

Comprehensive Cost-Benefit Assessment on the Medicine Pricing Policy (Preliminary findings)

Public Consultation Document

29 November – 6 December 2021

Unified Public Consultation

UNIFIED PUBLIC CONSULTATION (UPC) NOW OPEN FOR FEEDBACK ON THE COST BENEFIT ASSESSMENT (CBA) STUDYING THE PROPOSED IMPLEMENTATION OF MEDICINE PRICE CONTROL. The preliminary findings from the CBA on the proposed implementation of medicine price control is now available for feedback on the Unified Public Consultation (UPC) portal. This CBA is a public-private collaborative study between the government and other key health and economic stakeholders and is undertaken by an appointed independent global data science company. The study aims to analyze the costs and benefits of implementing medicine price control in Malaysia in a comprehensive approach. It will also serve to complement a previously conducted CBA study of the same by providing a more holistic impact assessment of this pricing policy through data-driven insights. MPC as the lead government coordinating body has coordinated and facilitated the collaboration between the relevant government agencies, independent economists, the Pharmaceutical Association of Malaysia (PhAMA), the Malaysian Organization of Pharmaceutical Industries (MOPI), the Association of Private Hospitals, Malaysia (APHM), the Malaysian Medical Association (MMA) and the Pharmaceutical Research & Manufacturers of America (PhRMA). Since the study kicked-off in August 2021, MPC has ensured constant, fair, robust and transparent governance processes. A series of extensive consultation sessions on the CBA were held with both public and private sector stakeholders data was collected and feedback was received. The unified public consultation session will take place from 29th of November 2021 to 6th of December 2021. MPC invites and strongly encourages participation from the public to provide written feedback on the impact of implementing this pricing policy via this UPC platform, which will serve as crucial input for the country's policy direction and is key to effective policy making. This public consultation process on the CBA ensures that all views are represented for a more holistic discussion with policy makers, identifying critical aspects in regard to the nation's productivity, economic and industry growth, innovation, competitiveness and job creation.

Purpose of the consultation and guiding questions

Purpose of the consultation:

- To seek feedback of interested parties on the report and in particular the preliminary findings of the cost-benefit assessment on proposed medicine pricing policy before the consultant finalise their analysis.

Overall guiding questions:

- What are your views on the preliminary findings of the cost-benefit assessment conducted on proposed pricing policy?
- Are there any elements of the study which require further clarification?
- Are there other elements which should be considered?

Executive summary

1

Context and methodology



- MOH is considering the **medicine price control** for the private healthcare (PHC) sector in Malaysia – using external reference pricing (ERP) to control wholesaler prices and regressive markup for retailer prices of prescription drugs in private hospitals, clinics and pharmacies.
- TPC has been engaged by MITI and the private healthcare sector to conduct a **comprehensive cost-benefit assessment (CBA) – CBA 2.0**, building on top of the first CBA, to **assess the cost and benefits of medicine price control on the PHC sector and wider Malaysia society over the next 15 years**. The CBA 2.0 output is **measured in MYR at net present value or NPV**.
- TPC built the **CBA 2.0 model** using its **proprietary drug sales databases as the foundation** and incorporated **information sourced from engagement with Malaysian Government and PHC** to understand the long-term medicine price control economic impact on PHC sector.

2

Key findings



- Today, the **PHC ecosystem is a strong economic growth engine** for Malaysia, and at status quo it **will generate MYR 1 trillion** over the next 15 years. The **medicine price control will severely impact PHC's stability** as a sector and **result in overall loss of MYR 206 Bn, decreased access and poorer health outcomes** for Malaysian *rakyat*.
- medicine price control will result in **~1-14% more patients** in PHC with **~90% of the increase coming from the M40 and T20** groups. Additionally, patients will **save MYR 64 Bn (NPV)** which includes medicine bill savings and insurance premium savings.
- However, **2,600 private clinics (MYR -51 Bn NPV) will likely close**, especially smaller clinics resulting in reduced healthcare access. In the short term, **private hospitals (MYR -41 Bn NPV) will shut down outpatient services** to stay afloat and in the long run may **consider leaving** the Malaysia market. **Pharmacies (MYR -18 Bn NPV) and distributors (MYR -2 Bn NPV) will also be impacted** albeit to a lesser extent, further **disrupting access along the healthcare supply chain**. Critically, **pharmaceutical manufacturers (MYR -51 Bn NPV) may withdraw current innovative drugs and delay new innovative drug launches**; while **generic drugs may be diverted for export**. As a result, the **poorer health outcomes (MYR -71 Bn NPV) will further be borne by the Malaysian rakyat**.
- From the **economical (MYR -31 Bn NPV)** perspective, **91-136k PHC jobs and salaries** will likely be impacted. The Malaysia Government will also see **reduced income from tax, investment (MYR -9 Bn) and medical tourism (MYR -10 Bn)**.

3

Conclusion



- Based on the CBA 2.0 output, the **overall cost-to-benefit ratio is ~4.3:1** – i.e. **for every MYR 1 saved, around MYR 4.3 is lost to Malaysia**.
- Hence, we **recommend the Malaysia Government to re-evaluate alternative options to medicine price control or mitigating solutions to reduce medicine price control impact**

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Introduction

The **Comprehensive Cost-Benefit Assessment (CBA 2.0)** on the **Medicine Pricing Policy** is a collaboration project between public sector (MITI, MPC) and private sector (PhAMA, APHM, MOPI, MMA, PhRMA) and in engagement with a **third-party, independent consultant (TPC)**. The CBA 2.0 is augmented and build upon CBA 1.0 which will expand the product scope beyond CBA 1.0 and cover ~5,000 products. The main role of this CBA 2.0 working group is to assess the wider economic impact of medicine price control on the private healthcare ecosystem, the health of the Malaysian *rakyat* and the impact on overall economy and aspects of the Malaysian government.

