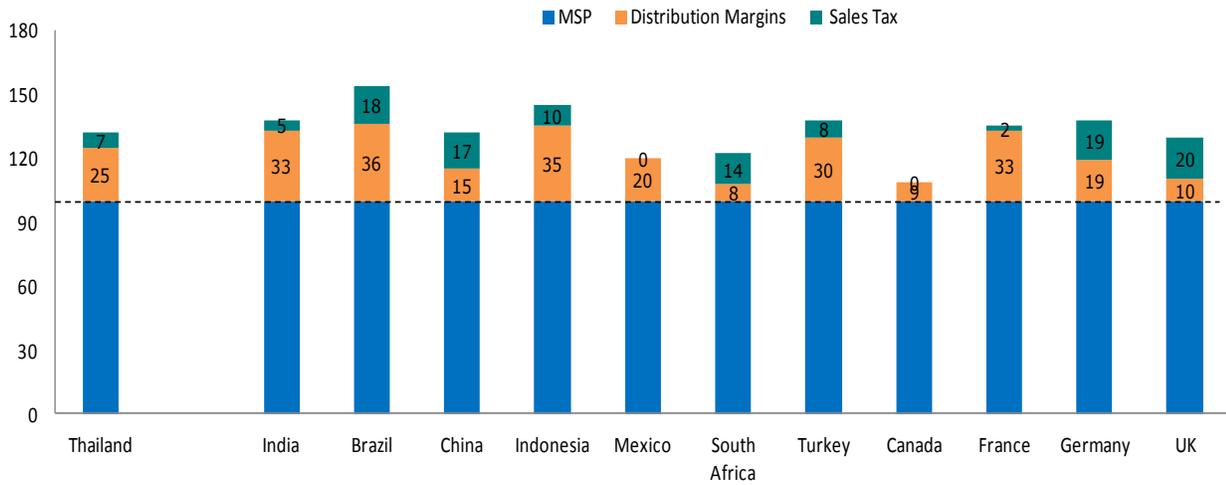
In this section, IMS MIDAS data has been used to determine the prices of generic and patented drugs in the benchmark countries. The pricing data is taken from drugstore sales but does not include tender based procurement or direct procurement by hospitals.

Given the nature of Thailand market with its high percentage of procurement directly done by hospitals, this benchmarking may not provide the most accurate representation and will require adjustment of 20-30%% for comparable analysis.

### Price Build Up Across Pharmaceuticals Value Chain in Benchmark Markets

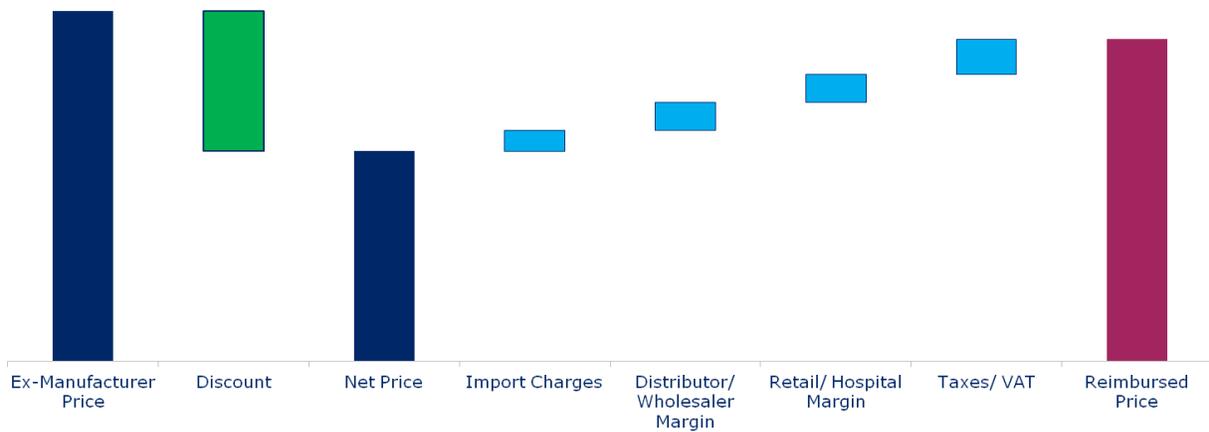
When comparing prices across countries it is important to note that some differences in the reimbursement price or the end price could be attributed to the varying tax structures, margins added along the supply chain, and trade discounts in each country. The variation in tax structure and distribution margins is shown in Exhibit 50, while a typical price build-up is shown in Exhibit 51. Due to variance in mark-ups and discount depending upon country, product type and other factors, the ex-manufacturer price was used in further analysis to compare prices across countries.

