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PhAMA
'Innovative Medicines for Malaysia'

Is Reference Pricing Right for Malaysia?

An analysis of proposed pricing reforms for pharmaceuticals in Malaysia

Contents

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PhAMA
'Innovative Medicines for Malaysia'

Abstract

BACKGROUND

This paper analyzes Malaysia's medicine pricing system in the context of the country's macroeconomic environment and certain evolving healthcare trends. The paper also outlines the Pharmaceutical Association of Malaysia's (PhAMA) position on the recently proposed Ministry of Health (MoH) reforms in medicine pricing, particularly the use of reference pricing as a tool to increase affordability.

METHODOLOGY

IMS Health, an independent 3rd party provider of healthcare information, consulting and technology services, was commissioned by PhAMA Malaysia to conduct this study. The evidence presented herein is the result of a thorough review of both primary (IMS Health proprietary data) and secondary sources, including a structured review of 78 published references on international reference pricing and therapeutic reference pricing.

In addition, IMS Health leveraged its proprietary data asset, IMS MIDAS, which covers pharmaceutical sales data in more than 100 countries (representing 95% of the value of the global market), to analyze medicine pricing across countries as well as the public use of medicines following inclusion in the Malaysian Ministry of Health formulary.

Other IMS Health data assets such as IMS Knowledge Link and IMS Market Prognosis were also used to analyze medicine launch timelines and healthcare trends.

KEY FINDINGS

1. After analyzing prices for 47 branded original products (on and off patent) in the top 5 therapy areas (by sales) in public and private markets across Malaysia and 10 other Asia-Pacific countries, it was determined that medicine prices in Malaysia are not higher compared to other countries, even when considering high cost therapy areas such as oncology. In fact, prices in reimbursed markets such as Taiwan are approximately 8% higher than Malaysia on average.

2. Malaysia's healthcare expenditure, at 3.9% of GDP is at the borderline of what is recommended by the World Health Organization (WHO) as a minimum for universal healthcare coverage. Furthermore, out of pocket expenditures constitute a large portion of total healthcare spending (36%), placing pressure on household healthcare spending, especially as healthcare costs continue to rise[1].
As Malaysia aspires to achieve status as a developed nation, it will be critical to develop fair and sustainable healthcare financing, either through general revenue or the establishment of a social health insurance system.

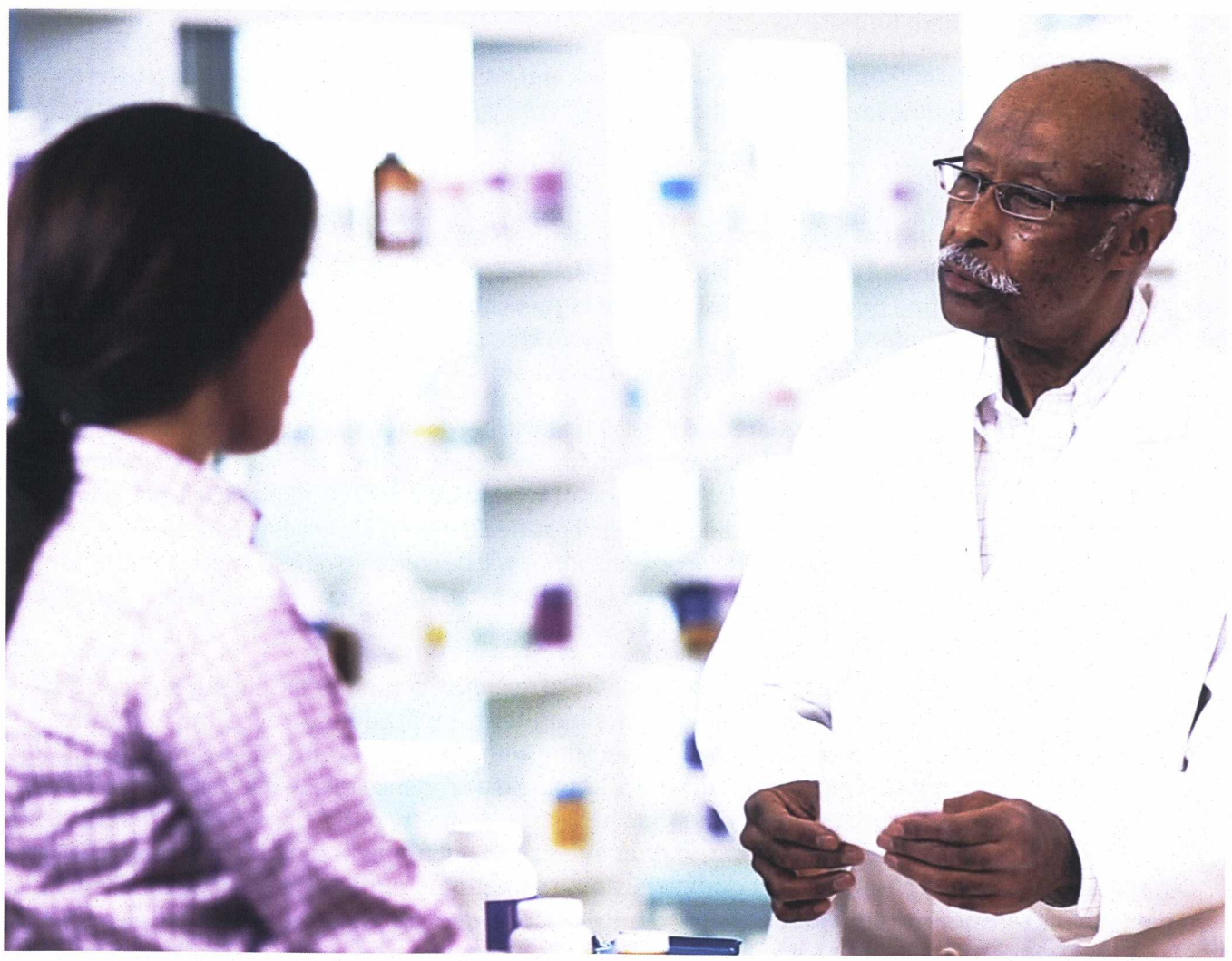
3. Analysis of published evidence shows that international reference pricing, while effective in reducing medicine prices in the short term, can have negative long-term implications on access to innovative medicines, as seen in the delayed launches and medicine withdrawals in South Korea and Taiwan. Internal reference pricing also presents certain risks, as there is a tendency to assume that all medicines are identical in the reference cluster, eroding the intellectual propriety rights of medicines that do in fact differ across efficacies, side effects and drug interaction outcomes. Internal reference pricing can also undermine the physician's freedom to customize treatment options based on the individual patient characteristics and conditions, allowing price to cloud decisions and the optimal choice.

CONCLUSIONS

As a result of the evidence available, PhAMA's position is that reference pricing is not a suitable tool to address the accessibility and affordability issues of medicines in Malaysia, as it only has a short-term impact in lowering medicine prices but does not address fundamental issues around patient access and medicine availability. Furthermore, there is evidence that the use of reference pricing as a cost containment tool can delay launches of new medicines, which could have a future impact on healthcare investments, medical health tourism, and pharmaceutical research and development, resulting in adverse effects on the country's health outcomes and economy.

PhAMA recognizes that affordability and patient access are key concerns in Malaysia, but urges the Ministry of Health to consider more sustainable and more balanced pricing and access management tools that include a broader perspective of all stakeholders needs, and that place improvements in health outcomes at the center of focus.

PhAMA reaffirms its commitment to collaborate with the Ministry of Health to improve access to medicines in Malaysia, but firmly believes that systematic and exhaustive approaches in the evaluation of medicine prices such as Health Technology Assessments (HTAs) can, and should, be employed to fairly reflect the true value of medicines brought to the Malaysian market.



Abbreviations used in this paper

- ASEAN – The Association of Southeast Asian Nations
- ATC - Anatomical Therapeutic Chemical classification system
- CAGR - Compound Annual Growth Rate
- DDD - Defined Daily Dose
- DUNas - Dasar Ubat Nasional (Malaysian National Medicines Policy)
- EMP - Ex-Manufacturer Price
- GDP - Gross Domestic Product
- GRP – Generic Reference Pricing
- HIA – Health Action International
- HIRA – Health Insurance Review Agency (S. Korea)
- HTA - Health Technology Assessment
- KRPIA – South Korea Research-Based Pharmaceutical Industry Association
- MAC – Maximum Allowable Cost
- MAT Q1 2014 - Moving Annual Total Quarter 1 2014
  (Data for a full year from quarter 2 2013 to quarter 1 2014)
- MIDAS - Multinational Integrated Data Analysis System
- MoH - Ministry of Health
- NHIA – National Health Insurance Administration (Taiwan)
- NHIS – National Health Insurance System (S. Korea)
- NICE – National Institute of Health and Care Excellence (UK)
- OECD–Organization for Economic Cooperation and Development
- OFT – Office of Fair Trading (UK)
- PBRS – Pharmaceutical Benefits and Reimbursement Scheme (Taiwan)
- PhAMA - Pharmaceutical Association of Malaysia
- PPP - Pharmacy Purchasing Price
- PRP - Pharmacy Retail Price
- TFDA – Taiwan Food and Drug Administration
- TPR - Therapeutic Reference Pricing
- WHO - World Health Organization