The **two-tier governance structure** is as follows:

1. Steering Committee (SteerCo) made up of senior leadership from government and private industry groups that provides guidance and endorsement of the CBA 2.0 methodology, results and conclusion;
2. Technical Committee (TechCo) made up of the working group members from government and private industry groups and is responsible for information sharing and provide initial alignment

SteerCo: Chair – Deputy Secretary General, MITI

TechCo: Co-Chair – Deputy Director General Malaysia Productivity Corporation; Co-Chair – Senior Industry Representative PhAMA

Secretariat/Facilitator: Malaysia Productivity Corporation – Mr. Mohammed Alamin Rehan, Deputy Director, MPC

Members:

Government bodies:

Ministry of International Trade and Industry (MITI)
Ministry of Health (MOH)
Ministry of Finance (MOF)
Bank Negara Malaysia (BNM)
Economic Planning Unit (EPU)
Malaysia Health Tourism Council (MHTC)
Intellectual Property Corporation of Malaysia (MyIPO)
Department of Statistics Malaysia (DOSM)
Malaysia Productivity Corporation (MPC)

Private industry groups:

Pharmaceutical Association of Malaysia (PhAMA)
Malaysian Organisation of Pharmaceutical Industries (MOPI)
Malaysian Medical Association (MMA)
Association of Private Hospitals of Malaysia (APHM)
Pharmaceutical Research & Manufacturers of America (PhRMA).

Academicians:

Emeritus Professor Datuk Dr Zakariah bin Abdul Rashid
Professor Kenneth Kwing Chin Lee, Monash University Malaysia
Dr. Nur Ain Shahrier, Sunway University Malaysia

Objectives of conducting CBA 2.0 (Comprehensive CBA)

Overall goal

Provide an independent assessment on likely economic impact to the healthcare value chain (including patients) of a new pricing proposal by the government, by conducting a structured, data-driven and unbiased assessment that also considers ease and scale of implementation

Objectives

1

Establish a comprehensive framework and diligence process

2

Measure impact of planned pricing changes

3

Quantify risk and drivers of variances

4

Address feedback received in CBA 1.0 to develop a more robust analysis

Government considerations

Dasar Ubat Nasional (DUNAS)

To encourage equal accessibility and rational use of essential medicines that quality, safe, effective and affordable to improve the health of the people.

Components

1. Governance in medicines
2. Quality, safety and effectiveness of medicines
3. Medicines accessibility
4. Quality use of medicines
5. Partnership and collaboration for the healthcare industry

Mechanism requirements medicine prices in the public sector and private

- Affordable medicine
- Transparency of medicine price
- The cost does not become obstacles to availability of medicines to the people

CBA 2.0 will serve to complement CBA 1.0 by providing a more comprehensive assessment that accounts for more variables

CBA framework

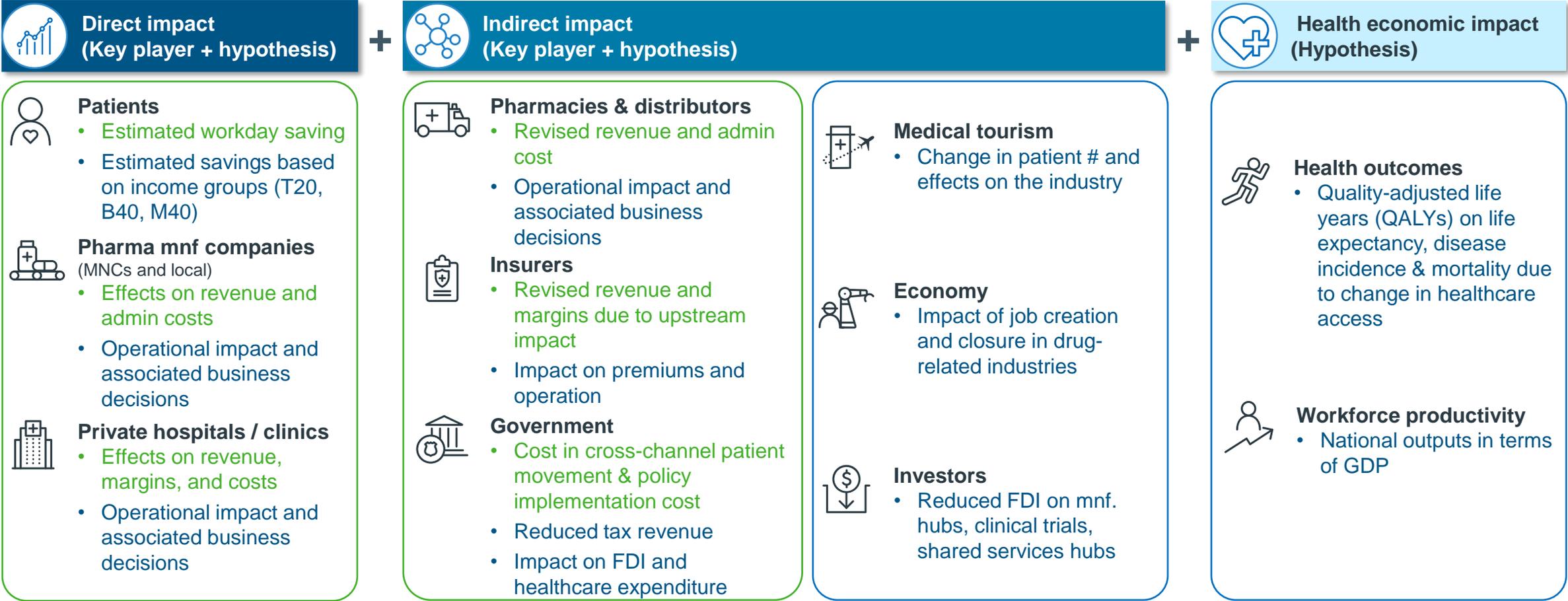
CBA 1.0

CBA 2.0

Addressed in CBA 1.0 & CBA 2.0

Addressed in CBA 2.0

Not exhaustive



Source: TPC analysis

The project was completed using a methodology aligned upon by Technical and Steering Committee members

