



What Drug Price Controls in Malaysia Mean for the Pharmaceutical Industry

On May 2, the Malaysian Cabinet announced that price control measures for pharmaceutical drugs would be implemented in 2019. With mentions of “external reference pricing” and “price ceilings at the wholesale and retail levels,” sweeping drug price controls that are potentially benchmarked to substantially lower prices in other countries could mean a significant impact that cascades across the pharmaceutical value chain, from the retail side to manufacturers. But before alarm bells ring, industry players must keep in mind that there are various price control mechanisms yet to be considered and potential hurdles to overcome that will determine the extent to which they are impacted by new price regulations and the corresponding action they should take.

What do we know (and not know) from the recent announcement?

The recent announcement made clear three key intentions of the Malaysian government:

- External reference pricing (ERP) will be used to benchmark against cheaper drug prices in other countries

- The ceiling price set will be an average of the three lowest prices identified
- Price controls will be implemented at both the wholesale and retail levels (i.e., at clinics, hospitals and pharmacies)

However, the specific mechanisms to be used to implement ERP are yet to be determined, including:

- Countries against which Malaysia is to be benchmarked
- Drugs to be targeted by the price controls

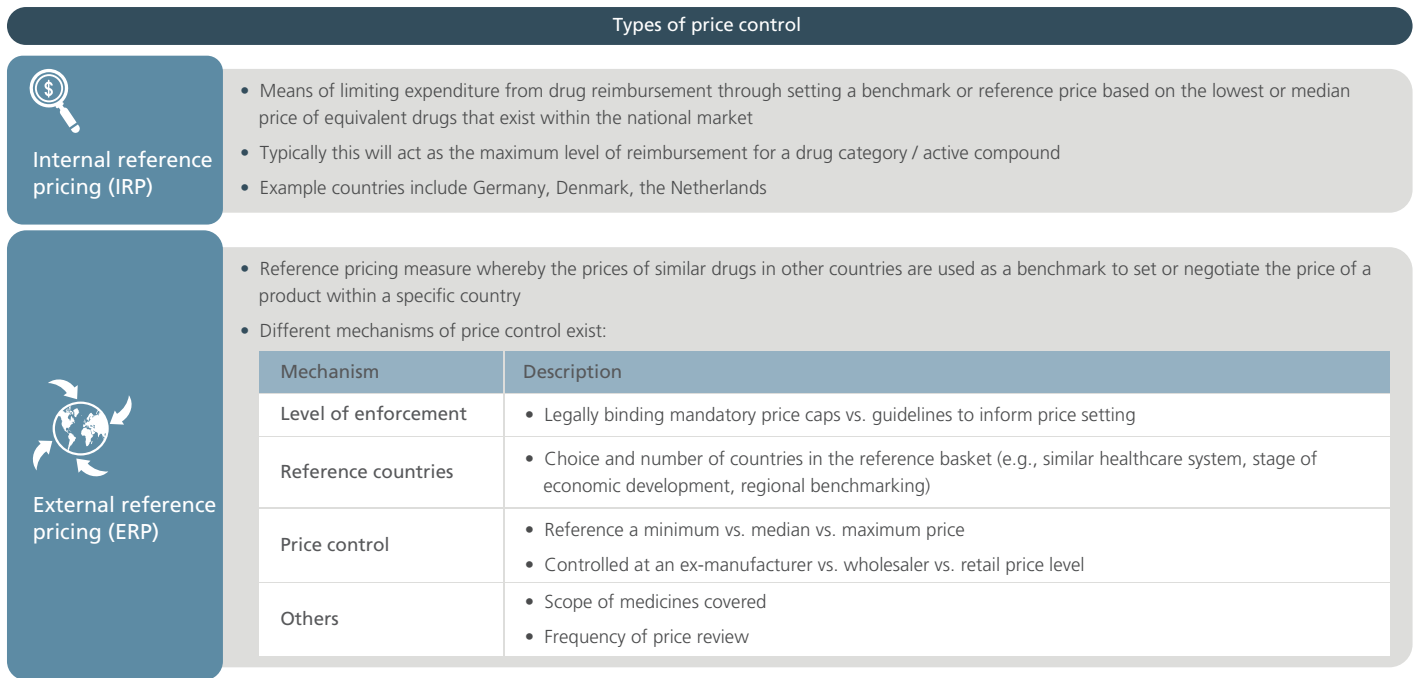
What is reference pricing and how is it implemented?