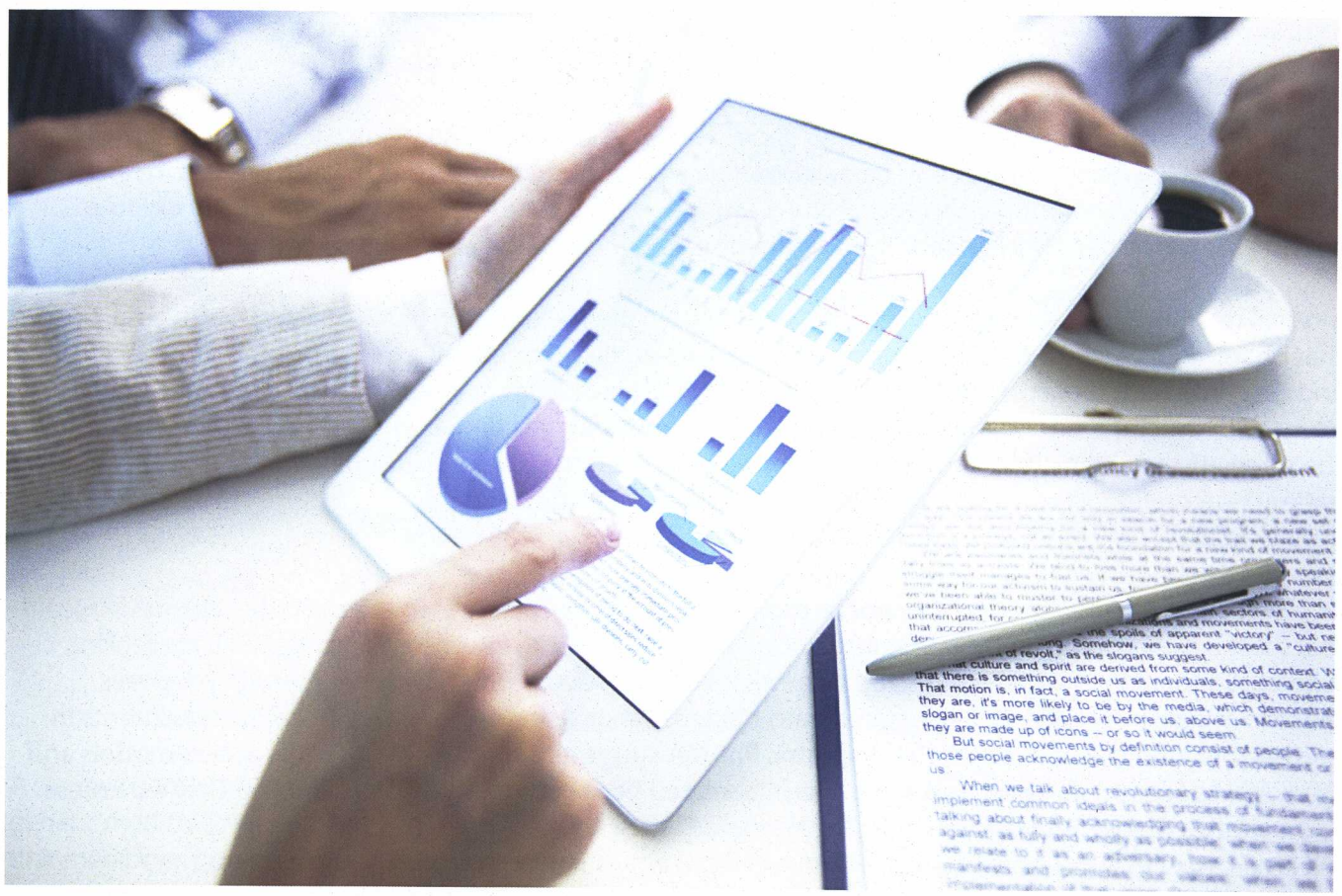
Additionally, affordability and medicine access in the context of the paper are defined as the following:

- **Affordability:** Affordability in the context of this paper is defined as "patient affordability" - i.e. patients' financial ability to gain access to medicine regardless of funding source (self pay or government reimbursed)

- Medicine access: Medicine access in the context of this paper is defined as a patient's opportunity to receive medicines, based on its availability, affordability and supply

Chapter 1: Executive Summary

Malaysia has achieved impressive health gains for its population with a low-cost health care system that provides universal and comprehensive services, funded through general taxation. However, this system is coming under considerable pressure as healthcare costs continue to rise due to changing disease patterns and lifestyle trends. In particular, Malaysia's free pricing system for medicines has recently come under scrutiny as a result of the public's perception of high medicine prices and subsequent perceptions of inequitable access and reduced affordability of medicines. This claim was supported by evidence published in 2007 (Baber), that showed in a survey of 30 commonly used medicines in Malaysia, prices for branded and generic medicines were 1.3 times higher in Malaysia than international reference prices[2,3].



Using the latest IMS MIDAS pharmaceutical sales data (MAT Q1 2014), IMS Health conducted an independent comparative pricing analysis of Malaysia and 10 Asia Pacific Countries using a common basket of 47 branded medicines across the top five therapy areas in Malaysia (by sales). The findings indicate that medicine prices in Malaysia are, in fact, not currently higher than in other countries, even when considering branded medicines in high-cost therapy areas such as oncology. For example, average prices in Taiwan are approximately 8% higher than Malaysia. Furthermore, comparing Malaysia to another middle income, semi-reimbursed market such as China shows that Malaysia's prices are, on average, 30% lower, even though its GDP per capita is 54% higher [1].

Therefore, the pricing analysis in this paper indicates that the access issues in Malaysia in fact go deeper than medicine pricing alone. Sustainable and adequate public healthcare financing continues to be a key challenge, as out-of-pocket payments constitute almost 36% of total health expenditures[1]. Additionally, in 2012 the Malaysian government spent approximately 10.7% of its total public health expenditure on medicines[2]. This is notably lower than the proportion of total public expenditure spent on pharmaceuticals in South Korea (25%) and Taiwan (25%)[3, 4].

Sustainable financing has also been linked to the availability of medicines in the public sector. The pricing research conducted by Babar and Ibrahim, evaluating the price and availability of 48 medicines from government hospitals, private pharmacies, and dispensing doctors, concluded that essential drugs are not universally available in Malaysia[5]. The availability of innovative medicines in particular is low, with only 5% of the 41 medicines listed on the National Essential Drug List and Drug Formulary of Malaysia available to the public. While reducing prices may expand the affordability of medicines in the short term, without sustainable financing, price regulation will only result in driving innovative medicines out of the market in the long term, and perpetuating availability challenges. Although the adoption of pharmaceutical innovation needs additional resources, the estimated benefit of adopting innovative medicines generally far exceeds the cost, indicating that it is a worthwhile investment to the society on the whole[6].

International reference pricing in particular should be used with caution because it can be a relatively unsophisticated tool which skews price outcomes based on the country basket, product basket, reference price and price calculation methodology used. Furthermore, it tends to be over simplistic, ignoring a country's intrinsic healthcare needs such as the disease burden and healthcare priorities.

Internal reference pricing also has its pitfalls, particularly when referencing at ATC3 levels, which assumes that pharmacologically different products in the same reference basket have the same efficacy, side effects and drug interaction outcomes. Even referencing at ATC4 levels has its risks because it assumes that drugs with different, but nearly identical, molecular structures and similar pharmacological benefits have the same efficacy, side effects and impact on individual patients. These assumptions can not only harm patient outcomes, but can also erode the benefit of patent protection and hence diminish incentives for innovative R&D[7].

However, while reference pricing may not be the solution to current access challenges, PhAMA acknowledges that there is a need to tackle the immediate pricing pressures faced by low-income patients who are seeking high-cost, innovative, patent-protected treatments for their conditions. Therefore, PhAMA proposes that the Ministry of Health considers innovative access schemes and Health Technology Assessments in partnership with the pharmaceutical industry. PhAMA suggests a number of potential access models and innovative approaches to expanding access in a related position paper entitled "Building Greater Access to Innovative Medicines – What is Next for Malaysia?"

Chapter 2:
Current and Future Malaysian Pricing System

The 2nd National Medicines Policy, or DUNas II 2013, aims to, among other goals, improve health outcomes of Malaysians by promoting equitable access to essential medicines and ensuring the availability of affordable medicines of good quality[8]. Medicine price is one of the government's key areas of focus for medicine policy due to a growing concern about the affordability of medicines for middle- to low-income patients[9-11].

A survey conducted in Malaysia in 2007 looking at 30 commonly used medicines found that branded and generic medicines were cheaper in the public than in the private sector[5, 12]. Furthermore, the study concluded that medicines from the local concession company and tender were 60% cheaper than in the private sector, but were still 1.3 times higher than the International Reference Price[5]. The study used the standard survey methodology developed by Health Action International (HAI) in collaboration with the WHO that allowed for systematic data collection, reporting, and comparative analysis of a basket of medicine prices within and across countries. The main limitation of the 2007 Baber study was its scope; the survey was a one-time, cross-sectional study with a small sample of 20 hospitals, 32 private sector pharmacies and 20 dispensing doctors[13].

In a separate analysis, IMS Health conducted a review of medicine prices in Malaysia versus other Asia Pacific countries using latest IMS Health proprietary data. The result of this analysis is discussed below.

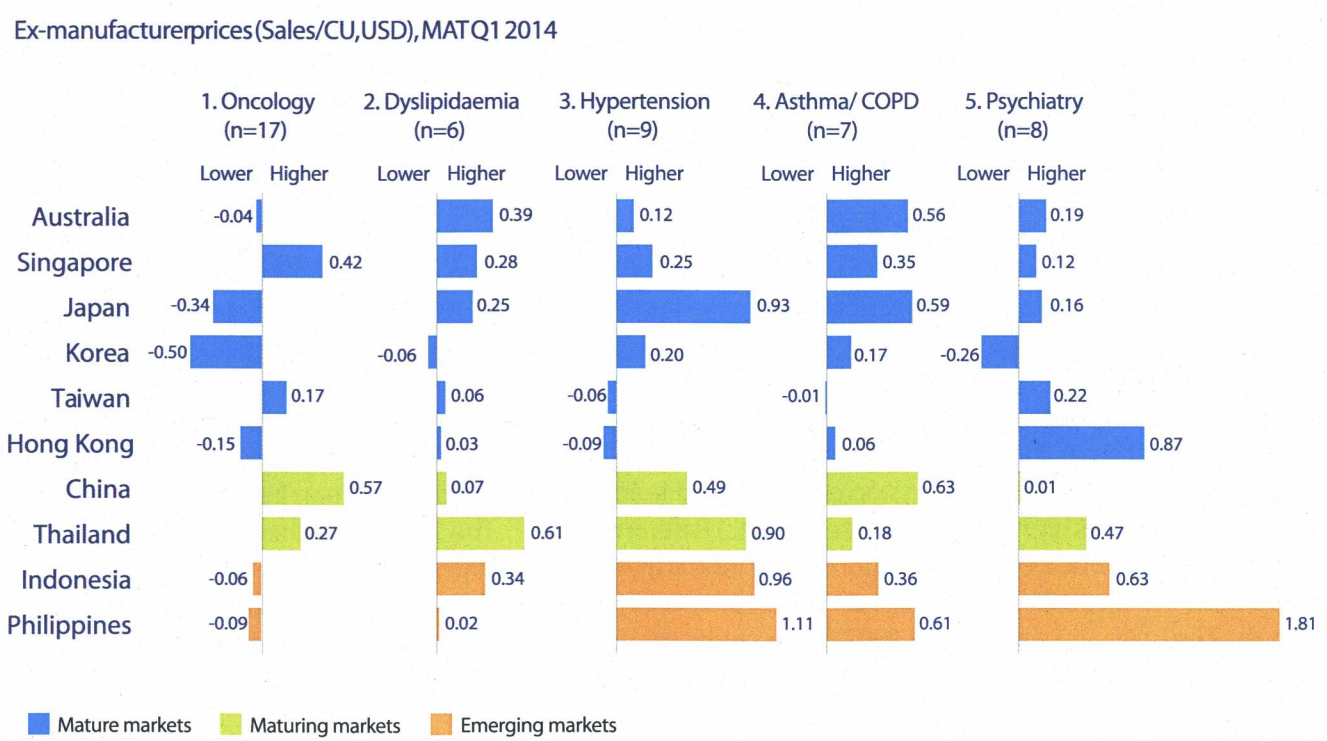
2.1 COMPARATIVE ASSESSMENT OF MALAYSIA'S MEDICINE PRICES