**Exhibit 50: Tax structure and margins of benchmark countries**



In general, overall taxes and margins are lesser in developed markets compared to emerging markets. Taxes and distribution margins contribute 20% to 35% in most countries with lower tax structure.

**Exhibit 51: Top Level View of Price Build-up**



Given the price build-up, countries can manage the end reimbursement price in 2 ways:

- Manage the ex-manufacturer price through PPA (rules or negotiations)
- Reduce the supply chain margins through government regulation

**Generic Medicines**

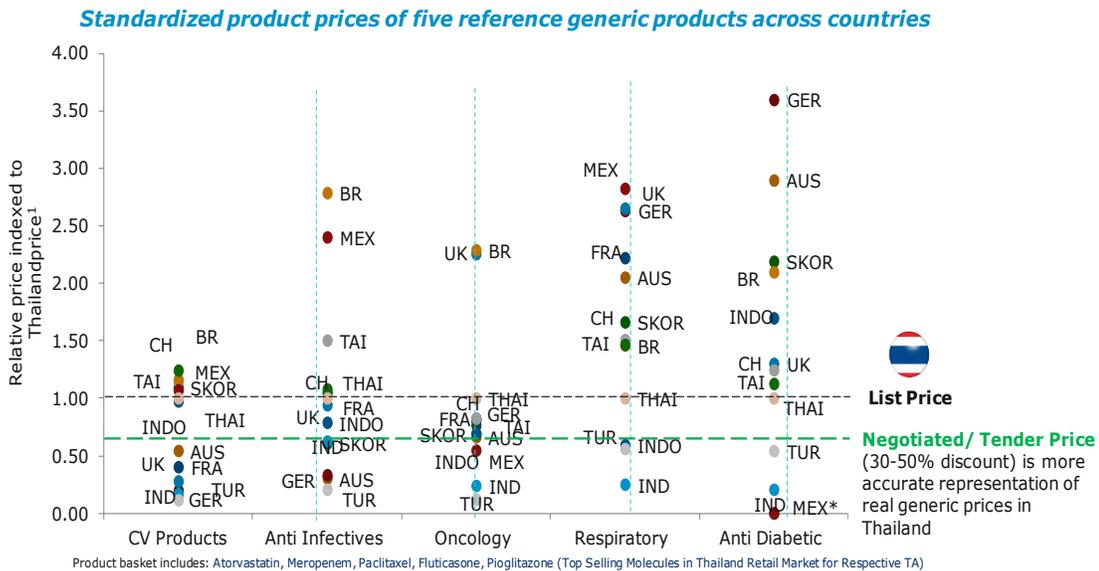
IMS MIDAS data was used for analysis of cost of generic medicines across the benchmarked countries using the following methodology:

1. Drugs from the five therapeutic areas which represent the maximum diseases burden across the benchmarked countries were identified:
  - Cardiovascular disease
  - Anti-infectives
  - Oncology
  - Respiratory disease
  - Anti-diabetics
2. The value wise top selling molecules in Thailand were selected to create a product basket and the value and volume data for selected products basket were extracted
3. The weighted (by sales) average price of all the products for each molecule and the per milligram price from weighted average price were calculated

Data from the World Bank’s **DataBank** was used for GDP per capita.