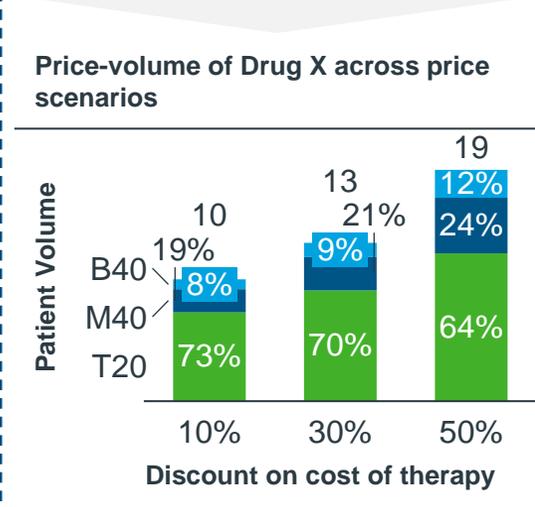
Methodology

① Policy input

- Policy details:** List of drugs, reference countries, list of pvt. HC providers affected, regressive mark-up, ERP criteria, enforcement costs
- Mnf / Distributor / Wholesaler information:** Margins information & assumptions by value and drug, list of targeted companies
- Gov't HC expenditure:** Total gov't spending on HC, public hospital operations costs, Gov't spending on bluebook drugs
- Patient/consumer:** Healthcare expenditure by income (assumptions), catastrophic healthcare expenditure, insurance premiums
- HEOR¹:** HTA on pharma products by MOH/MaHTAS, clinical trials pipeline, HEOR studies/assumptions for key diseases

② Model foundation: Price-volume analysis

- Quantitative market research & sample questions**
- Specialists (Based on key disease)**
- 1. What will be the % patient share for Drug X based on various pricing scenarios?



③ Stress-testing business decisions (Monte Carlo)

- MNC Pharma co.
- Local Pharma co.
- Retail pharmacy
- Pvt. hospital / clinics
- Insurance providers
- Distributor / Wholesaler

- Topics for stress-testing (Qual. PMR)**
1. Revenue and business decisions on OPEX and CAPEX due to policy
 2. Pricing & margins of pharma value chain
 3. Change in insurance premiums & payouts
 4. Change in drug pipeline (planned launches) and FDI on manufacturing
 5. Impact to medical tourism industry

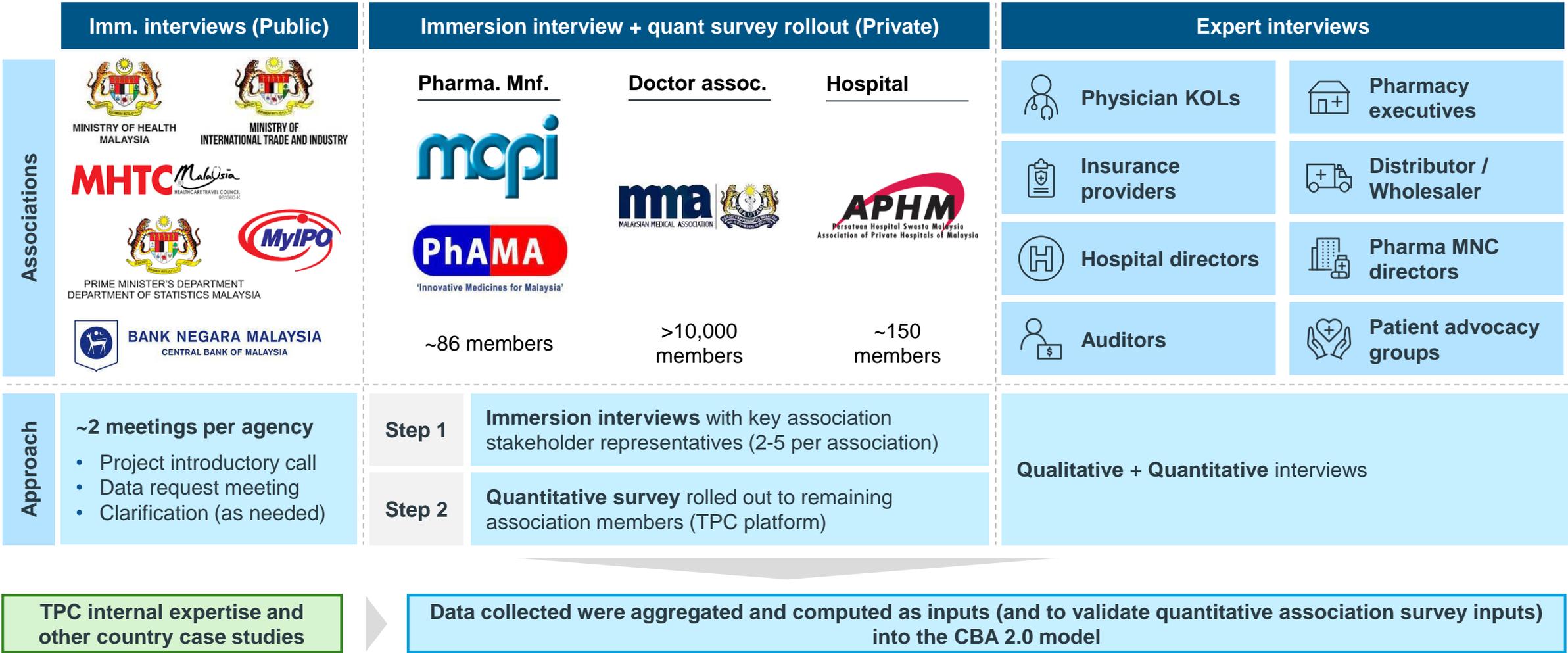
④ Medicine price mechanism output

- Derived from stress testing**
- Direct impact
 - Indirect impact

- Derived from MOH data and HEOR data (e.g., QALYs)**
- Health economic impact

The CBA output is informed by information captured from all key private and public players across the healthcare drug value chain

Data collection sources



Source: TPC analysis

We have obtained information across multiple associations & agencies while incorporating TPC's data to arrive at our findings