METHODOLOGY

IMS Health conducted a comparative analysis of prices in Malaysia versus 10 other Asia-Pacific countries using latest IMS MIDAS pharmaceutical sales data (MAT Q1 2014). IMS MIDAS data is captured through pharmaceutical sales audits, reflecting over 4 decades and 100+ countries. Data is typically collected through a sampling of indirect sales from wholesalers to retail or hospital pharmacies, and direct sales from manufacturers to retail or hospital pharmacies. This data is then projected to estimate sales for the total number of pharmacies in a country. In some countries, sampling is based on pure usage or consumption data sourced from pharmacy departments. In Malaysia, IMS Health data captures pharmaceutical sales in the government channels (100% coverage of 126 government hospitals and 3 institution hospitals via census data) and private channels (75% coverage including 152 doctors, 2869 hospital beds, 57 pharmacies and direct manufacturer panels) at ex-manufacturer prices, net of rebates and commissions.

The 10 Asia-Pacific countries reviewed were: Australia, Singapore, Japan, South Korea, Taiwan and Hong Kong as high-income Asia Pacific countries; China and Thailand as middle-income countries; and Indonesia and the Philippines as low-income countries. Singapore, Philippines, Indonesia and Thailand were also selected due to their membership in ASEAN, while South Korea and Taiwan were selected as models of countries that have adopted reference pricing systems. China and Hong Kong were included due to their semi-reimbursed systems, which are comparable to Malaysia. Finally, Australia and Japan were included to ensure price comparisons could also be made against fully reimbursed systems.

Figure 1: Comparative Pricing analysis of top 5 therapy areas across Asia Pacific countries



Source: IMS PADDS data, MAT Q1 2014
Note: Includes prescription products from all channels, including public and private sectors; Common products available in the same form(s) across markets

The analysis compared prices across a common basket of 47 original products with the same formulation in the top 5 therapeutic areas by sales across the countries. The prices compared are ex-manufacturer level across all countries to allow for like-to-like comparisons. The therapy areas included were oncology, dyslipidaemia, hypertension, asthma/COPD and psychiatry. The analysis focused on the pricing of original or branded medicines (on and off patent) and the price index was calculated using the average price (ex-manufacturer net of rebates / commission) per counting unit across all channels in each country *[see Figure 1]*. The same counting units were applied for the same product in different countries.

RESULTS

As shown in Figure 1, when indexed to Malaysia, prices across the therapy areas in other countries were, on average, higher than their Malaysian counterparts. In oncology, for example, the same basket of products in Singapore was 42% more expensive than in Malaysia.

When prices of medicines were averaged across the 5 therapy areas, prices in Taiwan was found to be approximately 8% higher than Malaysia, while prices in South Korea were 9% lower. Furthermore, when IMS Health compared Malaysia to other semi-reimbursed markets such as China, Malaysia's prices on average were approximately 30% lower, although its GDP per capita (current price, USD) is approximately 54% higher [1].

It is important to note that the average price calculation per therapy area per country included the prices of off-patent originals, which tend to have lower prices than on-patent brands, particularly in countries such as Japan and South Korea with annual or bi-annual price cuts. A simple average across products in each therapy area was chosen as the methodology versus weighting by volume due to the differing counting units of each product within any given therapy area.

2.2 MEDICINE AVAILABILITY IN MALAYSIA

In addition to medicine price, there is also evidence that availability of medicines may be a challenge, with patients not receiving treatments despite reimbursement on the MoH formulary[5]. For 41 medicines on the National Essential Drugs List and Drug Formulary of Malaysia, Babar and Ibrahim's research showed that in the public sector, median availability was 40% for the "Lowest Priced Generics", 0% for the "Most Sold Generics" and 5% for the "Innovator Brands"[5]. In contrast, private sector retail pharmacies had median availability of 43.8% for the "Lowest Price Generics", 18.8% for "Most Sold Generics" and 40.6% for "Innovator Brands"[5].

In a separate analysis, IMS Health conducted a review of medicine availability in the public and private sector in Malaysia using latest IMS Health proprietary data. The result of this analysis is discussed below.

ANALYSIS: MEDICINE UPTAKE POST LISTING IN THE MINISTRY OF HEALTH FORMULARY

METHODOLOGY

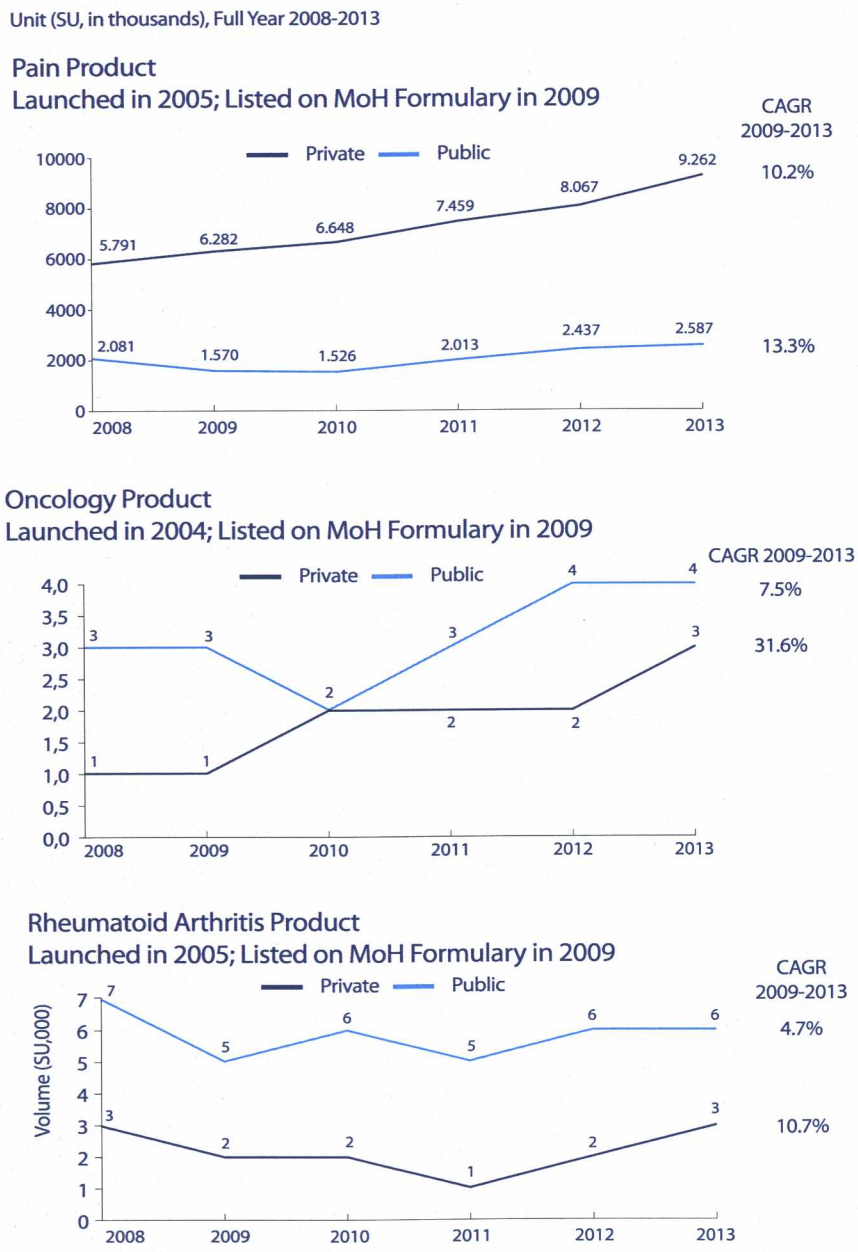
The sales uptake (by volume) of 3 high-cost branded original products in the private and public sectors was analyzed before and after listing on the MoH Formulary using the IMS MIDAS data. The products represented 3 of the top therapy areas by sales - oncology, pain and rheumatoid arthritis. The IMS Health data was collected from both the public and private sectors, as described earlier in the comparative price analysis methodology. Finally, the 2009 MoH formulary was extracted from the Pharmaceutical Services Division website to identify the listings of the three branded original medicines.

RESULTS

The analysis in Figure 2 demonstrates that there was no sharp increase in the volume uptake of these medicines in the public sector, even 4 years after listing on the MoH formulary. In the case of oncology, the growth in public sector uptake over the four-year period was about 7.5%, while the rheumatoid arthritis product saw a 4.7% growth in the same time frame. The pain product showed better public sector growth at 13%, however overall sales volumes were higher in the private sector versus the public sector.

These results suggest that, other than listing in the MoH formulary, other relevant issues such as funding availability may need to be addressed in order to improve access to medicines for patients receiving care at public facilities.