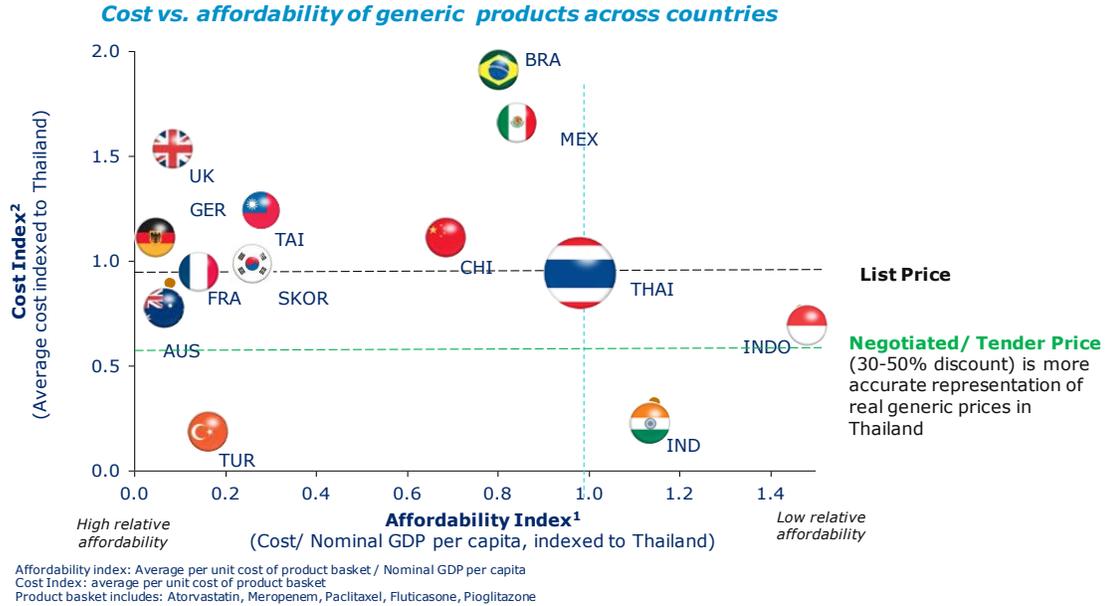
When the average per milligram price of generic medicines in Thailand market was compared with other benchmark countries, the results showed that price of generic medicines in Thailand are marginally higher as compared to the benchmarked developing countries. For some therapeutic areas such as oncology, the price of generic medicine in Thailand is higher as compared to most benchmarked countries. However, for respiratory and anti-diabetic medicine price in Thailand is comparable to other developed and developing countries. Results are shown in Exhibit 52.

**Exhibit 52:** Benchmarking of generic pricing



The affordability of generic medicines in Thailand is lower as compared to other developed market countries (Exhibit 53). In addition to higher prices, the lower affordability of generic medicines is also driven by the lower per capita GDP as compared to other benchmark countries.

**Exhibit 53:** Benchmarking of affordability of generics



**Source:** IMS MIDAS Data, only includes retail and hospital sales– does not include tender based procurement, Based on Price to Retailer/Hospital and not list price/effective consumer price, World Bank (GDP Data)– 2013, 2012