Database

	Stakeholder / agency	Data obtained		Data source	Description
Govt. agency	 Ministry of Health	Policy mechanics & methodology and list of products	+	 TPC data assets	<ul style="list-style-type: none"> National and international pharmaceutical sales data Past project references
	 Ministry of Int' Trade & Industry	Pharma industry employment, wages and sales			
	 Ministry of Finance	Pharma industry tax payment			
	 Dept. of Statistics M'sia / EPU	Employment figures, private healthcare sector statistics			
	 Bank Negara Malaysia	Health insurance coverage			
	 M'sia Health. Travel Council	Historical data			
	 MyIPO	Patent protection revenue			
	 M'sia Productivity Corp. (MPC)	Implementation assumptions		 Expert interviews	<ul style="list-style-type: none"> Industry experts Clinicians
 M'sia Medical Assoc. (MMA)	Clinics business decisions, price-volume prescription decisions				
 Assoc. of Pvt. Hospitals (APHM)	P&L estimates, historical and forecasted business performance, and business decisions in view of policy				
 Pharma. Assoc. of M'sia (PhAMA)					
 M'sia Org. Pharma. Indus. (MOPI)					
Private assoc.			 Secondary research	<ul style="list-style-type: none"> World Health Organization (WHO) Other secondary researches e.g., medical journals 	

Source: TPC analysis

The private healthcare sector is expected to be a socio-economic growth engine for Malaysia in the next 15 years

Private healthcare's contribution to the Malaysian economy over the next 15 years

~ MYR 1 Trillion

Economic value generated

~ 13 Million

Patients served annually

~ 100,000

New jobs created in the private healthcare sector

~ MYR 23 Billion

Projected contribution of the medical tourism sector to Malaysia

~ MYR 44 Billion

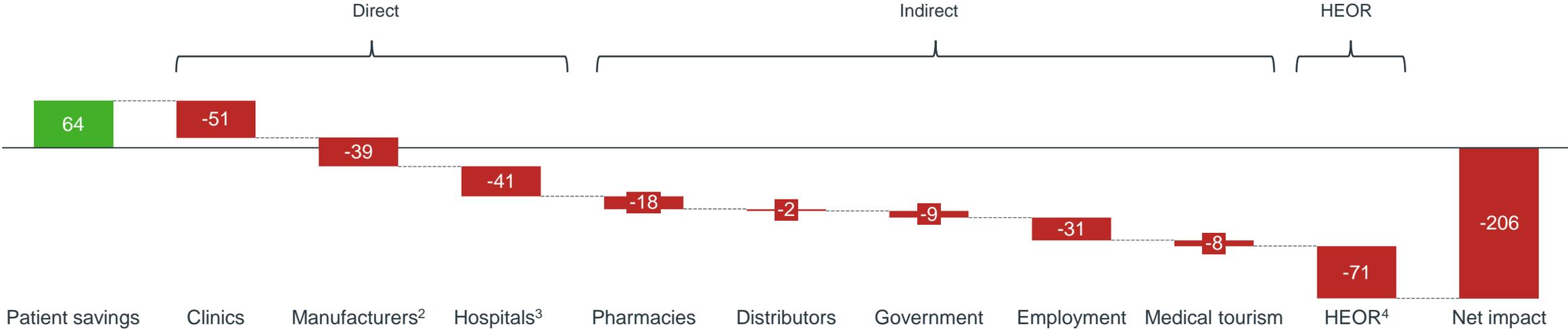
Planned investments in Malaysia

The costs of medicine price control outweigh the benefits over a 15-year period, resulting in ~MYR 206 Bn in economic value erosion

Results from the CBA model (base case¹)

Projected medicines pricing policy impact by stakeholder
MYR Bn, 2022-2037 NPV

Positive impact Negative impact



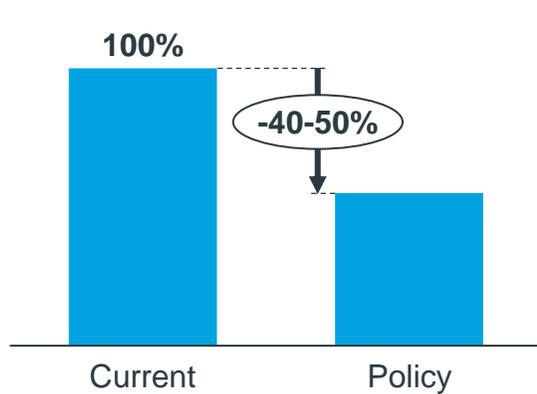
The expected economic erosion would be equivalent to 3-4% of national GDP annually

1. Based on medium ERP levels and most likely impact level, 2. Includes impact of investments and clinical trials; 3. Hospitals will adjust other fees to prevent losses and shutdown, 4. Health economic outcomes including Quality of Life and productivity
Source: Expert interviews, primary market research surveys, TPC analysis

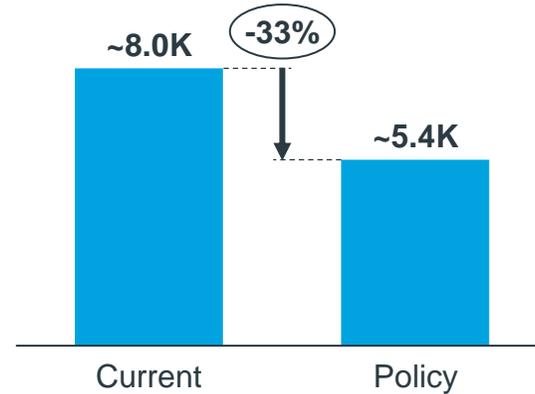
With price control implemented, certain patient groups will benefit from lower prices, but accessibility will also decline in the long-run

Private healthcare access

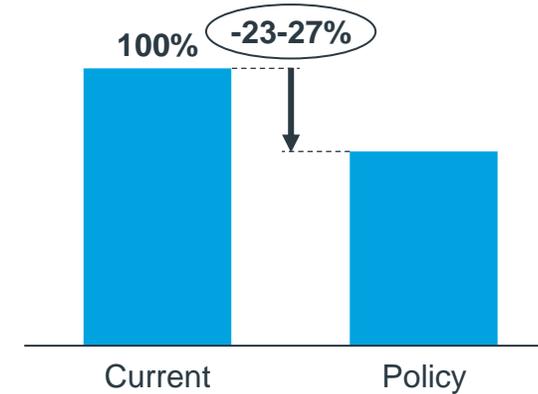
Patient savings in private clinics



Private clinics access points



Patient savings in private hospital



- Policy will result in **50-60% savings for private clinic patients** as drugs comprise a significant portion of spend.
- Due to **regulation on consultation fees**, clinics rely on drug revenue to remain operational and **will be unable to remain profitable**. As a result, **~33%, or 2,600 clinics will shut down**. This will result in **decreased access points** for patients, especially in less urban areas that serve B40 and M40 MY citizens.

