

POLICY BRIEF

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Drug Price Controls In Malaysia: Implications and Considerations

Recommendations

Addressing the cost of healthcare is incredibly complex and differs from country to country.

There is no one-size-fits-all approach or quick fix to achieving an optimal balance between paying the costs of providing high quality healthcare and ensuring equitable, accessible and affordable treatment for all.

On 12 April 2019, the Cabinet approved imposing price control measures for pharmaceutical drugs utilising the Price Control and Anti-Profiteering Act 2011.

No price regulation or control mechanism is currently in place for the pharmaceutical industry in Malaysia.

- **A Regulatory Impact Analysis (RIA) of the proposed price controls regulation** must be conducted¹ to determine impact of drug price controls on general practitioners, patients, hospital service providers, pharmaceutical manufacturers, and other stakeholders. The results should be made publicly available and shared with all stakeholders.
- **A Cost Benefit Analysis** should be carried out by an independent party and presented to the Cabinet before gazettment to ascertain the impact to the industry.
- **The issue of price controls should be referred to the Parliamentary Select Committee on Health, Education, Community and Social Development** before the policy is implemented.

- The Ministry of Health should be **more transparent in sharing proposed changes to legislation and timelines**.
- The Ministry of Health should **conduct timely and meaningful consultations with all industry players** and publish their concerns.

Price controls are meant to **resolve short-term supply and demand anomalies** rather than to resolve long-term costs as per existing price control regulations for other goods.

Background

In August 2018, the government announced its concern regarding the escalating cost of healthcare in Malaysia. Malaysia's annual nett medical inflation rates in 2016, 2017 and 2018 were 11.5%, 12.1% and 12.4% respectively. For 2019, it is projected to hit 13.6%. This is considered one of the highest in Asia, where medical inflation in the region averages at 10%.

One aspect under intense scrutiny were the prices of pharmaceutical products, specifically drugs and medicines. A price control mechanism for these products has been under serious consideration. This follows regional trends in countries which have seen significant increases in public health spending such as the Philippines, Vietnam, Taiwan and South Korea.

There is currently no price regulation or control mechanism in place for the pharmaceutical industry in Malaysia. The free market approach to this industry is intended to help foster and encourage innovation and competition, leading to better value for consumers, for the private sector and the government.

¹ A RIA is required as per the Chief Secretary to the Government's circular dated 15 July 2013 "National Policy on the Development and Implementation of Regulations" (Pekeliling Am - Bilangan 1, Tahun 2013)

However, the government and consumer groups have expressed belief that drug prices have been significantly marked-up or being overcharged by the private sector (e.g. general practitioners, hospitals and pharmaceutical companies) affecting the general affordability of healthcare in Malaysia. Data from the Ministry of Health's Medicine Prices Monitoring in Malaysia 2017 report has been used to substantiate this claim.

However, drug prices in Malaysia across mature therapy areas are already, on average, lower compared to many other countries of similar economies and scale.

The shortage in supply of various medicines to public hospitals in recent years has also been attributed to the government being forced to stretch its medicines budget to accommodate the increasing disease burden of non-communicable diseases among Malaysians and ensuring sufficient quantities of innovator and generic drugs, needed to treat illnesses such as cancer and rare diseases.

The government currently spends 11.1% of its budget on medicine procurement, out of which RM916.2mil is spent on central contract tenders, RM773.93mil on approved product purchase list items and RM417.47mil on local purchases.

On 12 April 2019, the Cabinet approved imposing price control measures for pharmaceutical drugs utilising the Price Control and Anti-Profiteering Act 2011 (PCAPA 2011). Implementation has been targeted for either late 2019 or early 2020.

Policy Outline

At the time of writing, the policy and operational frameworks for the pharmaceutical price control measure have not been fully shared or explained to the majority of stakeholders.

Inference of what will be imposed by the government has been made based on the public statements made by senior Ministry of Health leadership and officials, and through industry consultations. The following has been confirmed:

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

- The three lowest prices from those countries will be averaged to determine the ceiling price for pharmaceutical products in Malaysia
- Imposition of the ceiling price will be at the wholesale and retail/consumer levels (e.g. clinics, hospitals and pharmacies)

The relevant legislation, the Price Control and Anti-Profiteering Act 2011 (PCAPA) is under the purview of the Ministry of Domestic Trade and Consumer Affairs (KPDNHEP). Therefore, KPDNHEP will appoint Ministry of Health officers as price assistant officers to enable them to carry out drug price control enforcement activities.