Before delving into the impact of reference pricing in Malaysia, we took a look at what the process entails and how it is enforced in different countries around the world.

Reference pricing is an approach used by policymakers to cap drug prices and hence contain healthcare costs in a country. Reference pricing can be done either internally or externally (see Figure 1 on page 2). Internal reference pricing (IRP) compares pricing across equivalent drugs within a country, and external reference pricing (ERP) compares pricing of similar drugs in another country or a basket of countries.

A study of reference pricing across a variety of countries (see Figure 2 on page 3) reveals that different pricing mechanisms and enforcement approaches are used to implement price controls. While methods may vary, it is important to note that

Figure 1
Types of reference pricing



Source: WHO; RAND; L.E.K. research and analysis

reference pricing is typically implemented only on drugs that are publicly reimbursed, with manufacturers and retailers free to set prices for the private pay or out-of-pocket market.

What is the likely outlook for implementation of price controls in Malaysia?

There are three stages of price controls that are likely to unfold in Malaysia (see Figure 3 on page 4).




- Stage 1:** Initial rollout of the program in the next one to two years is likely to focus on the public sector, where price controls are most easily enforceable, as evidenced by other countries that have implemented reference pricing. Additionally, price controls are likely to target high-value or potentially single-source or originator drugs, as drug prices in Malaysia across mature therapy areas are already, on average, lower than they are in other countries (see Figure 4 on page 5).
- Stage 2:** The next stage of rollout over a three- to four-year time frame will likely continue to stay focused on the public sector, but with price control mechanisms established in Stage 1 extended to a broader range of drugs, including generics, where even small price adjustments to high volumes could yield significant cost benefits to the public payer.

- Stage 3:** The final stage of rollout at five years and beyond may see some efforts made toward containing prices in the private sector. However, these are likely to come in the form of pricing guidelines rather than legally binding controls that could risk violation of WTO free trade agreements. But in the nearer term, price containment efforts for the private sector may also come in different forms, such as a database for drug price transparency that mandates disclosure of ex-manufacturer, wholesaler and recommended retail price and is then made available to the public.

The rollout of price controls in Malaysia is also contingent on authorities overcoming other hurdles such as the affordability vs. access trade-off, among others. Key considerations include:

- Ensuring that pharmaceutical companies are not dis-incentivized to bring innovation into the country or to list innovative drugs in Malaysia's Blue Book; this would diminish access to drugs by a large portion of the population that is reliant on public reimbursement
- Preventing stakeholders across the pharmaceutical supply chain with potentially thin margins from running out of business, which would further limit access to medicine