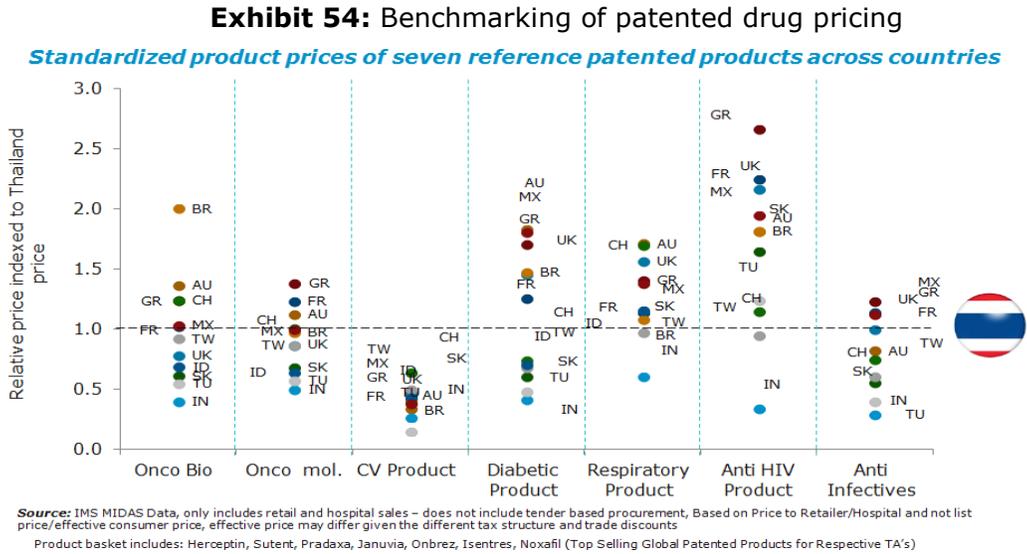
### Patented Medicines

IMS MIDAS data was used to analyse the relative cost of original medicines across the benchmarked countries. Data from the World Bank DataBank was used for GDP per capita. The following methodology was employed for the analysis of patented medicines:

1. The price of products across seven therapeutic areas representing the maximum disease burden across the benchmarked countries was compared:
  - Oncology biologics (Onco Bio)
  - Oncology molecules (Onco mol.)
  - Cardiovascular disease
  - Diabetes
  - Respiratory disease
  - Anti-HIV products
  - Anti-infectives

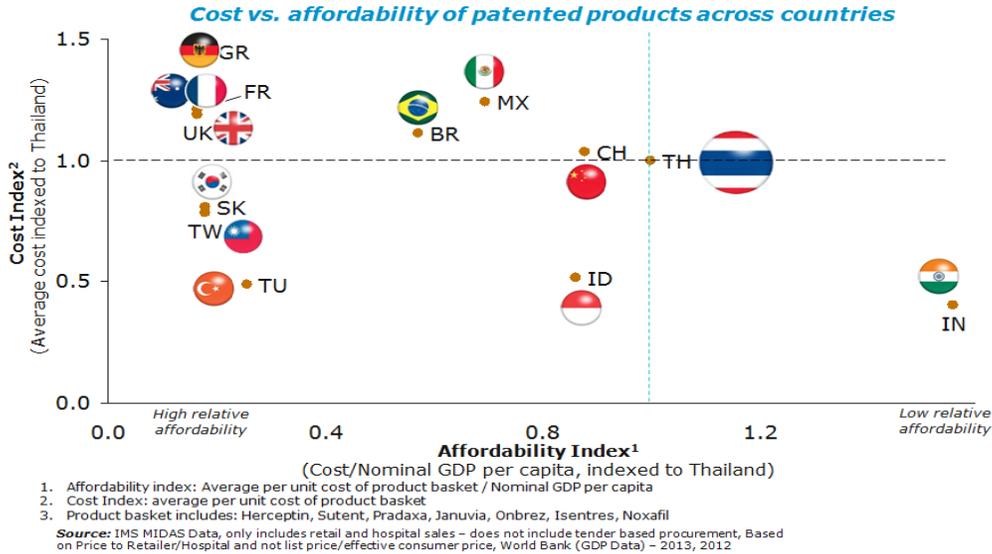
2. The top selling molecules by value in Thailand were selected to create a product basket; value and volume data for the selected products basket were extracted
3. The weighted (by sales) average price of all the products for each molecules and the per milligram price from weighted average price were calculated
4. Cost index was calculated by indexing the average per milligram cost of medicines with the price in Thailand
5. Affordability index was calculated by indexing the ratio of average per milligram cost of medicines and nominal GDP per capita to Thailand's value

For most of the therapeutic areas examined, the prices of original medicines in Thailand are equivalent to the rest of the benchmarked countries. Only the price of *Pradaxa (CV Product)* is highest (almost 200%) in Thailand, the prices in Thailand for the other TAs are around the median of benchmarked countries (Exhibit 54).