Figure 2: Volume uptake of branded original drugs after inclusion in the MoH formulary in 2009



Source: IMS PADDS data, Full year 2008-2014, Unit (SU, in thousands)

2.3 SUFFICIENCY OF HEALTHCARE FINANCING

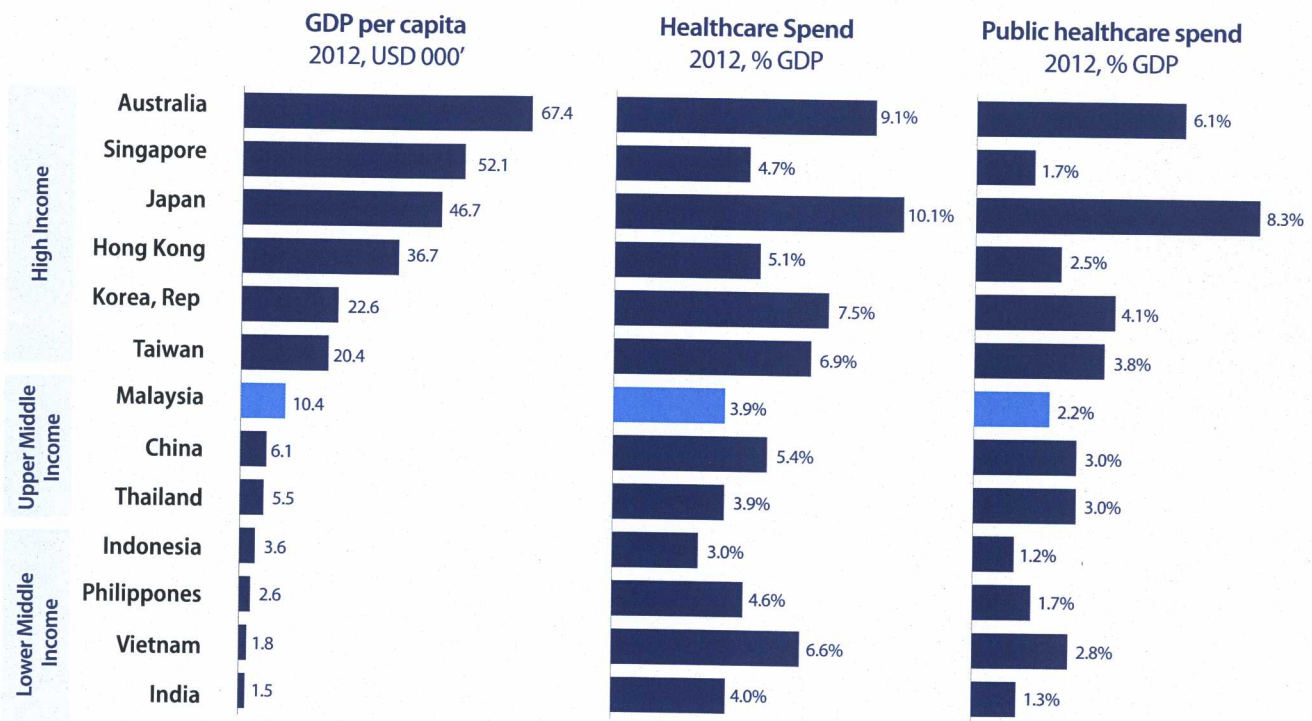
The Malaysian public healthcare system is tax-financed while private healthcare is largely funded out-of-pocket (79% of private healthcare expenditure in 2012) (14). However, demographic and lifestyle shifts have created a need for expensive, long-term treatment that public spending is finding hard to sustain. Furthermore, advancements in medical technology and a more empowered patient population are resulting in higher demands for quality healthcare services, putting additional pressure on public healthcare funding.

ANALYSIS: IS MALAYSIA'S HEALTH SYSTEM ADEQUATELY FINANCED?

According to the WHO Health Financing Strategy for the Asia-Pacific Region (2010-2015), total health expenditure should be at least 4%-5% of the GDP to sustain universal healthcare coverage, while out-of-pocket expenditure should not exceed 30-40% of total healthcare spending. Malaysia sits on the borderline, with total healthcare expenditure at 3.9% of GDP in 2012 and out of pocket expenditure at 36% of total healthcare expenditure[1].

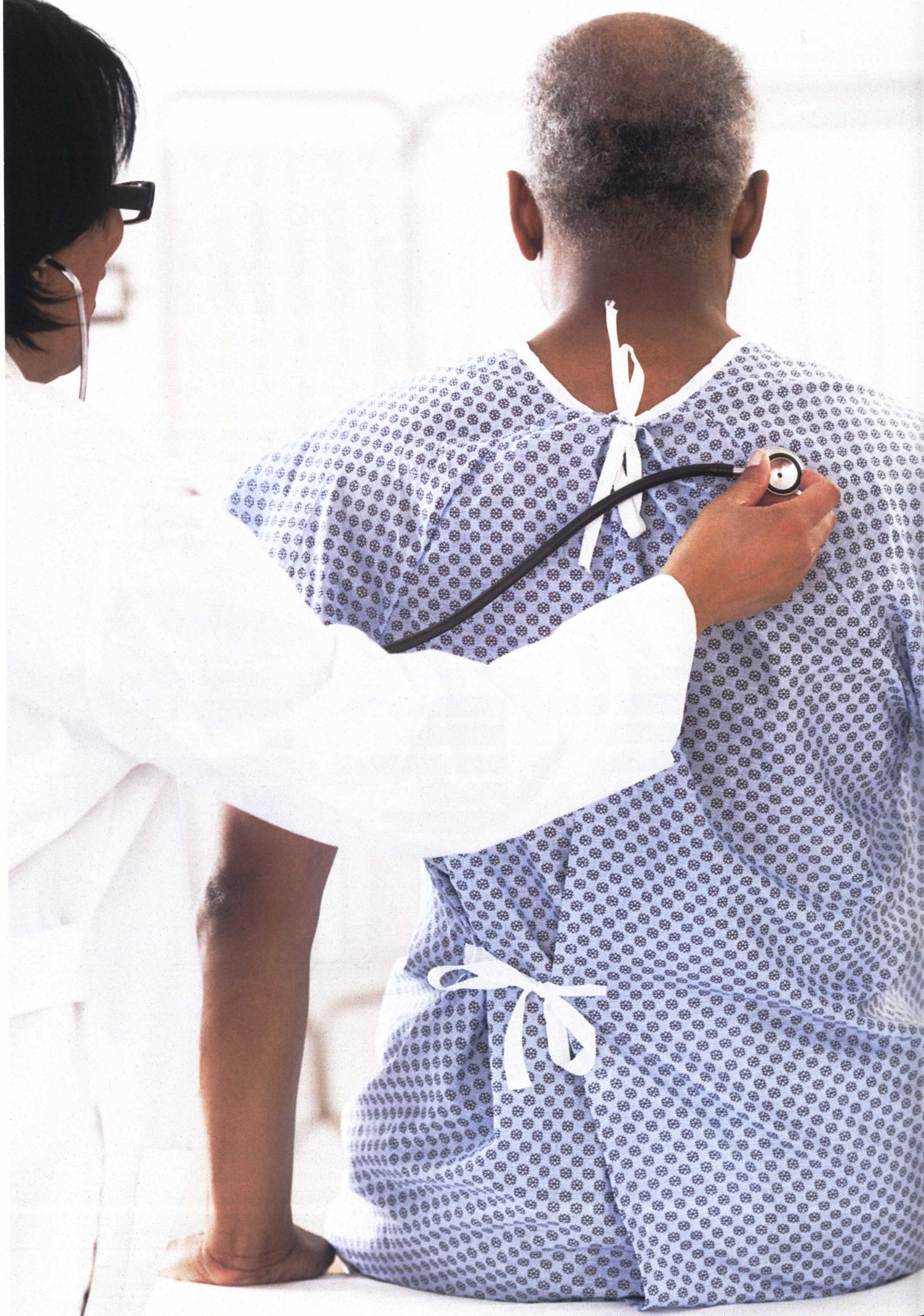
Comparing Malaysia to a broader set of Asia-Pacific markets (the ten countries used earlier, adding India and Vietnam), Malaysia has the highest GDP per capita (USD $10.4k) relative to other upper middle-income markets; healthcare spending, however, is lower by comparison *[see Figure 3]*.

Figure 3: Comparison of macroeconomic status of Asia Pacific countries



Source: World Bank 2012 (latest available data), Hong Kong Census and Statistics Department, National Statistics Taiwan

In terms of public spend on medicines, the Malaysian government spent approximately 10.7% of its total public expenditure on medicines in 2012[2]. This is notably lower than the national pharmaceutical expenditure as a percentage of public spend in South Korea (25%) and Taiwan (25%)[3, 4].



Chapter 3:
Reference Pricing as an Affordability and Access Tool

As part of the National Medicines Policy, the Malaysian government intends to address affordability and equitable access to medicines by using a national price referencing system which includes the monitoring of local and international medicine prices. In addition, the government intends to foster healthy competition in medicine pricing by introducing a Generic Medicines Policy[15, 16].

Across most countries, international reference pricing is either used as a supportive tool for reimbursement decisions or as a cost containment tool to achieve short-term reductions in medicine prices[17].
Internal reference pricing is most commonly used to regulate prices of off-patent originals and generic products, particularly to stimulate price competition and increase generic shares in the market[18].

In the following sections, the use of reference pricing as a means to increase affordability and access to medicines is discussed, including the details of price calculation methodology, the benefits and risks of price referencing, and the considerations that need to be addressed in implementation.

3.1 INTERNATIONAL REFERENCE PRICING

DEFINITION

International reference pricing, more often known as external reference pricing, is defined by the WHO as "the practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country"[19].
In general, it is used in two main contexts. First, as a pricing and reimbursement tool to support reimbursement listing; second, and in the majority of cases, as a cost containment tool that governments adopt to curb increasing healthcare expenditure[17, 20].

