

FAIR PRICING IN PRACTICE



- **Background**
 - Access to Medicines and Affordability
 - Challenges to Access in Health Care System Worldwide
 - ✓ **High Pricing of Most Patented Medicines**
- **Progresses made by Malaysia towards Fair Pricing**
 - Strategies/Initiatives for Fair Pricing in Improving Access to Medicines
 - ✓ **Malaysia's Model in Improving Access to Innovative High Cost Medicines**
- **The Way Forward**
 - **Way Forward Strategies Towards Fair Pricing for Better Access to Medicines**

Factors Influencing Access



Guiding Principles of Fair Pricing

- **What is a ‘fair price’?**

- affordable for health systems and patients
- provides sufficient market incentive for industry to invest in innovation and the production of medicines

(Fair Pricing Forum Q&A, Amsterdam, the Netherlands, 11 May 2017)

- **Concept of ‘fair pricing’ versus the principle of affordability?**

The principle of affordability and access to quality medicines guides the fair pricing initiative and remains a stalwart of WHO’s work on access to medical products. “Fair Pricing” aims to increase access through better affordability. It **focuses on new, high-priced medicines and vaccines that are currently unaffordable in most countries. But it also looks at old medicines whose prices have been so reduced that they no longer present any kind of incentive for manufacturers.**

(Fair Pricing Forum Q&A, Amsterdam, the Netherlands, 11 May 2017)

- From the point of view of global public health, the **way forward for “Fair Pricing” to improve affordability must be comprehensive and sustainable** if we are to eradicate treatable infectious illnesses, effectively address the upsurge of non-communicable and chronic diseases and care for our aging populations.

*(Marie-Paule Kieny, WHO Assistant Director-General, Health Systems and Innovation-
A comprehensive and fair solution to the price of medicines-Commentary -5 July 2016)*

Unknown pricing mechanisms

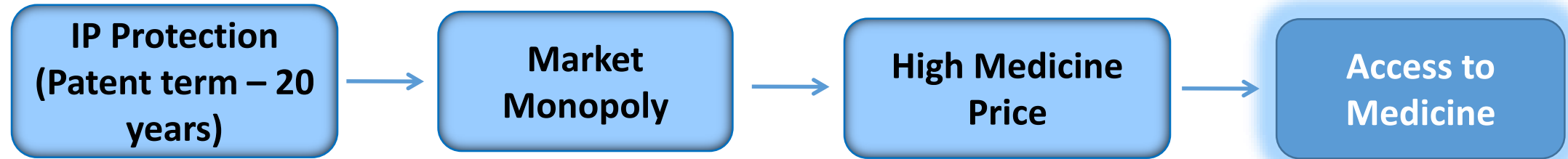
- No one seems to understand how, exactly, medicines prices are set.
- For years, pharmaceutical research companies have cited the large investment of time and resources that go into bringing a drug to market. More recently, they argue that their medicines are actually saving money by preventing expensive medical interventions like surgery and hospitalization.
- But whatever the argument used, the price setting mechanisms for commodities that are inextricably linked to people's health and survival must be made more transparent so that we can, as a global community, devise effective solutions.

*(Marie-Paule Kieny, WHO Assistant Director-General, Health Systems and Innovation-
A comprehensive and fair solution to the price of medicines-Commentary -5 July 2016)*

WHA 70.12, Agenda item 15.6

- At the Seventieth World Health Assembly in 2017, Member States adopted resolution WHA70.12, Cancer prevention and control in the context of an integrated approach.
- prepare a comprehensive technical report that examines **pricing approaches, including transparency, and their impact on availability and affordability of medicines** for the prevention and treatment of cancer, including any evidence of the benefits or unintended negative consequences, as well as incentives for investment in research and development on cancer and innovation of these measures, as well as the relationship between inputs throughout the value chain and price setting, financing gaps for research and development on cancer, and options that might enhance the affordability and accessibility of these medicines.

Challenges in Health Care System Worldwide



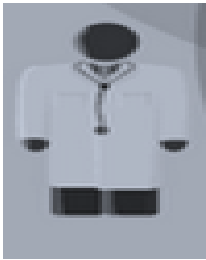
- Finding a balance in the protection of intellectual property between the short-term interests in maximizing access and the long-term interests in promoting creativity and innovation is not always easy.



*Access – availability & affordability

What are policy-makers trying to do?

What is the most cost – effective treatments?