- Policy will severely impact hospital revenues, resulting in **35-40% drop of total hospital revenue**
- Hospital industry operates on **tight margins** and the policy **may force certain hospitals to reduce investments and consider shutting down outpatient wings** to focus on non-drug and inpatient services

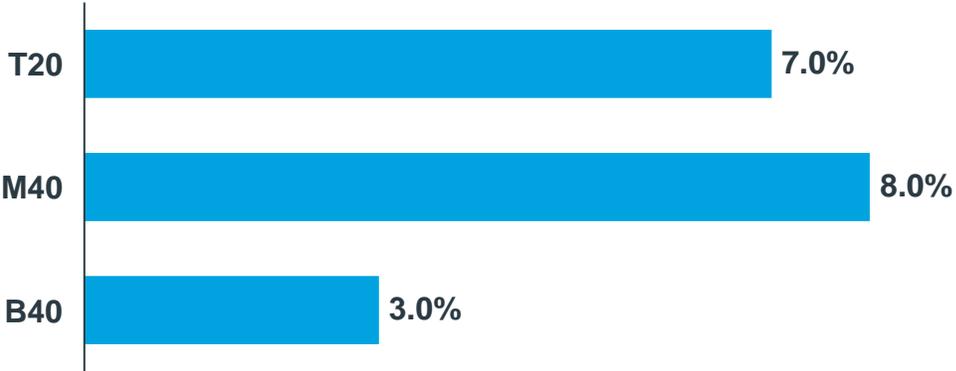
1. Based on median ERP price impact of 22% across overall private drug market
Source: Expert interviews, primary market research surveys, TPC analysis

Even then, the increase in private healthcare usage will mainly come from T20 and M40, with B40 least likely to benefit

Income group adoption and insurance savings

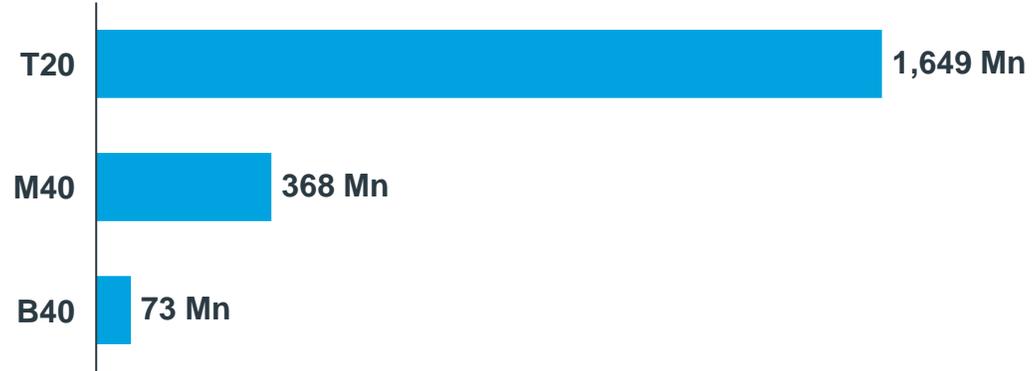
Preliminary

Increase of private sector patient volume due to policy¹



- Policy impact on drug prices will result in significant savings for patients seeking medical services in the private clinics but a lower price difference in hospitals.
- As a result, **T20 and M40 consumption is expected to increase by 7-8%** but **B40 consumption increase is capped at 3%**.

Annual premium cost avoidance for insured patients (2037, MYR)¹



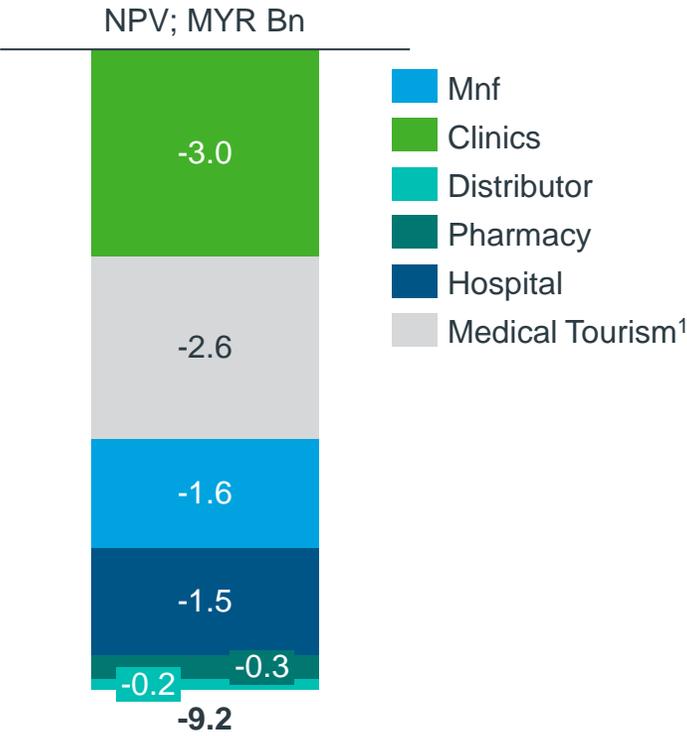
- Private insurance pay outs will decrease and **insurers will likely delay premium increase.**
- As a result, **T20 patients benefit the most due to high premium base and could save ~MYR 1.6 Bn annually.**