COMMON APPLICATIONS

Decision makers use international reference pricing primarily to inform pricing and reimbursement decisions. It is used to set medicine prices, or as a criterion to influence reimbursement negotiations, of which price is a key component. International reference pricing can either be the main decision making tool, or a supplemental tool used in conjunction with other price evaluation processes. In the majority of cases, international reference pricing is used as a supportive criterion and part of several other pricing and reimbursement tools[17].

In the current environment of increasing healthcare costs, international reference pricing has also become a tool adopted by several countries to enable cost containment and cost minimization, where medicine prices are set at the lower end of the reference basket[21].

This tendency to reference the lowest available price can have negative implications on launch decisions, as observed in Spain and Greece[22]. Where reference pricing is used for price setting, a fair application should be allowed for price adjustments - both upwards and downwards - depending on the benchmarked countries, as done in Japan[23]. As a result, Japan's prices can vary between 150% above or 75% below the reference countries prices[24].

IMPLEMENTATION

To implement international referencing, there are 4 main components to consider:

- Country basket
- Product basket
- Reference price calculation
- Infrastructure and implementation processes

While the methodology and framework for international referencing has been extensively discussed[21, 24-27], the heterogeneity of the international referencing systems in European countries has provided evidence that there is no single reference pricing approach.

Country basket

Selecting the right basket of reference countries is critical to ensuring prices are fair and comparable for referencing. Criteria used in the selection process include geographical proximity, comparable GDP levels, product country of origin and price levels of comparator products in the referenced countries[17, 20]. Pricing and reimbursement systems of the potential referenced countries should also be considered when selecting the country basket to ensure applicability of the prices referenced[28]. Finally, disease burden and trends should be comparable across the reference basket[28]. According to the WHO's working paper on external reference pricing, the choice of the reference countries should be consistent with the objectives of price regulation. Using price availability as a criterion, while pragmatic, can lead to biased results due to confidential discounts and other commercial strategies that distort the actual transaction price. The WHO paper reiterates that choosing countries of the same region and of similar socio-economic characteristics is a practical criterion that legitimises the prices obtained[24].

Product basket

The application of international reference pricing on product types also varies. It can be applied to all marketed products or to specific subgroups such as reimbursed medicines, prescription-only drugs, and patented or generic products only[24]. The status of marketing approval and the approved indications, the availability of the product and the level of reimbursement are also factors for consideration when choosing the product reference basket[29].

Overall, depending on the purpose of adopting international references, the referenced products should align across features such as formulation, packaging and approved indications.

Reference price calculation

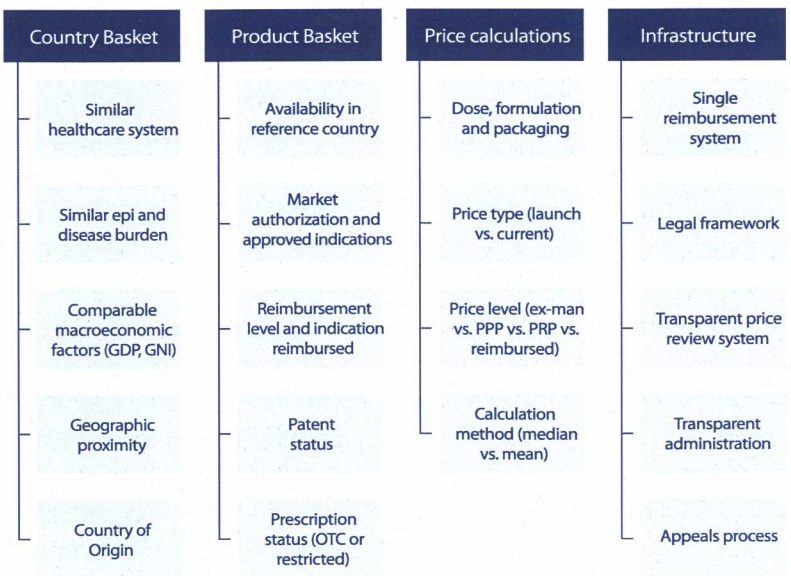
Once the purpose of reference pricing and the country and product basket has have been determined, the reference price level is then decided. Policy makers need to determine the type of prices to be referenced (launch vs. current) before deciding on the level of prices for comparison. This is because different levels of pricing data exist, such as ex-manufacturer price (EMP), pharmacy purchasing price (PPP) or pharmacy retail price (PRP). The reference price can be set either at the lowest price in the basket, at the simple average of all prices, at the weighted average of all products, or a combination of the three. Product names, packaging and dosage forms also contribute to pricing decisions [18]. When a product is new to the market and there is no pricing information available in the majority of the reference countries, a preliminary price can be determined based on available countries. Although countries do determine a target price from the reference countries, in reality, the reference price rarely becomes the actual market price. Furthermore, the price of the same product in a reference country tends to vary over time because of price adjustments and re-evaluations by local authorities[30].

Infrastructure and implementation processes

In addition to determining the countries, products and prices for reference, the maturity of the country's healthcare system and the availability of a pricing and reimbursement infrastructure also determines the success of implementing international reference pricing[21]. For countries with a successful referencing system, the following capabilities are often in place[21]:

- A detailed legal framework to allow for a transparent assessment process
- A pharmaceutical price review system to systematically select the price basket and methodically calculate prices for referencing
- A transparent administrative process with opportunities for appeals and price revisions at the request of **different stakeholders**
- A reimbursement system (since international reference pricing mostly applies to reimbursed markets)

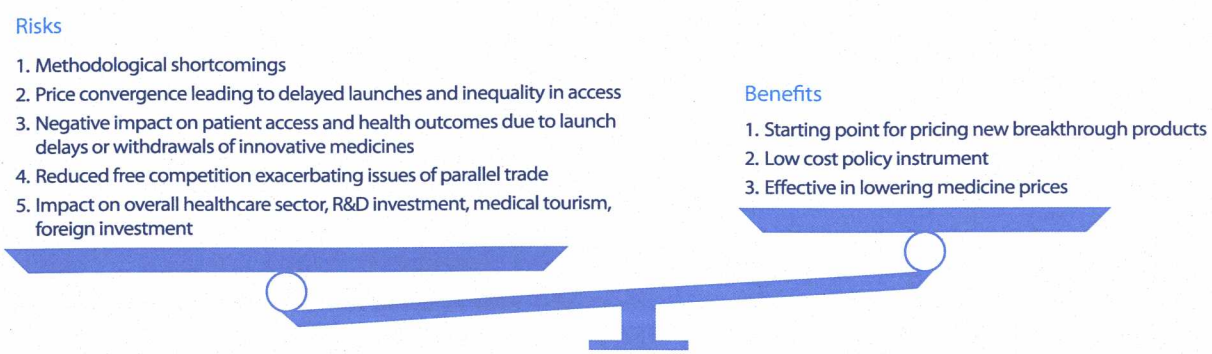
Figure 4: Considerations of an International Price Referencing System



BENEFITS AND RISKS OF INTERNATIONAL REFERENCE PRICING

International reference pricing has both benefits and risks when implemented, as summarized in Figure 5.

Figure 5: Benefits and Risks of International Reference Pricing



Benefits of International Reference Pricing

International price benchmarking

A key benefit of international reference pricing is that it allows for international comparisons and benchmarking. For breakthrough innovations with no domestic comparators, international price comparisons provide a starting point in the effort to determine the price of the product. Publicly available reference prices also provide security that payers are not overpaying in relation to countries that already have pre-determined prices. Price comparisons between countries over time can also be useful in monitoring pharmaceutical price differentials, the effects of various drug policies, and the strength of respective healthcare systems.

Low-cost price setting

International referencing is a relatively low-cost policy instrument. The government's administrative body is the main stakeholder conducting the evaluation and announcing decisions, and therefore there is little need for additional evidence or cost in the evaluation process. For smaller countries where resources are limited to pursue a standalone regulation assessment system, international referencing system can be helpful[21].

Effective cost containment

Many studies have suggested that reference pricing can be effective in bringing down medicine prices[22, 31-33]. International reference pricing has become one of the most common cost-containment tools to reduce prices for on-patent pharmaceuticals in Europe [17].

Risks of International Reference Pricing

Methodology shortcomings

One of the several limitations of international reference pricing is that it can be a relatively unsophisticated tool that can skew price outcomes if not used appropriately. The process of international reference pricing can also be over simplistic, as it relies on external factors of pricing and reimbursement in the referenced countries. Therefore, it ignores a country's intrinsic healthcare needs such as addressing disease burden or promoting effective drug use, which can lead to a negative impact on health outcomes. Furthermore, it is important to take into account differences in currency fluctuations such as exchange rates, depreciations/ appreciations and overall volatilities in order to ensure a stable reference environment[21].

Although the administration of international referencing is perceived to be simple, in order to conduct a transparent process, the system can be resource-intensive and administratively complicated due to the intensity and precision of the pricing information required[21].

With regards to the process of gathering external prices for referencing, the availability of different levels of prices is often unbalanced; some countries list prices at the ex-manufacturer level, while others at the retail level, etc. It can therefore be difficult to adjust to a consistent price level for comparison[21].

The publicly-available reference price can also be distorted by confidential arrangements such as payback, general pricing discounts and risk sharing agreements[21]. This means that the prices countries ultimately reference may not reflect the real transaction price, which can bias outcomes [21]. Therefore, as the actual cost of purchasing medicines is often unknown, care must be taken when using the list price for international reference pricing[34].

Price convergence

The long-term impact of referencing across a large number of markets may cause a price convergence that pulls down prices across the board. Reference pricing across countries often serves as a barrier to differential

pricing, a mechanism whereby prices are determined by market supply, demand and differences in the willingness and ability to pay for a product[22]. Differential pricing works in a free pricing market with less regulation of transactions between insurers, providers, and consulters, and may actually encourage and result in more competition, more medicine choices, and eventually lower costs[35, 36].

With international reference pricing, manufacturers are aware of the spillover effects of low-price countries affecting markets with bigger shares. They are therefore more cautious to voluntarily lower prices for less affordable countries[37]. In an effort to optimize their international pricing strategies, manufacturers are often pressured to keep medicine prices high in certain countries, despite loss of market share, in an effort to ensure that this price is referenced in other countries. Such a strategy ultimately negatively impacts manufacturers as it leads to sub-optimal in-country price and access decisions, while payers in the referencing countries also lose out due to higher prices[24] [38].