Health System/
Government

Need to make a profit
to invest in new
research?



Industry

What is the best treatment to
extend life and improve the
quality?



Patients

➤ Aim of health care systems is to maximise health outcomes using available resources.

Scarcity



Choices



Opportunity cost

- The Government/ Ministry of Health has a fixed budget – not a bottomless pot
- Resources must be allocated in a reasonable way

Drug Pricing Issues = Affordability Issues



- ✦ Worldwide, government intends to reform the way in which drugs purchased are priced
 - ✦ **Aim: to ensure that drug prices fully reflect clinical benefit and to improve patient access to new innovative treatments**
- ✦ **High pricing for most patented medicines (mostly claimed as innovative drugs)**
- ✦ This note the **importance of pricing policy** and “**value-based pricing**” (links cost to clinical evidence)
- ✦ **Challenges in assessing the value of drugs:**
 - **Cost-effectiveness** can be measured only once a drug has been licensed, allowing assessment over time through comparisons with other treatments available (**take a long time**)
 - In some instances, even drug is claimed to be **cost-effective based on initial assessment**, there is still no consensus as to whether treatment is cost-effective even after so long being used in practice (**uncertainties**)

Drug Pricing Issues = Affordability Issues - The Scenario in Malaysia

Decision problem: What should the MOH pay for?



Health Ministry urged to approve drug to help patients with spinal muscular atrophy

NEWS
Gov't doesn't seem to want to make cancer drugs affordable

Hepatitis C cure too expensive in Malaysia

Of cancer and high drug prices
GLOBAL TRENDS
As cancer cases and deaths shoot up, doctors and patients complain of the exorbitant cost of medicines and call for action to be taken.
Monday, 3 Mar 2014

Why new cancer drugs are unavailable in Malaysian public hospitals

Modified on 8 Nov 2017, 4:09 pm

Star ONLINE

News Business Sport Metro Tech Lifestyle Opinion Video

TOPICS ▶ 1MDB | True or Not | Star Golden Hearts Award | Star Empowerment

Concerns on medicine raised

NATION
Saturday, 28 Oct 2017

Make healthcare, medicines affordable, consumer groups urge govt
Nurul Azwa Aris | June 5, 2018

Fomca and Consumer Association of Penang commend the accessible services of the public healthcare sector but complain of high prices of treatment in private hospitals.

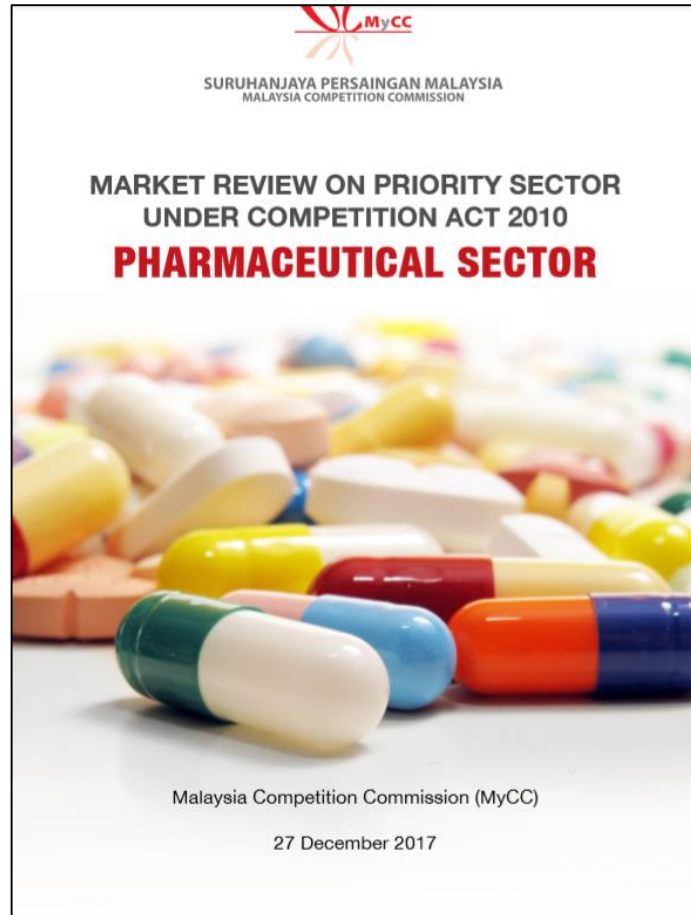
Drugs for Hepatitis C can cost as much as RM300,000