1. Based on median ERP price impact of 22% across overall private drug market
Source: TPC analysis, DOSM

There are also tax revenue impact and policy implementation costs in ensuring compliance across the healthcare value chain

Impact on Government

Tax revenue impact



Implementation cost

	Estimated costs (NPV; MYR)	Elements
Enforcement	~68 Mn	<ul style="list-style-type: none"> Labour cost per unit hour Estimated # of enforcement officers Non-labour intangibles
Database	~830 k	<ul style="list-style-type: none"> Upfront investment Maintenance costs
Gazette	~84 k	<ul style="list-style-type: none"> MYR 5 per page, with 5 drugs in 1 page Applied to ~11,900 (Phase I and Phase II) drugs affected by the pricing policy
Training & awareness	~10 Mn	<ul style="list-style-type: none"> Historical costs of training and awareness campaigns e.g, "Know your medicine"

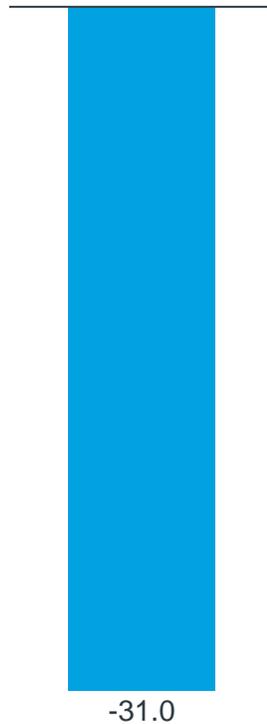
- The decrease in tax revenue for the government may impact the **fiscal balance**, currently at -6.2%, and the GDP growth target of **4.5%-5.5%** per annum as per the **Twelfth Malaysia plan**

Note 1: Medical tourism tax revenue contains the tax associated with direct medical spend by medical tourist and the associated non-medical spend
 Source: TPC analysis, press search

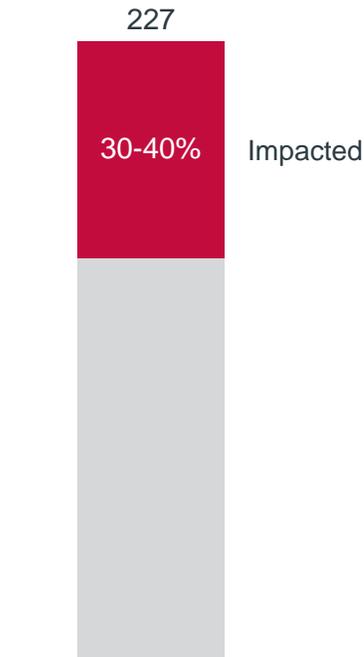
Employees in the private healthcare sector could lose up to ~MYR 31 Bn in wages across 15 years

Employment

Salaries affected¹ (NPV, 2022-2037)
MYR Bn



Job affected¹ (2037)
MYR, Bn; Jobs, K



Key insights

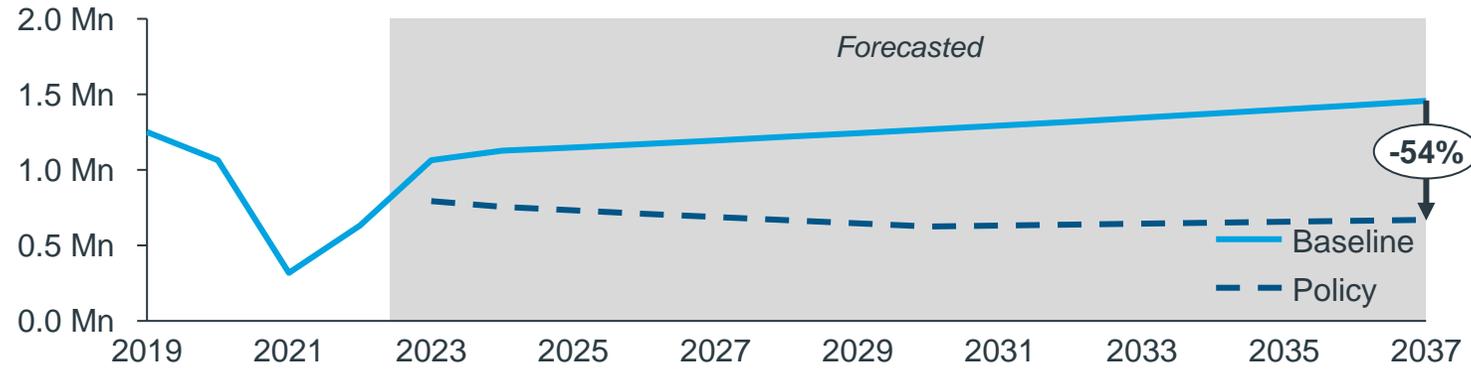
- Private healthcare sector hires an estimated **133k employees in 2021** and is projected to **grow at 9% between 2021-2037**
- In 2037, policy implementation will result in an estimated **~91-136k jobs worth ~4.5-6.1 Bn** that may see **pay cuts, freeze in salary growth or layoffs**
- Impact measured here **excludes downstream impact on industries reliant on the private healthcare sector** – such as commercial landlords, building services, etc.

1. Based on medium ERP levels and most likely impact level
Source: TPC analysis

Medical tourism is expected to decline despite 7% growth in volume, resulting in NPV loss of ~MYR 8 Bn to the economy