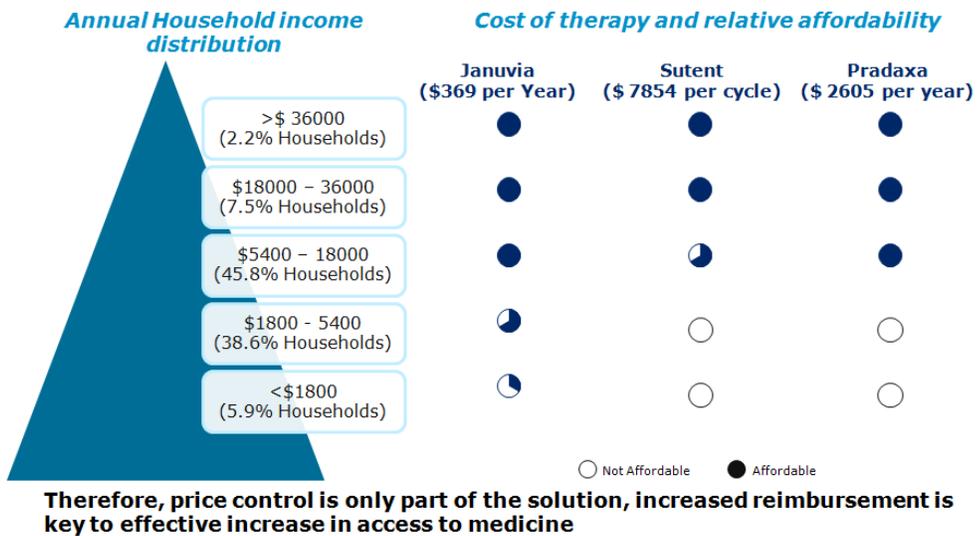
Additionally, the affordability of patented medicines in Thailand is lower as compared to other developed and low and middle income countries (Exhibit 55).

**Exhibit 55:** Benchmarking of affordability of patented medicines



Further, the affordability of original medicines varies with therapy and household income. Original medicines for chronic therapies and high cost treatment such as cancer are unaffordable for majority of the population in Thailand. Anti-cancer therapy with *Sutent*, which costs US \$7,854 per cycle, is unaffordable for almost half of the population. Similarly for cardiovascular therapy with *Pradaxa* and anti-diabetic therapy with *Januvia* is unaffordable for the 40% and 20% population respectively (Exhibit 56).

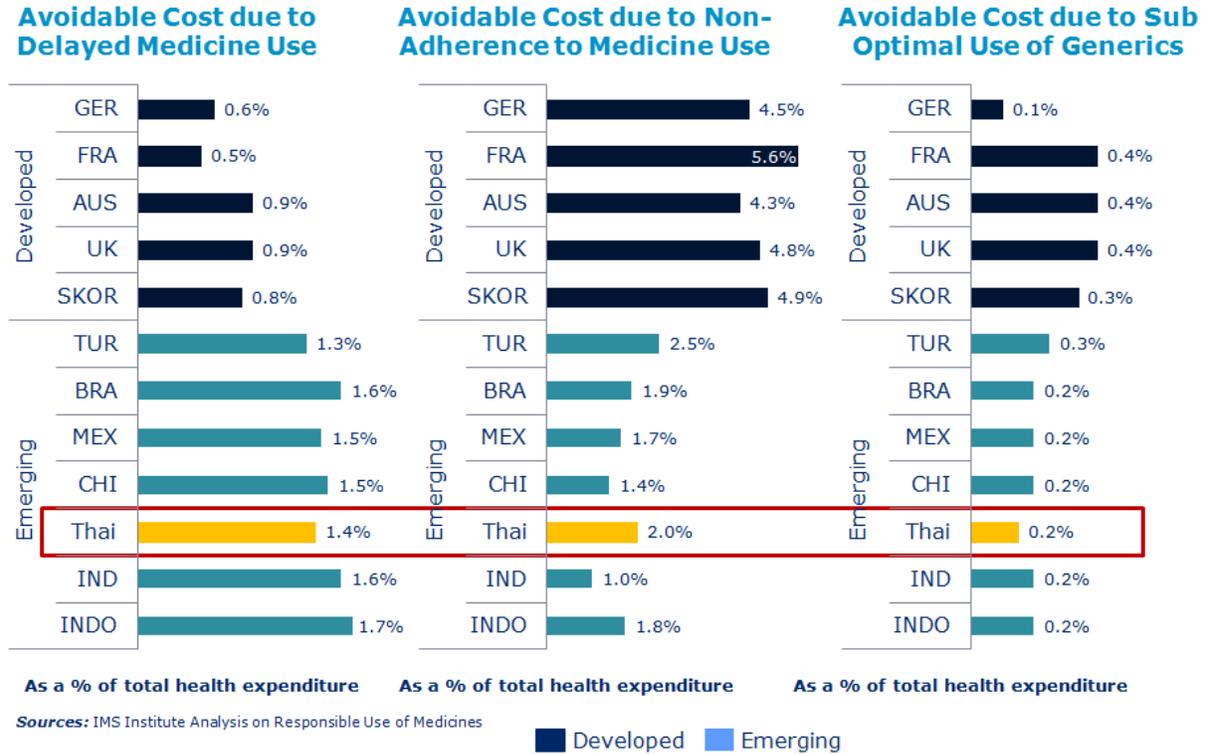
**Exhibit 56:** Benchmarking of treatment affordability