Example: Pembrolizumab (Keytruda)

- Burden of disease: 1,300 patients over 5 years
- Clinical effectiveness:
Pembrolizumab offers **additional 2 months** in **median overall survival (OS)** for second line metastatic non-small cell lung carcinoma (NSCLC) as compared to standard of care in MOH Medicines Formulary.
- **Drug cost/patient/treatment (5 cycles): RM180,000 (USD 43,000)**
- Budget Impact Analysis:
~Total 5 year incremental cost is **RM200 million (USD 48 million)**



Summary Report



“The Review found that available studies generally show that prices in Malaysia tend to be higher compared with other countries.”

Progresses made by Malaysia towards fair pricing

Accessibility

ACCESS = AVAILABILITY + AFFORDABILITY

PRICE vs FINANCIAL MEANS

Just because a product is registered, it does not mean that it will be used!

- Drug not marketed
- High pricing for most patented medicines (mostly claimed as innovative drugs)
- This note the importance of “value-based pricing” in the pricing policy.

Effectiveness vs Affordability

- New treatments-target therapies that are highly effective but only for a limited and defined group of patients
 - **Very expensive drugs**
- Price is not based on costs, but on value
 - Kalydeco for cystic fibrosis priced at \$307,000 per year in the US
 - Crizotinib for non-small cell lung cancer priced at \$100,000 per year in Korea
 - Sofosbuvir for hepatitis C at \$84,000 for 12 weeks in the US
- Inclusion of such expensive new drugs in the MOH formulary means **significant burden on budget**, which has implication in terms of opportunity cost
 - **Sustainability** of the very expensive new drugs is questioned considering

“The only treatment that works is the one that we can afford to give”

What is value?

➤ Value from the perspective of Ministry of Health as the payer

MOH Principle

To provide clinically relevant and cost effective medicines for the management of **common disease** affecting the **majority of patients**.

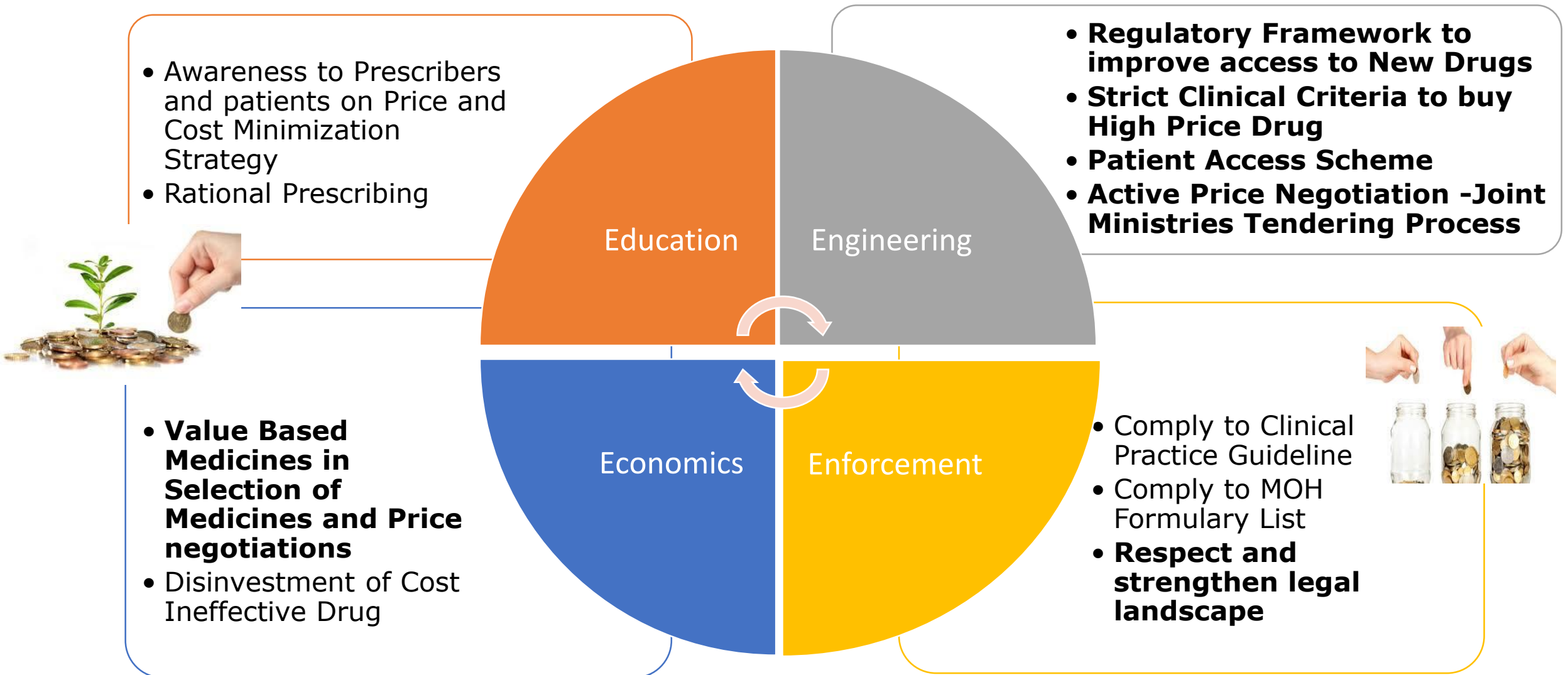
To control, promote and encourage **rational, safe and cost effective medicines** prescribing and usage in Malaysia.