Figure 2
A comparison of reference pricing across select countries

Country	Board	Products	Mechanism
 Australia (1960)	Pharmaceutical Benefits Pricing Authority (PBPA)	All PBS-listed drugs (originator drugs and generics)	<ul style="list-style-type: none"> Reference pricing is set for groups of drugs that are deemed to be interchangeable (i.e., with similar safety and health outcomes, including both originators and generics); the lowest-priced medicine sets the maximum reimbursement amount for a drug in the same cluster Manufacturers are required to disclose sales revenue, volume and discounts through which a weighted average disclosure price (WADP) is calculated If currently approved ex-manufacturer prices (AEMP) are more than 10% above the WADP, the current AEMP is then reduced to the new WADP
 Japan (1961)	Chuikyo (Central Social Insurance Medical Council)	Originator drugs	<ul style="list-style-type: none"> Prices are determined through cost-based analyses (for a new drug), or through benchmarking to other similar drugs within the country Further adjustments are made by then benchmarking to prices in France, Germany, the U.K. and the U.S.
		Generics	<ul style="list-style-type: none"> A factor is applied based on the price of the originator, which varies depending on the number of other brands in the market and type of formulation (biosimilar, oral preparation, etc.)
 Taiwan (1995)	National Health Insurance Administration (NHIA)	Originator drugs	<ul style="list-style-type: none"> External reference pricing is based on the median retail price in Australia, Belgium, Canada, France, Germany, Japan, Sweden, Switzerland, the U.K. and the U.S.
		Generics	<ul style="list-style-type: none"> Prices are capped at 80% of the lowest listed originator price, and prices of subsequent generics cannot exceed the lowest price of generics already listed in the reimbursement scheme that have the same ingredient, specification, dosage form and dose
 Korea (2000)	Health Insurance Review and Assessment (HIRA)	Originator drugs	<ul style="list-style-type: none"> Maximum allowable price (MAP) is set through external reference pricing of the average wholesale prices of the same drug in Germany, France, Japan, Italy, Switzerland, the U.K. and the U.S. No markup is allowed between the wholesale price and the retail price; instead, the government provides retailers with a fulfillment fee for each filled prescription
		Generics	<ul style="list-style-type: none"> There has been a single price system since 2012: off-patent originators and their generic counterparts are priced uniformly at 53.55% of the prices of the originator before patent expiry
 South Africa (2004)	Pharmaceutical Economic Evaluations (PEE) Directorate	All drugs	<ul style="list-style-type: none"> A single exit price (SEP) was set for drugs sold in the private sector to limit allowable markups from dispensing pharmacists on four different tiers (5%-46%) depending on the type of drug External reference pricing is done for both on- and off-patent products based on ex-manufacturer pricing in Australia, Canada, New Zealand and Spain A number of other policy changes were introduced with SEP, including mandatory prescription of at least one generic where available, as well as the removal of bonuses and trade discounts

Source: Pharmaceutical Benefits Scheme (PBS), Australia; Ministry of Health, Labour and Welfare (MHLW), Japan; National Health Insurance Administration (NHIA), Taiwan; Health Insurance Review & Assessment Service (HIRA), Korea; World Health Organization (WHO); L.E.K. interviews and analysis

- Establishing the right capabilities to execute and monitor price control mechanisms
- Aligning initiatives to a fundamental Ministry of Health objective of decongesting public hospitals, where drug price controls alone may be insufficient as drugs may only be a smaller proportion of spend.

What are the implications of implementing price controls on the industry?

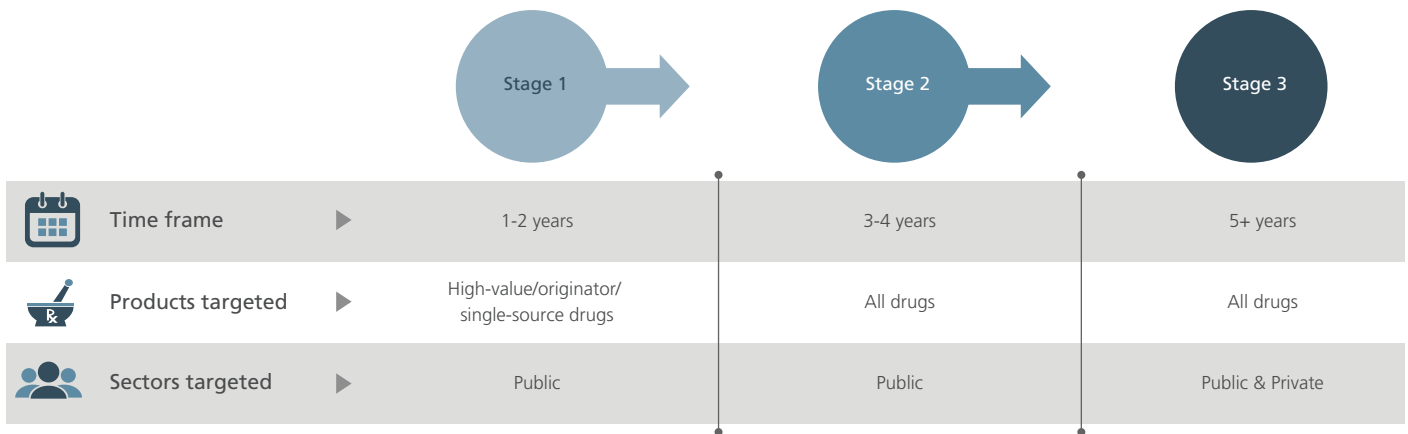
The implementation of price controls and effective capping of trade margins for drugs in Malaysia are expected to cascade across the pharmaceutical value chain, affecting clinics, hospitals and pharmacies, as well as distributors and drug manufacturers.