Impact on access to innovative medicines

International reference pricing also negatively impacts patient access to innovative medicines, and can therefore impact long-term patient health outcomes. Reference pricing leaves manufacturers with no choice but to make strategic decisions to delay access to, or not launch, products in countries that are referenced by other high potential countries[39]. Historically, evidence indicates that manufacturers have shown a preference to initiate product launches in countries with free pricing, such as the UK (before 2012), Germany (before 2012) and Sweden[26]. A study in 2005 showed that countries with lower than expected prices not only had longer launch delays and fewer products available in the market, but also the drugs available were usually older, less innovative and had weaker formulations[27, 40]. For the same reason, the absence of certain product launches has been observed in the countries such as Taiwan and South Korea. Such delays or withdrawals of innovative product launches will very likely result in negative health outcomes in the long term.

Impact on parallel trade

In Europe, international reference pricing has also contributed to an increase in the parallel trade of pharmaceuticals from lower priced countries such as Greece, which strives to achieve the lowest EU price through referencing, to higher priced countries such as the UK, where the Pharmaceutical Price Regulation Scheme (PPRS) permits free pricing of new medicines[41]. Parallel trade between such countries often leads to a shortage of medicine supplies in exporting countries[41, 42].

In general, parallel trade has a negative effect on drug safety, price and investment on innovation in the region[41-43]. In particular, parallel trade can lead to safety issues that are driven by the practice of printing of misleading information for practitioners, differences in formulation and composition information, and even the failure to translate or provide information on batch numbers and other requirements for marketing authorizations[41]. The reduced revenues to pharmaceutical manufacturers due to parallel trade also directly impacts the sustainability of R&D and development of – and investment in – innovative drug treatments[41, 42]. While parallel trade is not yet a significant issue in Asia, with the harmonization of the ASEAN, it may become a concern for patients and manufacturers in the near future.

Impact on overall investments in the healthcare sector

For investment-friendly countries such as Malaysia, international reference pricing can also have a negative impact on foreign direct investment, medical tourism and the local pharmaceutical industry. As reference pricing strategies focus solely on price and ultimately drive down profitability, manufacturers may shift their focus from attracting overall healthcare investment to winning through both pricing and commercial strategies[44]. In terms of medical tourism, where the core benefit is high quality care, delays in drug launches and availability may reduce the attractiveness of medical tourism for Malaysia.

3.1.1 CASE STUDIES: SOUTH KOREA & TAIWAN

Due to their geographic proximity to Malaysia, and their economic and healthcare development trajectories, which bear many similarities to Malaysia's own goals, a deep dive into South Korea and Taiwan provides an excellent opportunity to practically assess the impact of international reference pricing[45].

SOUTH KOREA

Introduction

South Korea runs a compulsory, fee-for-service reimbursement National Health Insurance program for the majority of the population. As the country went through extensive economic development between the 1960s and 1990s, the prevalence of acute diseases diminished and chronic lifestyle diseases became the country's biggest healthcare burden. Subsequently, healthcare expenditure has been increasing at a higher rate than economic growth[46].

Total health expenditure on the NHI increased by 11% annually in the early 2000s, while drug expenditure grew at an annual rate of 12-15% between 2001 and 2005[47]. To curb the financial burden on the government, the 'Drug Expenditure Rationalization Plan' was introduced in 2006 with a vision to reduce the percentage of drug expenditures by the NHI. Strategies to manage drug prices and reasonable drug use were implemented, including the introduction of the positive reimbursement list and a change from a price cut-oriented model to a system that considers volume consumption and total expenditure. The shift from a formula-based international reference pricing system to a negotiation-based process that considers price-volume usage, clinical benefits, cost effectiveness and budget impact, was implemented to determine which originator drugs would be included in the positive reimbursement list[47, 48].

Use of international reference pricing

The current pricing and reimbursement process in South Korea begins with an initial evaluation of the clinical usability and economic value of new pharmaceuticals by the Health Insurance Review Agency (HIRA). HIRA sets a maximum allowable cost (MAC) for all drugs listed and manufacturers then negotiate prices with the National Health Insurance Service (NHIS) within the MAC range. Prices in OECD countries, as well as those in Singapore and Taiwan, may be referenced to provide additional evidence to negotiate for higher prices with the NHIS. While the countries that are referenced are reported to vary on a case-by-case basis depending on the product, it is understood that they usually take the average of ex-manufacturing prices from countries including Australia, France, Germany, Italy, Japan, Singapore, Spain, Switzerland, Taiwan, the UK and the US[48]. However, although these international prices are often referenced, it is still an informal benchmarking process used as supporting evidence for the pricing-volume negotiations. Negotiation decisions are thought to be fairly arbitrary in South Korea and the double review process by both HIRA and NHIS often drives prices down[47].

Impact of international reference pricing & price regulation

1. Decrease in listing rates: HIRA saw a decrease in listing rates from 76% in 2006 to 67.5% in 2009, following the reform [47].

2. Lower prices of new drugs: According to the South Korea Research-Based Pharmaceutical Industry Association (KRPIA), a significant number of new drugs approved between 2007 and 2011 were priced at 43% of the OECD average; 74% of new pharmaceuticals came in at the lowest price level among other OECD countries [49].

3. Investment and launch delays: A direct consequence of low expected prices for new drugs and challenges with listing is that it has made the South Korean market unattractive for further research investments. Moreover, with the MAC being publicly available on the HIRA website, and with South Korea as a reference country for Saudi Arabia, Turkey, Taiwan, and China, manufacturers are concerned that South Korea's low pharmaceutical prices will drive down prices in these countries and are therefore holding back launches in South Korea (50). According to an IMS Health analysis comparing the launch timing of recent innovative, high-cost drugs across six therapy areas for both primary and specialty care, South Korea is consistently among the last launch countries in Asia after markets such Taiwan, Hong Kong and Malaysia. In terms of medicine availability, these medicines were launched in South Korea between 13 and 36 months after the initial launch country, resulting in barriers to patient access [see Figure 6]

Figure 6: Delay in launch of new molecules reimbursement

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	US	Germany, UK	Taiwan, US	Hong Kong, Spain, Italy, France	Korea, Australia		Japan, China	
Anti-HIV	ISENTRESS	2007	US	Australia, UK, Spain, Germany	Italy, Hong Kong, Japan	US	Taiwan	Korea	China	
CV	PRADAXA	2008	Germany, UK		Italy, Spain, France, Australia	US, Hong Kong		US, Japan	Korea, China	China
Oncology	SUTENT	2006	US	Germany, UK	Italy, Spain, France, Australia	Korea, US, Taiwan, Hong Kong		Taiwan, Japan		
Anti-Inf.	MYCAMINE	2005	Japan					US		
Respi.	ONBREZ	2009	Germany	UK	Italy, Spain	Australia	Hong Kong, Japan, Taiwan	US, US, Korea	China	

Source: IMS Knowledge Link

US Germany UK Taiwan Malaysia Hong Kong Spain
Italy France Korea Australia Japan China

TAIWAN

Introduction

Taiwan also has a national health insurance mechanism funded by premium contributions, tax revenue and employment-based funding. The National Health Insurance system is managed by the National Health Insurance Administration (NHIA) and drugs included in the reimbursement list are evaluated based on safety and efficacy data, budget impact, comparison to current alternative treatment options and the medical need of the drug from a disease burden perspective.

All new drugs also need to go through a Health Technology Assessment (HTA) process for the evaluation of clinical and budget impact[51]. Since the 2013 'Second Generation (2G) National Health Insurance' healthcare reform, the Pharmaceutical Benefits and Reimbursement Scheme (PBRS) Joint committee -consisting of representatives from the NHIA, relevant government agencies, experts, patients, employers, and medical providers - was set up to make pricing decisions for reimbursed drugs based on therapeutic value[51]. International reference pricing is used in combination with this therapeutic value evaluation and a dosage regimen ratio for reimbursement pricing decisions.

Use of international reference pricing

Each potential product to be included in the reimbursement list is evaluated by reviewing therapeutic and budget impact against the standard of care [51]. Depending on the outcome, higher international prices might be adopted to reward innovation. The 10 advanced international countries (A10 countries) referenced include:

- US Red Book prices (average wholesale price)
- Japan Ministry of Health, Labour and Welfare (reimbursement price)
- UK National Health Service Prescription Service (reimbursement price)
- Canada Saskatchewan Formulary (reimbursement price)
- Germany Rote Liste (Average wholesale price)
- France Base des Medicamentset Informations Tarifaires (reimbursement price)
- Belgium Centre Belge d' Information Pharmacotherapeutique (reimbursement price)
- Sweden Farmaceutiska Specialiteterl Sverige (reimbursement price)
- Switzerland Arzneimittel kompendium der schweiz (reimbursement price)
- Australia Pharmaceutical **Benefits** Scheme (reimbursement price)

Two mechanisms are used for calculating the reference price; the A10 medium or lowest price can be adopted, or an 'international price regimen ratio' can be applied. As reimbursement prices are decided based on future therapeutic value compared to the existing standard of care, new drugs are evaluated and categorized according to three different pricing bands.

- Category 1: Breakthrough with **significant** improvement compared to the standard of care
- Category 2A: Moderate improvement compared to the standard of care
- Category 2B: Similar therapeutic value compared to the standard of care

Products granted Category 1 status are eligible for the A10 median price. A Category 2A product is often eligible for the lowest A10 price, with the A10 median price as the ceiling. Price in the origin country, the international price regimen ratio and the dosage regimen ratio are also taken into consideration.
For Category 2B products, a price of 70% of the lowest A10 country can be considered. However for this category, internal reference pricing is most often applied, rather than international reference pricing[51].

In conjunction with this value-based reimbursement pricing system, the NHIA has also conducted discount-based price cuts every two years over the past decades in order to contain expenditures.