Deep dive page on medical tourism: most likely scenario

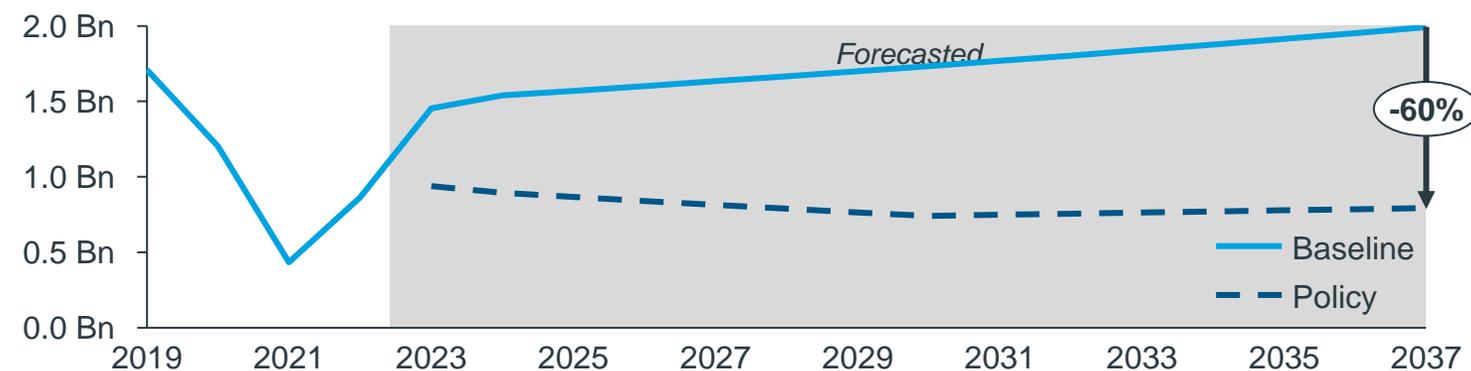
Medical tourism volume (HTs)



Key insights

- Policy will likely result in loss to 10-35% innovative drug access critical for medical tourism, especially for foreign fly-in patients from key markets such as Indonesia
- As a result, overall MT volume will drop by 54% and revenue will decrease by ~60% in 2037
- Between 2021-2037, the NPV impact of policy on medical tourism is estimated at a loss of MYR 7.9 Bn

Medical tourism total impact² (MYR)



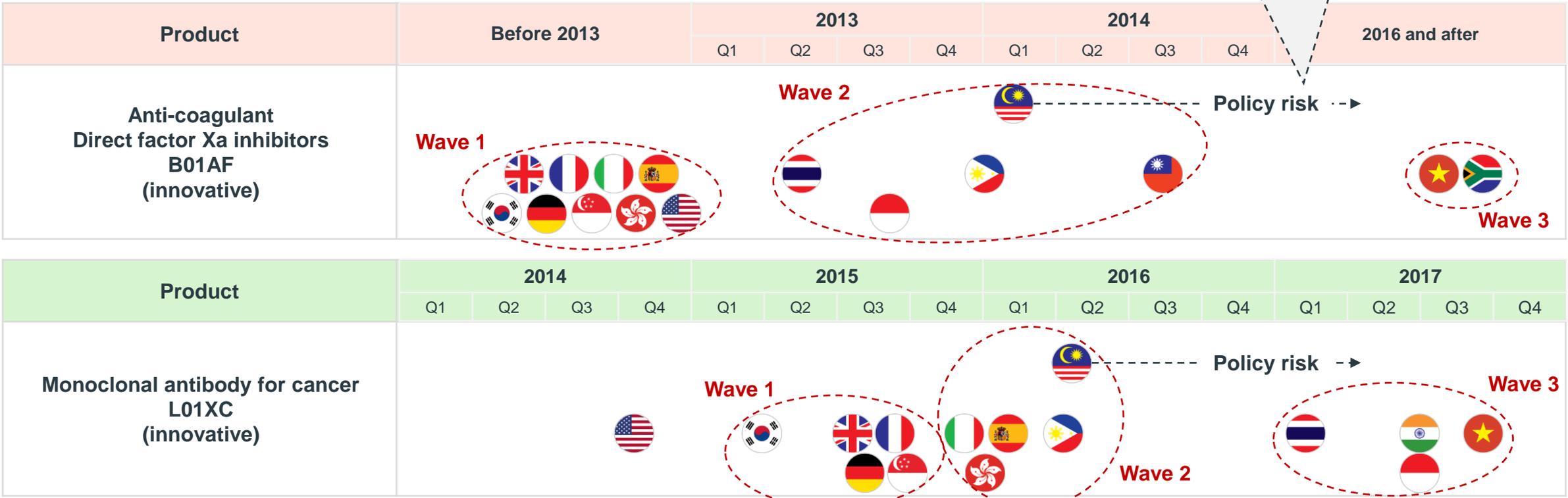
Note: 1. Malaysia Healthcare Travel Industry Blueprint 2021-2025; 2. Medical tourism total impact includes direct medical spend and non medical spend, HT – Health tourists which includes fly-in patients and foreign residents
Source: MHTC, TPC analysis

Medicine price control may also reduce Malaysia's attractiveness as a priority market by pharma companies for new launches

Access delays in innovative medicines

Launch date comparison across countries

MNCs may view MY as less attractive deprioritizing it to be a Wave 3 country



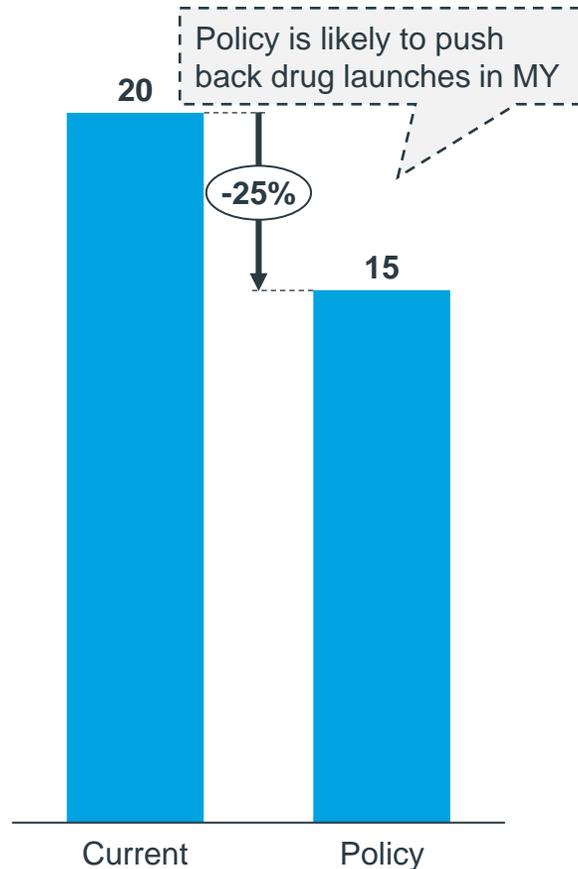
- Malaysia is typically prioritized as a **'Wave 2' country** by most MNCs where launches are usually **2-3 years behind US** (benchmark) for innovative drug launches
- Policy implementation may result in MNCs viewing Malaysia as a **less attractive market**, deprioritizing it to **'Wave 3'** with a **risk of drugs not being launched**