The degree of impact, however, will likely depend on the distribution of product markups across the value chain, where those with the highest markups are expected to face the greatest margin pressures. How the industry responds and what strategies participants adopt to minimize the impact on their bottom line will vary. Overall, with price controls primarily affecting publicly reimbursed drugs, strategies adopted by industry players will need to lean more heavily toward capturing value in the private sector and on other value-added services.

Hospitals/clinics

Service providers will effectively need to reduce their reliance on high-margin prescription drugs in order to drive overall profits. Instead, they will need to seek additional value capture through incremental revenue streams.

Figure 3
Likely rollout of price controls in Malaysia



For example, hospitals could try to ensure that patients continue to fill prescriptions for ongoing treatment at the hospital rather than switch to retail pharmacies after the initial sale. Additionally, strategies to ensure patient retention and loyalty to the hospital or clinic can also support future revenue streams. Digital solutions could prove to be invaluable in pursuing these patient retention strategies, allowing service providers to follow the patient beyond the hospital or clinic to maintain ongoing touch points and communications.

Distributors

As the middlemen in the value chain, distributors should first and foremost consider strategies to contain their product exposure. Price controls are expected to affect pharmaceutical prescription drugs, and exclude OTC, consumer health and MedTech products for the moment. Furthermore, pharmaceutical portfolios that have a substantial contribution from high-value, originator or single-source products are likely to come under more scrutiny in the near term. Hence, distributors could look to diversify their portfolios and seek principal partnerships that can minimize over-indexing to high-risk products.

Distributors could also consider expanding revenue streams through value-added services for manufacturers, such as account management, leading customer price negotiations, credit management and debt collection. They could also consider a range of potential services and digital solutions for customers, such as solutions for inventory and supply chain management, and continued medical education for healthcare providers. Distributors could also look for additional value creation opportunities such as operational efficiencies captured through

network optimization, greater support from manufacturers for sales and promotions, and contract renegotiation with principals for better and mutually beneficial terms.

Pharmaceutical companies

As pharmaceutical companies contemplate the impact these price controls can have on their business in Malaysia, there are strategies to consider beyond lobbying and ensuring that the right countries are included in the consideration set for external reference pricing.

Drug manufacturers will need to revisit their market access strategy, particularly as it relates to new launches and pursuing Blue Book listing in Malaysia. The private market may warrant a greater focus as price controls are likely to be enforced more strictly for publicly reimbursed drugs. Nonetheless, ensuring access to medicine and innovative drugs will remain a priority for the government, giving pharmaceutical companies some room for price negotiation on specific drugs to be listed.