- **Cost effective -it is about using scarce resources as efficiently as possible**
- **Price is what you pay and Value is what you get!**
- Health maximization
- health gain only? - other value considerations
 - Possibilities include:
 - convenience and access
 - severity of disease
 - rarity of disease

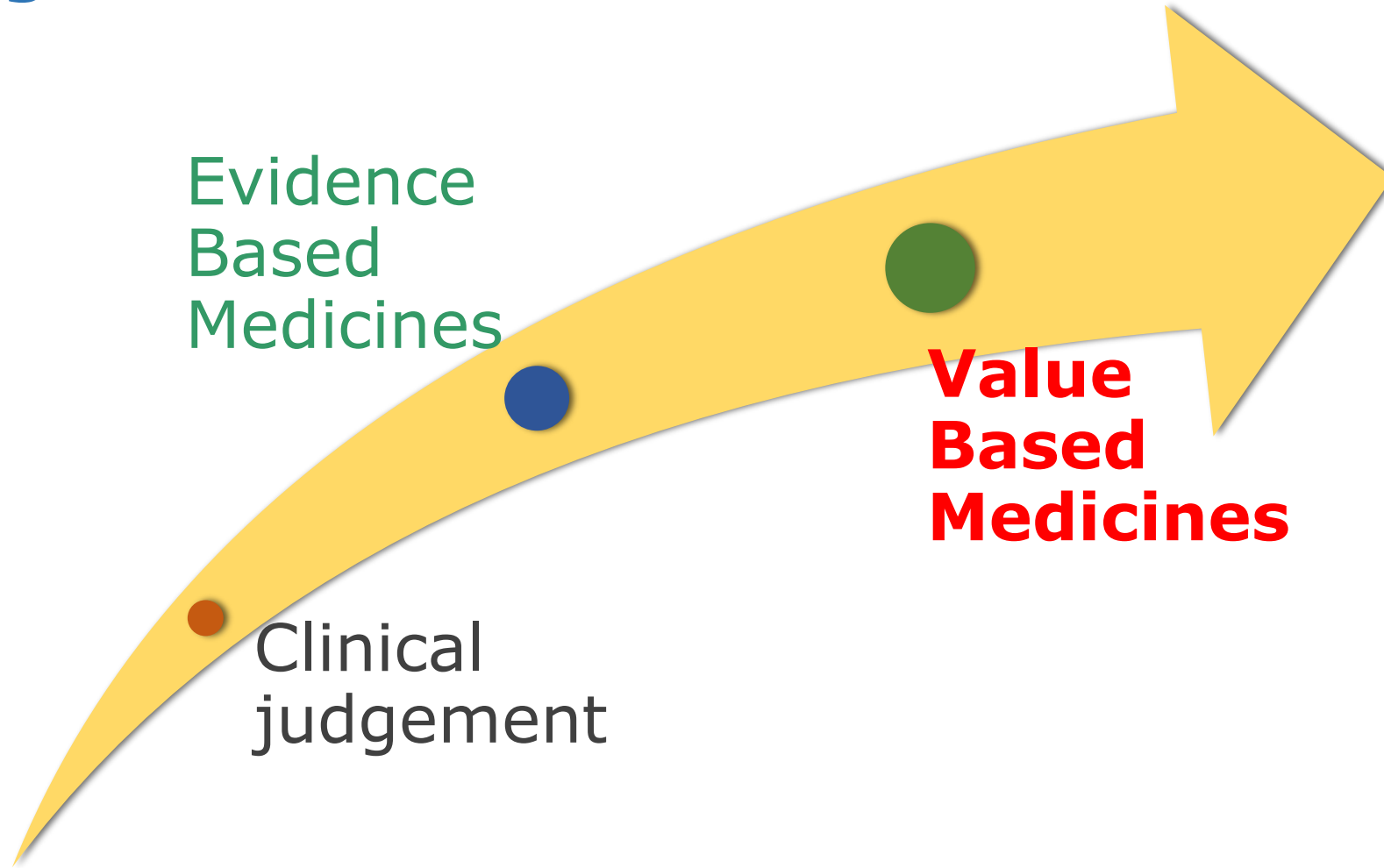


Strategies/Initiatives for Fair pricing in Improving Access to Medicines

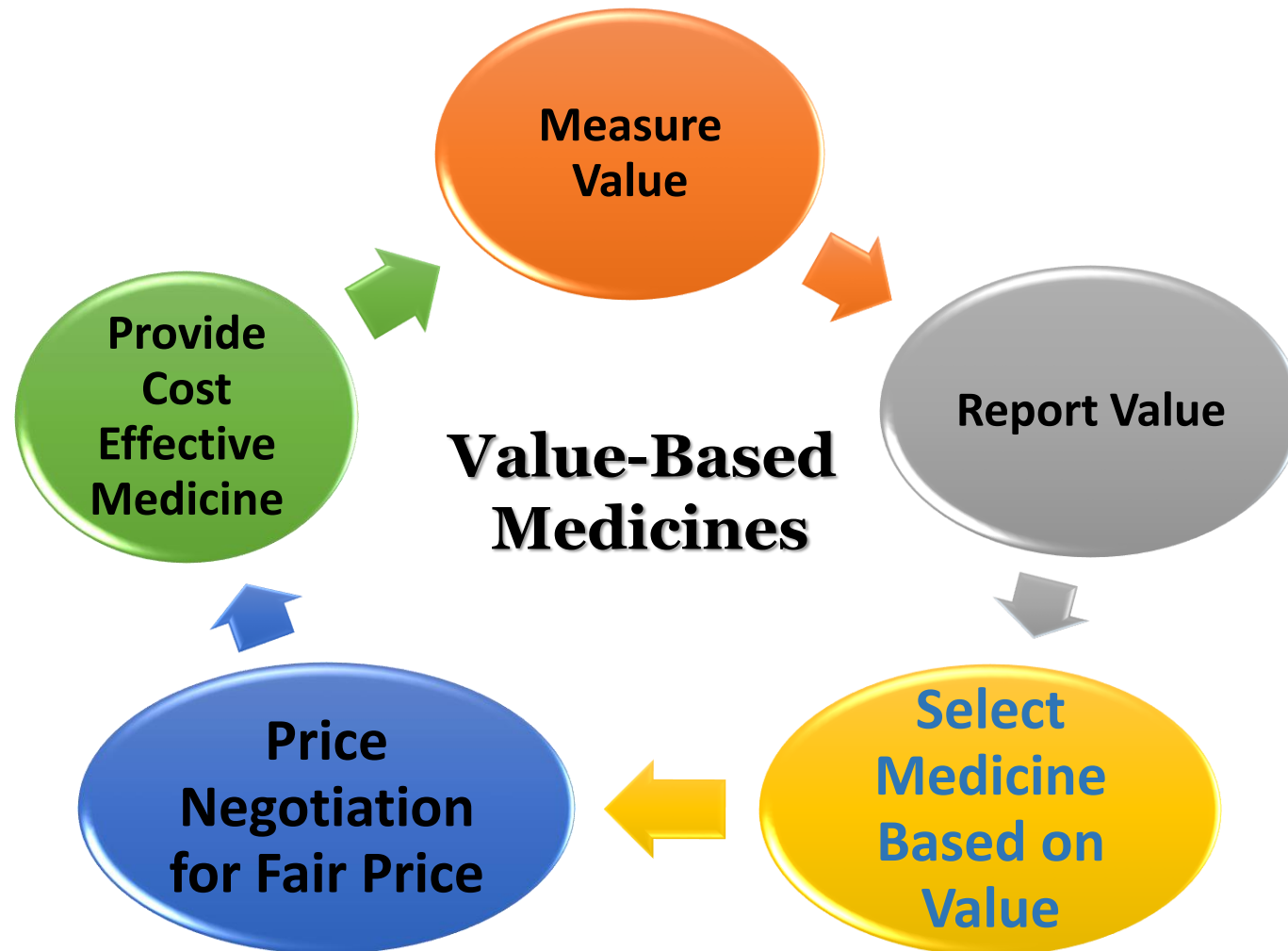
Malaysia's Model in Improving Access to Innovative High Cost Medicines