Impact of International Reference Pricing

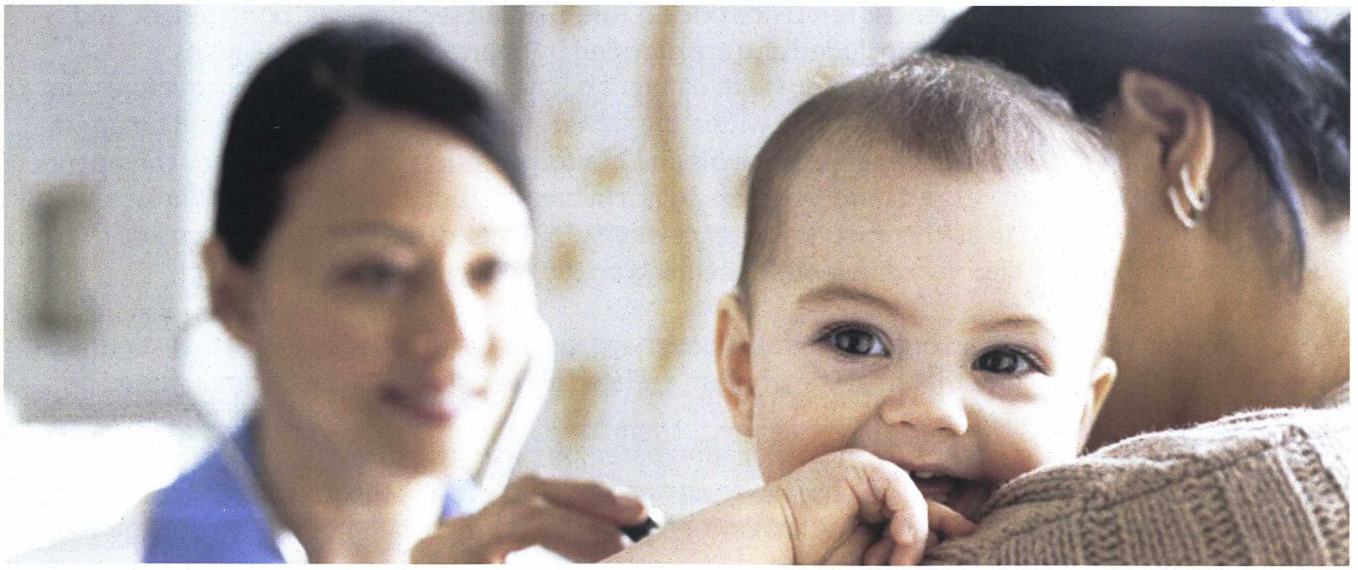
1. Lower new drug prices: Although the Taiwanese evaluation process appears to grant prices based primarily on therapeutic value, in reality the NHIA often chooses the lowest A10 price to contain expenditures whenever possible. Evidence shows that drug prices in Taiwan are considerably lower than in many mature healthcare markets, often below the 50% price level of its 10 reference countries[52]. The NHIA is very stringent with the review process and since 2011 only 6 products have been granted Category 1 Breakthrough status (IMS insight).

2. Delay in launch of new medicines: Many bigger markets around the region, including South Korea and China, reference Taiwanese prices. In fact many manufacturers launching in China have been asked to reduce prices to a level lower than that in Taiwan (3). As a result, companies are choosing not to launch, or delaying launch for up to 5 years, in Taiwan[3, 53]. For example, a breakthrough breast cancer drug that was approved by the Taiwan Food and Drug Administration (TFDA) in 2009 was eventually removed from the market as the company was not able to agree on a reasonable reimbursement price after 2 years[53, 54].

3. Withdrawal of innovative medicines: The bi-annual price cuts that have slashed innovator prices by more than 60% since 2004 have also forced many multinationals to exit the Taiwanese market[55]. Following the 6th bi-annual price review in 2009, up to 68 branded original drugs considered withdrawing[55]. One of the most commonly used oestrogen replacement therapy products also withdrew from the market after the NHIA slashed its prices by 15% in the review[55].

4. Withdrawal of local manufacturers: The issues with the government rewarding low reimbursement prices and conducting regular price cuts have not only impacted foreign pharmaceutical multinationals, but also local manufacturers; many local manufacturers now prefer to export to other countries than fighting the system[56]. The results of this decision not only impact the local business environment, but also patient treatments. In 2014, patients with Cystic Fibrosis who require an antibiotic inhaler are facing shortages, as the low reimbursed price no longer allows manufacturers to cover costs, causing a scale down in production for the Taiwanese market[57]. Due to this shortage, some private hospitals have admitted to only offering the drug to selective patients, affecting patients' fundamental rights to access medicines equally[57].

The Taiwan and South Korea case studies demonstrate that while international reference pricing may have its merits as a simple, effective tool to lower drug prices, it can also negatively impact patient access in the long term, particularly if reference pricing is used purely as a cost containment tool to drive down prices.



3.2 INTERNAL REFERENCE PRICING

DEFINITION

Internal reference pricing, including generic reference pricing (GRP) and therapeutic reference pricing (TRP), is commonly used to contain costs of reimbursed medicines and promote generic usage (20). In 2012, Dylst et al. defined internal reference pricing as more of a reimbursement system rather than a pricing system, as the reference price often establishes a ceiling for the reimbursement of drugs in a reference group.

COMMON APPLICATIONS

The main application of internal referencing is to contain public health expenditure by controlling the reimbursement level of drugs (18). It can increase price competition by stimulating manufacturers with higher priced products to lower prices and maintain competitiveness within the reference basket.

Internal reference pricing is more successful in markets where generics occupy a large market share, where there are substantial price differences within reference groups, and where medicine prices are considerably high[58]. For example, Poland has a high generic drugs market and has adopted an internal reference price system to support price competition between companies and maximize saving from generic medicine usage[18].

Internal reference pricing is also used by regulators to contain the costs of interchangeable 'me-too' products that are structurally similar to existing products. 'Me-too' products often enter the market patented, and therefore are priced higher than off-patent brands of the same therapeutic class, driving prices up[21].

IMPLEMENTATION

Implementing internal reference pricing, similar to international reference pricing, relies on systematically identifying the appropriate reference group and the price level for comparison.

Reference group

A reference group consists of interchangeable medicines clustered into the same reference price level. Depending on the breadth of classification, clusters can be defined at the active substance level, the pharmacological level, or the therapeutic class level[59].

The first and most accurately defined cluster level includes only off-patent branded products and their generic substitutes. This is a classification at the ATC5 level that includes substances with the same active ingredient and is referred to as 'generic reference pricing' (GRP). At the second level, both generic and on-patent original products can be included and are grouped by pharmacological similarities. This grouping is at the ATC4 level, where drugs with different but nearly identical molecular structures and similar pharmacological benefits are included within the same reference group. The third and broadest cluster includes generics, off and on-patent originals and me-too products, and is defined by therapeutic class (ATC3 level). These second and third levels may differ in breadth, but are qualitatively similar and together, they are referred to as 'therapeutic reference pricing' (TRP) *[see Figure 7]* [60]. For instance, Glucophage could be classified very differently depending on the ATC level used for grouping.

At ATC-1 (classification based on organ system), Glucophage would be classified as a 'metabolism' drug, along with all other medicines that treat 'metabolism' - related issues. At ATC-2 (Classification based on therapeutic subgroup), Glucophage would be classified as a 'diabetes' drug, along with all other medicines that are used to treat diabetes. At ATC-3 (Classification based on pharmaceutical subgroup), Glucophage would be classified as an 'oral blood glucose lowering agent' along with all other medicines that are oral blood glucose lowering agents. At ATC-4 (Classification based on chemical subgroup), Glucophage would

be classified as a 'Biguanide,' along with the other medicines that are members of the Biguanide class, including –Phenformin, Buformin, and Proguanil. At ATC-5 (Classification based on a chemical subgroup), Glucophage would be classified with patented and off-patent molecules with similar active ingredients.

Figure 7: Reference price groups

Therapeutic Reference Pricing (TRP)	Level 3	Defined by therapeutic class (ATC 3 level)
	Level 2	Defined by pharmacological class (ATC 4 level)
Generic Reference Pricing (GRP)	Level 1	Defined by active ingredient (ATC 5 level)

Price level

Similar to international reference pricing, regulators can set generic reference pricing and therapeutic reference pricing at either the average, weighted average or lowest price level of the reference group. Manufacturers can choose to set prices above the reference price, but this often means patients would co-pay the surplus in a reimbursed market [25]. Often, the difference in price level between the reference price and manufacturer set price will influence the potential of generic competition and the competitive price advantage of generic products, as seen in Poland [61].

For therapeutic reference pricing, due to the variations in dosages and forms between products within a given reference group, equivalent therapeutic doses need to be calculated and adjusted to enable like-to-like comparisons. However, due to the complexity of calculating therapeutically equivalent doses, reference prices are often grouped by the WHO-calculated defined daily dose (DDD), or cost of daily treatment [61].

The DDD is a unit of measurement used for presenting drug utilization statistics that reflects the average maintenance dose per day for the drug's main indication in an adult [62]. It is the most convenient measurement that takes into consideration variations in pack sizes and dosages between active ingredients.

BENEFITS AND RISKS OF INTERNAL REFERENCE PRICING

Benefits

Cost containment and generic usage promotion

Internal reference pricing can be used to increase generic market share. The reference price is calculated as a function of medicine prices and the number of generic competitors available. For reference groups with fewer generic competitors, a higher reference price is awarded to encourage future market entries of generic companies. For reference groups with a reasonable number of generic products, lower reference prices are set, as increasing price competition is the main objective [18].

Risks

Methodological shortcomings

The WHO-defined DDD is, in reality, not suitable for drug cost, pricing and reimbursement decisions as it is not a true reflection of therapeutically equivalent doses of different drugs and can change over time or differ between patients and countries [62].

Additionally, a product may have multiple indications, and may vary in efficacy, tolerability and adverse effects [63]. In situations where physicians make prescription decisions based on financial savings over clinical reasons and patient's interests, therapeutic reference pricing becomes a negative strategy in the system.

Low short-term cost savings

Whether internal reference pricing really generates savings in the long term is debatable. From a short-term perspective, it can result in substantial savings, especially in the first year of application. However, such results are thought to be short-lived and focused on the individual medicine level, rather than at the total pharmaceutical expenditure level [18, 64]. This is because, especially for therapeutic referencing, often only off-patent originals and generic substitutes are included in the therapeutic reference group [18, 64].
A study conducted by Koskinen H et al. suggests that the additional cost savings from reference pricing after previously-implemented generic substitutions are comparatively low[65].