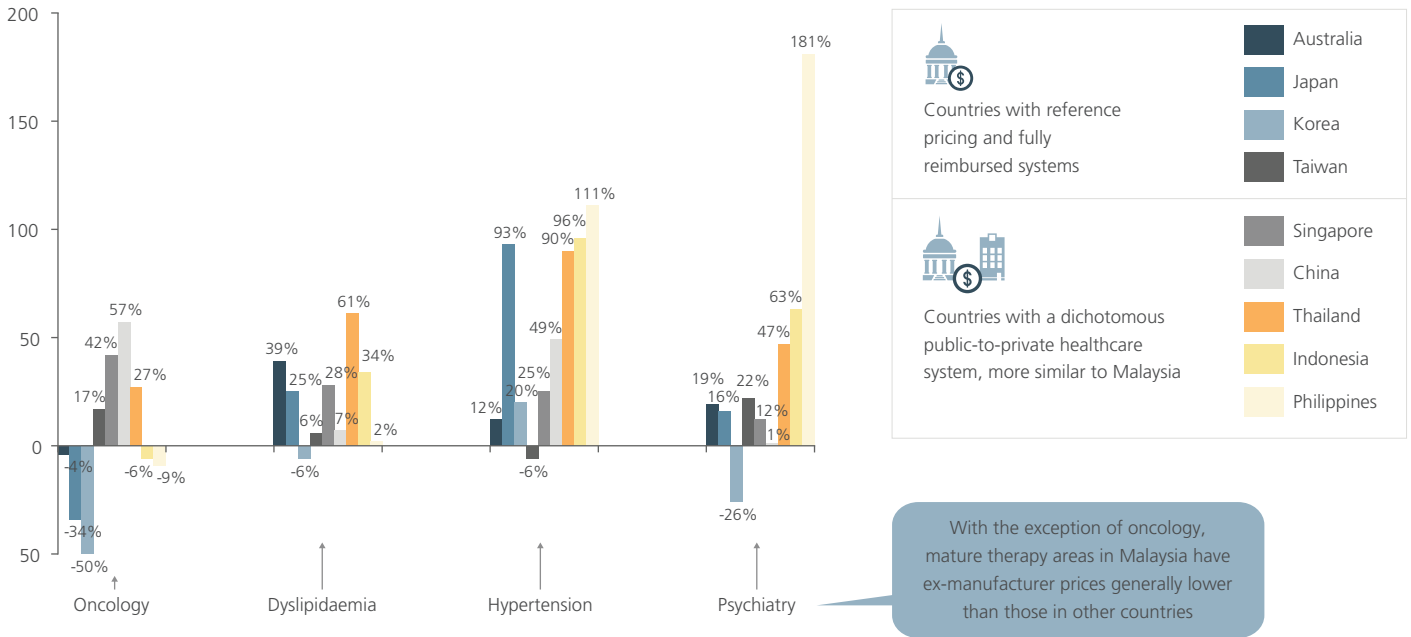
Additionally, pharmaceutical companies should seek ways to make the trade channel more efficient and minimize price pressures from being pushed upstream to them. This may involve the use of digital tools and automation to make the sales and marketing process more targeted and effective. Solutions could range from enhanced digital tools for physician engagement and customer profiling to advanced analytics and channel optimization. Trade channel efficiencies might even include distributor consolidation to drive scale benefits.

Pharmaceutical companies could also consider ways to support end customers, i.e., hospitals and clinics, in their efforts to capture and retain long-term patient revenues, whether through

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Figure 4
Ex-manufacturer drug price differential of other countries vs. Malaysia

Percentage above or below baseline of Malaysia's price in 2014



Note: Includes prescription products from all channels, including private and public sectors
Source: Pharmaceutical Association of Malaysia (PhAMA), IMS 2014

patient assistance programs or digital interventions to track and support patient compliance.

In summary, while there may be some tough times ahead for the pharmaceutical industry in Malaysia, there are a number of

strategies that industry players can adopt to continue to thrive in a future of price controls. A careful examination of the current operating model and business strategies will be essential to determine which individual actions to take and where to seek collaborative approaches to capturing value.

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