### 6.3.6 Baseline Diagnostic – Adherence

Medicine adherence refers to whether patients take their medications as prescribed, as well as whether they continue to take a prescribed medication. Medication non-adherence is a growing concern to clinicians, healthcare systems, and other stakeholders (e.g., payers / insurance providers) because of mounting evidence that it is prevalent, and associated with adverse outcomes and a higher cost of care. Exhibit 57 shows the avoidable costs incurred due to inappropriate use of medicine.

**Exhibit 57:** Avoidable Costs Due to Inappropriate Medicine Use



For adherence to medicines, three indices of avoidable cost were considered: the % of total health expenditure due to delayed use of medicine, non-adherence to medicine use, and sub-optimal use of generics. Data for this analysis was taken from the IMS Health report *Responsible Use of Medicine*.

The analysis suggests that cost incurred due to delayed use of medicine is 1.4% of total health expenditure for Thailand, which is higher than the developed market countries. However, for the other two indices, adherence and sub optimal use of generics, Thailand’s position is better than the other benchmarked countries. Overall, adherence to medicines is better in Thailand than the most benchmark countries. High level of awareness and high literacy rate (93.5%<sup>34</sup>) are the main contributing factor for adherence to medicines among Thai population.

<sup>34</sup> Census 2005

## 7 Glossary of Terms

<b>ATM</b>	Access to Medicine
<b>CDF</b>	Cancer Drugs Fund
<b>CSMBS</b>	Civil Servants Medical Benefits Scheme
<b>DALY</b>	Disability Adjusted Life Year
<b>DDD</b>	Defined Daily Dose
<b>DMSIC</b>	Drug and Medical Supply Information Centre
<b>DRG</b>	diagnosis-related group
<b>EMCI</b>	Essential Medicine Cost Index Score
<b>FDA</b>	Food and Drug Administration
<b>GDP</b>	Gross Domestic Product
<b>GNI</b>	Gross National Income
<b>GPO</b>	Group Purchasing Organisation
<b>HITAP</b>	Health Intervention and Technology Assessment Program
<b>HTA</b>	Health Technology Assessment
<b>ICER</b>	Incremental Cost-Effectiveness Ratio
<b>INN</b>	International Non-proprietary Name
<b>IP</b>	Inpatient
<b>IRP</b>	International Reference Pricing
<b>ISafe</b>	Information, Efficacy, Safety, Administration Restriction and Frequency of Drug Administration
<b>IT</b>	Information Technology
<b>LoE</b>	Loss of Exclusivity
<b>MEA</b>	Managed Entry Agreements
<b>MoPH</b>	Ministry of Public Health
<b>NDSDC</b>	National Drug Systems Development Committee
<b>NGO</b>	Non-Governmental Organisation
<b>NHSO</b>	National Health Security Office
<b>NICE</b>	National Institute of Clinical Excellence
<b>NLEM</b>	National List of Essential Medicines
<b>OP</b>	Outpatient
<b>PPA</b>	Pricing and Patient Access
<b>PPP</b>	Purchasing Power Parity
<b>QALY</b>	Quality Adjusted Life Year
<b>SoC</b>	Standard of Care
<b>SSS</b>	Social Security Scheme
<b>TRG</b>	Therapeutic Reference Group
<b>TRP</b>	Therapeutic reference pricing
<b>UC</b>	Universal Coverage Scheme
<b>UCS</b>	Universal Coverage Scheme
<b>WHO</b>	World Health Organisation