Value-Based Formulary Listing “Paradigm Shift”



Value-Based Medicines in Selection of Medicines and Price Negotiations



Value-Based Formulary Listing

Value-Based Medicine Concept

- ✚ Comparative analysis with current treatment (effectiveness, safety)
- ✚ Cost Analysis / Economic Evaluation
- ✚ Budget Impact Analysis (BIA) based on projected utilization data
 - Recommendation from BIA e.g:
 - *Low Budget Impact----- Accepted for listing (with possibility to disinvest other alternatives)*
 - *High Budget Impact -----Rejected for listing*
- ✚ **Value-based Medicine concept successfully brought down prices of New, Innovative High Cost Drugs within the same class**
 - e.g. Newer Oral Anticoagulants, Gliptins DPP4, Tyrosine Kinase Inhibitors (targeted Therapy) in MOH medicines formulary**

Other Mechanisms towards Fair Pricing: Regulatory Perspective



Incentives for Generic Pharmaceutical Industry



Conducive Regulatory Infrastructure



**Establishing Government to Government
Agreements**



Respect and Strengthen Legal Landscape

Establishing Government to Government Agreements

Mutual Recognition Agreements (MRA)

✚ Establishing government to government Memorandum of Understanding between selected countries

- Drug Technical Dossiers and Drug Technical requirements to facilitate drug registration processes for early market access into Malaysia and the respective countries

✚ ASEAN Pharmaceutical Harmonization - ACCSQ-PPWG

ASEAN Consultative Committee Standards Quality (ACCSQ)–Pharmaceutical Products Working Group (PPWG)

- To develop **harmonisation and reliance schemes** of pharmaceutical regulations for ASEAN Member States to complement and facilitate the objective of ASEAN Free Trade Area (AFTA)
- **Elimination of technical barriers to trade (TBT)** posed by regulations without compromising product quality, efficacy and safety

➤ Strategies : **Developments of common technical dossier (CTD) towards Mutual Recognition Agreements (MRA)**

Eg. of MRA amongst ASEAN Member States

- **MRA – Good Manufacturing Practice (GMP), signed in 2009, implemented from 1 January 2011**
- **MRA – Acceptance of Bioequivalent Study Reports, signed on 2 November 2017**