Specific issues still unknown:

- Will Malaysia be benchmarked against countries of similar economies, volume of procurement, multi-payer system
- Which drugs will be targeted by the price control regulation
- How often will the price control measure be reviewed and take inflation into account

The use of price controls is not prohibited under the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Implementation

Though the use of the PCAPA, specifically Part II and IV, allows for the possibility of wholesale imposition of price controls across both public and private sectors, it is likely that for practical purposes, implementation of price controls will be in two phases:

- **Phase 1:** The first year will likely target single source, high value or innovator drugs in high cost therapeutic areas such as oncology, sourced through public sector procurement.
- **Phase 2:** The next two years will involve innovator, biosimilar and generic medicines across both public and private sectors.

During this period, price controls will involve utilisation of recommended retail pricing based on disclosure to the

Pharmaceutical Reference Pricing

One method of controlling increases in health spending is reference pricing, a framework where a ceiling on the prices of medicines is imposed. It is usually utilised when there is a wide price variation for therapeutically similar drugs.

There are two kinds: internal and external. Internal reference pricing compares the pricing of equivalent drugs within the domestic market. External reference pricing, also known as international reference pricing, compares pricing of similar drugs in one or several countries. It is usually used to control public reimbursement of drugs. According to WHO, reference pricing is not supposed to be a form of price regulation.

government of research & development expenditures, manufacturing cost (maybe even production costs), wholesaler mark-ups and tender agent commissions. Arguably, at least a third of this information is already available.

Implications

General Practitioners / Private Clinics

General practitioner consultation fees which remain unchanged since 1992, have forced most private clinics to depend mainly on the mark-up and sale of drugs and medicines to sustain their operations. The expectation that these clinics remain immune from economic realities and maintain charges from almost three decades ago is unrealistic and unsustainable. It contradicts everyday realities of operating a small business amidst inflation, rising operating costs, ensuring adequate remuneration and increased cost of living. Drug price controls will significantly reduce revenue for private clinics as 70% of their revenue is dependent on the sale of medicines. The majority may not survive the imposition of price controls.

Community Pharmacists

Community pharmacies are already operating with very thin margins for the sale of drugs and have resorted to selling non-medical consumer products (e.g. cosmetics, ice cream) in order to continue to operate, a practice called "over-servicing". Drug price controls will mean that those margins will further shrink. Patients may no longer seek to buy their drugs at community pharmacies, if they can get them for the same price at chain pharmacies, clinics and private hospitals.

Private Hospitals

Private hospitals need to balance quality, cost and access in a strictly commercial setting without the benefit of public funds or government grants/ subsidies to reduce operating costs. Despite charging high rates for healthcare services, the ability to make profits (average of 5%-7%) is heavily dependent on the hospital's ability to attract and retain patients based on the quality of treatment and care provided. Compared to straightforward dispensing at a clinic or pharmacy, there are direct and indirect costs associated with dispensing medications (e.g. medication review, drug counselling, compliance monitoring, and titration of dosages) in a hospital setting, which varies depending on geographical locations, levels of service, and specialities. Drug price controls will likely cause a realignment of charges leading to possible increases in other chargeable areas of service.

Wholesalers & Distributors

Wholesalers and distributors are in charge of stocking drugs from numerous drug companies and dispensing them to pharmacies. A slice of each drug's sale price is charged for this service. They may therefore benefit when prices are higher. However, as they do not own the products they distribute, they have no power over pricing.

Distributors and wholesalers will need to diversify their existing portfolios and services to ensure they are able to better compete for business. They will likely strengthen value added services and solutions such as improved continued medical education for healthcare providers, upgraded digital solutions for supply chain management, better technical support, increased efficiency of logistical services and better credit terms.