Negative impact on patient outcomes

Therapeutic reference pricing, at both the ATC3 and ATC4 level assumes that all products treating the same condition are interchangeable, regardless of variations in efficacy, side effects, drug interactions and the individual patient needs [66]. By applying such a 'one-size-fit-all' formula to all drugs in a therapeutic category, or that are pharmacologically similar, prescription decisions may be based on price rather than the physicians' opinions, which negatively impacts health outcome [67]. Not surprisingly, studies have shown that therapeutic reference pricing is associated with greater discontinued use of, and lesser adherence to, medicines as patients may not ultimately receive the optimal medicine for their condition or situation [7].

The concern over therapeutic referencing and patients' subsequent negative health outcomes due to switching medicines is also often discussed. When new products are included in the reference group and patients are moved from a more expensive to a cheaper version, switching behaviors may increase, resulting in higher consumption of healthcare services and a reduction in compliance, negatively affecting both the patient's overall health status and the burden on the healthcare system.

For example, studies in Germany and British Columbia have shown that patients who have undergone medicine switching showed an increase in the number of physician visits or hospitalization rate, potentially due to the need of monitoring treatment outcomes [39, 61, 68].

Inhibiting innovation

Evidence has also shown that internal reference pricing leads to an increase in the inclusion of cheaper drug options within the reference group. To secure sales, manufacturers avoid reference pricing for the more expensive innovative drugs, leading to the inclusion of less effective, older drugs in the therapeutic reference group [61].

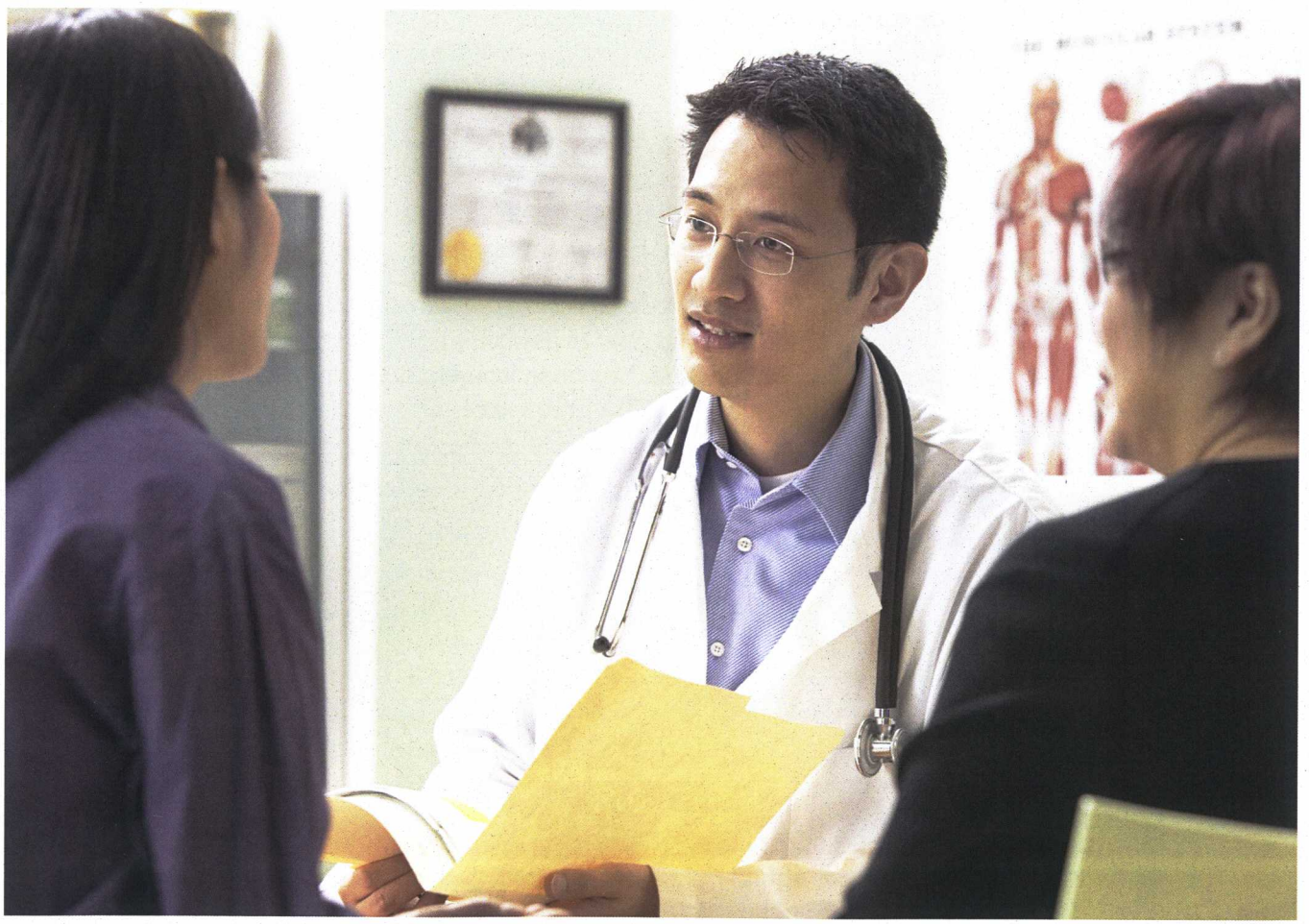
When different medicines are assumed identical and incremental improvements of drugs within a cluster is not recognized or rewarded, future innovation is often inhibited (60, 69). Furthermore, therapeutic reference pricing can erode intellectual property rights by either keeping prices artificially low, or, suppressing physician prescribing demand for medicines priced higher than the reference price for a medicine [7].

3.3 ADDITIONAL CONSIDERATIONS ON PRICING REGULATION

Free pricing has its advantages as it encourages effective competition and fosters a more demand-oriented pharmaceuticals market. However, if a price regulation system needs to be in place, it should recognize the science backing the innovation of the product and offer a rigorous and transparent evaluation process that is predictable and adequately rewards innovation. Health Technology Assessments, covered in a related publication ("Building Greater Access to Innovative Medicines – What is Next for Malaysia?") is one such mechanism that should be considered by the Ministry of Health.

Another is value-based pricing, which links the pricing of the medicine to the value achieved rather than volume. Value-based pricing regulation has been suggested as a replacement for the UK Pharmaceutical Price Regulation Scheme in the Office of Fair Trading (OFT) report. This would establish a maximum price for a pharmaceutical based on an ex-ante evaluation for new products and a rolling ex-post evaluation of existing products. The evaluation would be based on the existing NICE type cost-effectiveness evaluations [70]. However in November 2013, the UK government stalled their plans for a 'value-based pricing' system, announcing that pharmaceutical companies were still allowed to set prices for new products. It appears as though one of the key underlying concerns that still remains with moving from a free pricing system to value-based pricing is the potential risk of research and development investments moving overseas [71]

The UK example illustrates that moving away from a free pricing environment and adopting a price regulation system, even one that is value based, poses potential risks to the overall economy and should be carefully evaluated before implementing.



Chapter 4: Conclusions

PhAMA recognises that Malaysia is in need of certain healthcare policy changes, driven by increases in demand due to changing lifestyles, disease trends and the rising costs of healthcare services. However, PhAMA would suggest that the Ministry of Health utilize tools other than reference pricing to ensure that a sustainable and balanced approach is used to achieve cost savings while ensuring patient access the medicines they need. Specific points of consideration from PhAMA are as follow:

- Price regulation, particularly reference pricing, is not the ideal solution for expanding affordability and ensuring equitable access. Reference pricing is typically used as a supportive tool for pricing and reimbursement decisions and cost containment.
- International reference pricing should be used with caution because it can be a relatively unsophisticated tool which skews price outcomes based on the type of country basket, product basket, reference price and methodology used. Furthermore, it is overly simplistic and ignores the country's intrinsic healthcare needs such as the disease burden and healthcare priorities. Therefore, it can lead to unfavorable outcomes such as price convergence, parallel trade, innovator medicines withdrawals or delayed launches that have long term impacts on patient access, health outcomes, innovation and healthcare investment.
- If used, international reference pricing should not be applied to all drugs, but more selectively - for example, for adjusting the price of the essential genericised medicines that are perceived to have higher costs in Malaysia versus other countries.
- Pricing of, and access to, innovative, high-cost medicines should be governed by clinical and cost-effectiveness criteria through a systematic, evidence-based approach, such as Health Technology Assessments, to ensure the value of a medicine is appropriately rewarded. To reduce cost burden on such treatments, risk share agreements and patient assistance programs should be considered.
- Internal reference pricing such as therapeutic reference pricing, even at the ATC4 level, presents many risks as the methodology assumes that medicines, as well as the patients who need them, are identical and ignores intellectual differences in medical need and design. If therapeutic reference pricing needs to be applied, it should not be applied any lower than ATC5 to compare medicines with active ingredients that have been proven to be therapeutically equivalent.
- Medicine prices are only a "symptom" of the real challenges faced by the healthcare system in Malaysia. The true underlying issues lie with healthcare financing and medicine availability. These structural issues need to be tackled by rethinking the financing and access model of medicines in the public sector. A separate whitepaper, "Building Greater Access to Innovative Medicines – What is Next for Malaysia?" suggests a number of innovative strategies for the Ministry of Health to explore with industry stakeholders to address the current issues of financing and access. Although the adoption of pharmaceutical innovation needs additional resources, the estimated benefit of adopting innovative medicines generally far exceeds the cost, indicating that it is an investment to the society and on the whole worthwhile[6].
- With regards to pricing in particular, there are more sustainable ways to ensure that prices fairly reflect the level of innovation and usage of a product. One such approach is value-based pricing. In addition, risk sharing agreements with the manufacturers can be used to hedge against financial or performance related risks [see "Building Greater Access to Innovative Medicines – What is Next for Malaysia?"]

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Innovating for a Healthier, Economically Vibrant Nation

OUR VISION

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

OUR MISSION

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

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

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