Source: Expert interviews, TPC analysis

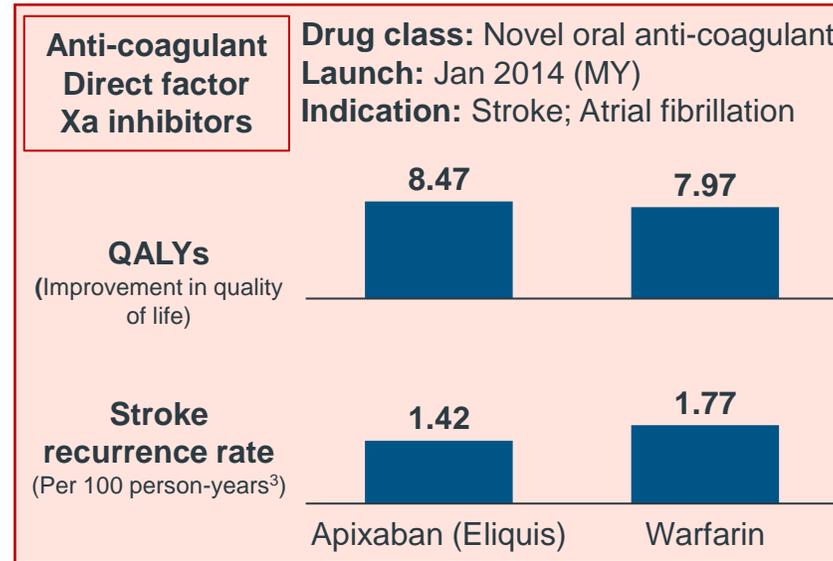
Health outcomes in Malaysia are potentially at risk as innovative drug access is likely to decrease or delay if price control is implemented

Change in innovative medicine access

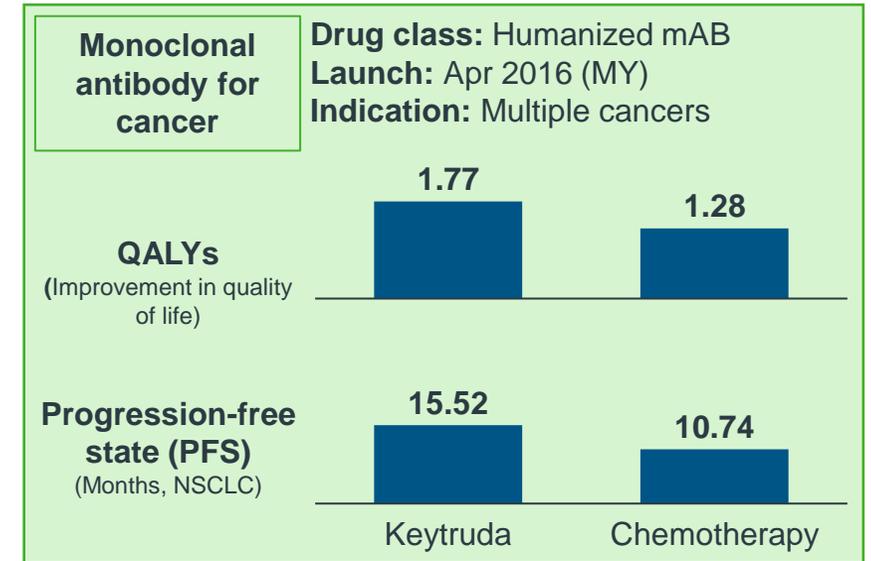
Drop in annual innovative launches¹



Examples of health impact gained from innovative drug access



This novel drug helps preventing stroke recurrence in post-stroke patients. This innovative drug can **decrease stroke recurrence by 20% and extend the quality of life in stroke patients by 6%**



This novel immunotherapy is used for several cancers, including lung cancer which has a poor prognosis and survival rate. Using this novel immunotherapy treatment can **delay progression in lung cancer patients by ~50%**

1. Estimated based on innovative drug launches in Malaysia in the last 5 years (2016-2020); 2. Across n = 39,840 Asian stroke patients; 3. QALYs: Quality-adjusted life years; Source: Therapeutic Advances in Chronic Disease, Sage Journals; Immunotherapy, Future medicine; Secondary research; TPC National Sales Audit; TPC analysis

Medicine price control will not address B40 access to healthcare; in addition, it could have major unintended consequences on the economy...

Impact to the Malaysian economy over the next 15 years

~ MYR 120 – 300 Billion

~15-38% economic value erosion

~ 113,000

jobs lost in the private healthcare sector

~ MYR 8 Billion

~30% erosion of the medical tourism sector

~ MYR 12 Billion

~40% reduction in planned investments

~ 3%

Only 384,000 of B40 patients cross over to the private sector

...as well as detrimental effects on long-term government priorities, i.e. 12th Malaysia Plan and MHTI¹ Blueprint 2021-2025

Long-term government goals at risk, as a result of the policy

Not exhaustive



MYR 258 Bn

Average Private Investment in Current Prices (per year)

4%

unemployment rate

4.5% to 5.5%

GDP growth per annum

MYR 57,882

GNI per capita by 2022



*“The success of the blueprint is attributed to three aspects; best-in-class-care, high-tech facilities and **timely access to high-quality, innovative medications which will support growth of this industry in the face of regional competition**”*

- APHM President Datuk Dr. Kuljit Singh -

Despite its good intentions, the policy will not likely achieve much improved healthcare access, rather, it could have detrimental effects on Malaysia's economy

1. Malaysia Healthcare Travel Industry
Source: Expert interviews, TPC analysis

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