Tender Agents

Bumiputera tender agents, who act as intermediaries or "middlemen" between the public healthcare system and local non-Bumiputera and foreign pharmaceutical companies, will be least affected by the imposition of drug price controls. Despite earning 2-3% in commissions for submitting tender documents on behalf of their suppliers, their exposure is limited and minimal. They do not take ownership of the products supplied. Pricing is determined by the principals and logistics are provided

"A competitive marketplace is the best way to ensure low prices for medicines. Proper organization of the market and application of anti-trust (monopoly) laws should facilitate price competition.

However, if the pharmaceutical market is not competitive and/or there is a need to contain medicine prices, governments may choose to institute price controls."

World Health Organisation report, 2008

by other independent distributors. Unless this policy changes, tender agents will gain the same percentage of commissions regardless of price controls.

Pharmaceutical Companies

Pharmaceutical companies will review their respective market access strategies, especially concerning new product launches in Malaysia. Should price controls be applicable to both the public and private sectors, in the short term, the prices of high value or innovator drugs would come down benefiting patients and the government. However, the local pharmaceutical industry

consisting mainly of generic drug manufacturers will be particularly affected.

Regulatory compliance already requiring generics to be bioequivalent are costly, up to RM1 million per drug. Restricting the industry's ability to recover such expenditures and investments through its pricing strategies, constricts and discourages local innovation and private sector investment in the local generics industry. In the long run, compared to their international counterparts who are importing both patented and generic drugs, local pharmaceutical companies are less likely able to absorb the effects of drug price-controls and to bounce back.

Despite the fact that more than 60% of the public healthcare system is currently dependent on generics, the ability to profit through sales is key to enable for that revenue to be channelled back into research and development. Price controls could mean that manufacturers would withdraw from production of drugs that are less profitable and expensive to produce. Instead they would focus on those which will produce sales, market share and profits. The diversity and availability of generic medicines could actually suffer. Price controls could severely affect the sustainability of local pharmaceutical manufacturers, causing a crisis in drug supply.

Risks

Two principal factors drive motivation for launching a new drug: demand or the size of the potential market (varies according to the type of drug, economic and noneconomic factors which differ from country to country, and the type of health financing); and a country's policy directions on competition, market regulation and intellectual property rights.

- Pharmaceutical companies, in particular multi-nationals, could be disincentivised to bring innovative products into the country. The India experience is particularly informative. The country deployed drug price controls for its list of essential medicines, first in the 1990s which were later expanded in 2013 and 2015. Launches of new drugs declined by 75% and when they were brought to market, delays occurred by more than five years despite already being available elsewhere around the world. Malaysians could be similarly disadvantaged from the perspective of access. Fewer new drugs would become available to patients, depriving them of the benefits of advances in medical research.
- Despite Indian drug prices being among the lowest in the world, out-of-pocket (OPP) expenditure of patients in that country remains at 61%. In Malaysia, it is at 38%. Will this be reduced as a result of price controls? Will the savings gained from this policy translate or trickle down to the

pockets of patients? Absent of a Regulatory Impact Analysis (RIA) or a similar assessment, it is unclear whether this is likely to happen.

Conclusion

The Ministry of Health is already looking to assess and optimise drugs and medicine purchases, through improved price negotiation, patient access schemes and pooled procurement. It is also looking at initiatives to amend prescribing behaviours. It also intends to avoid possible monopolies in procurement by encouraging open tenders.

With price controls, Malaysia's reputation could take another hit and the country regarded as a risky and unpredictable market to launch new high value innovative drugs for the treatment of illnesses such as cancer and rare diseases.

Contrary to popular belief, evidence from other countries show that price controls rarely encourage innovation and healthy competition for industry growth. However, when these measures are imposed, accessibility should be the driving principle, not just affordability.

A recent Malaysian example of competition successfully and significantly reducing drug prices without depending on regulation, involved targeted drug therapy for metastatic breast cancer. It does work.

Competition provides for the possibility of better and improved treatment options, lower drug prices, and increased affordability and coverage.

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The Galen Centre for Health and Social Policy is an independent public policy research and advocacy organisation based in Kuala Lumpur, Malaysia. It is committed to an approach which supports individual freedom, choice, and innovation in the development of patient-centric and community-focused health and social sectors.

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