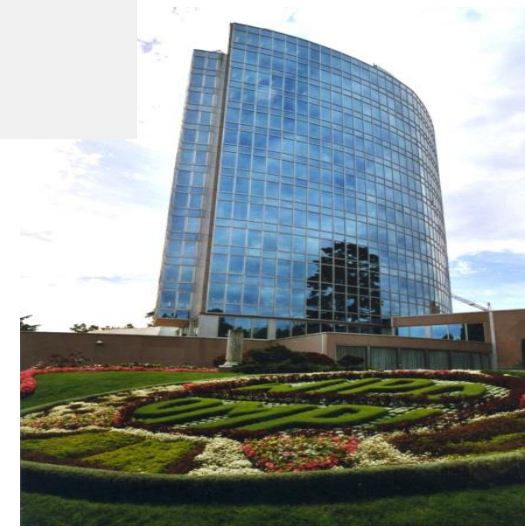
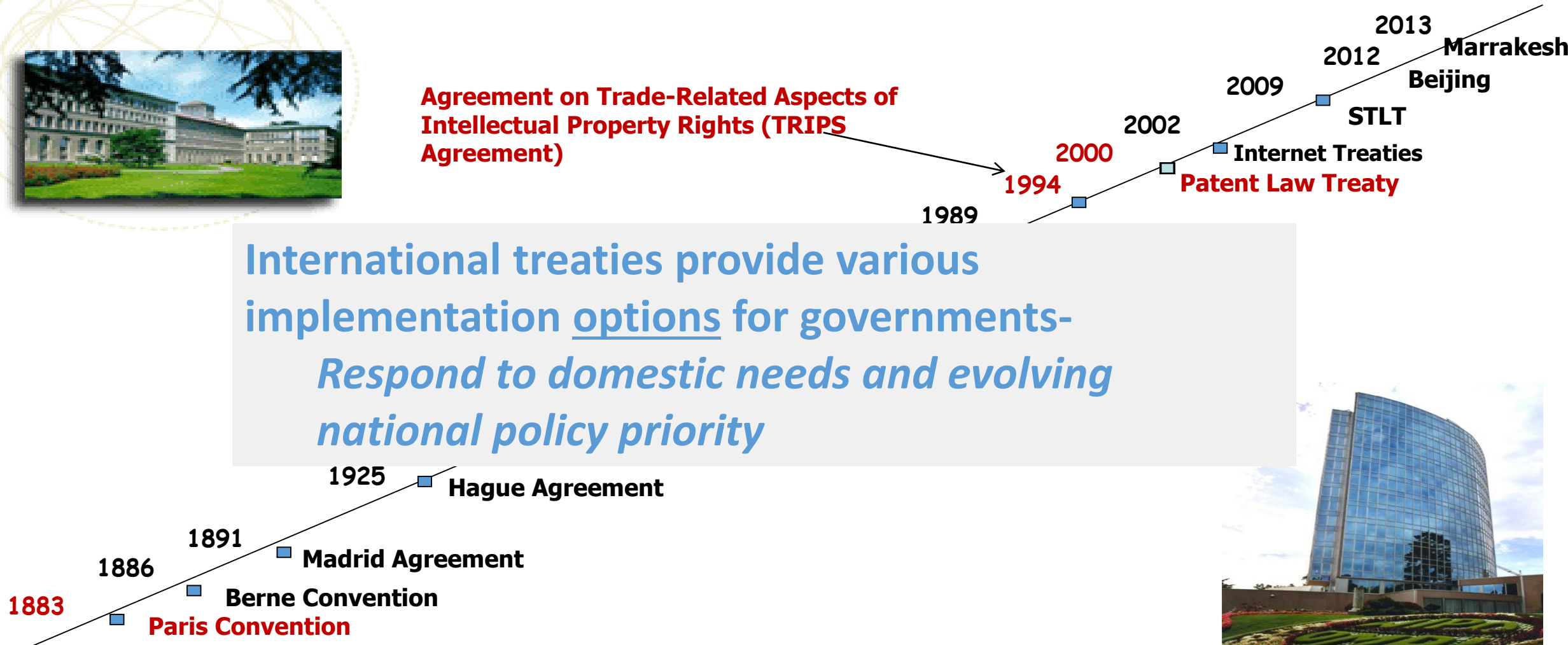
Respect and Strengthen Legal Landscape

International Treaties : 1883 to 2017



Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)

International treaties provide various implementation options for governments-
Respond to domestic needs and evolving national policy priority



WTO's TRIPS Flexibilities

➤ Under the TRIPS Agreement 1995, patent rights are not absolute but can be subject to such limitations or exceptions:

Bolar Provision (Article 30)

- Permits the use by generic producers of patented products, without authorization while patent is still in force, for the purposes of seeking regulatory approval from DRA for the marketing of their generic version as soon as the patent expires
- Malaysia's adoption : Malaysian Patent Act 1983 –Sect.37 (1A). This provision limited to pharmaceuticals, narrow and restrictive compared to most countries

Compulsory License (Article 31)

- Authorization of use to third parties to produce generic version of patented product without the consent of the patent owner
- Terms and conditions apply
- Malaysia's adoption : Malaysian Patent Act 1983 – Sect. 48-54. This Patent Act is currently under review for amendment, to adopt the Para 6 solution* in Doha Declaration

Rights of Government (Article 31)

- Authorization for public non-commercial purpose to produce generic version of patented product without the consent of the patent owner.
- Terms and conditions apply
- Malaysia's adoption : Malaysian Patent Act 1983 –Sections 84



The adoption of the **Doha Declaration on TRIPS and Public Health by the 2001 Ministerial Conference of the World Trade Organisation (WTO)**, had accordingly affirmed the right of national governments to take measures to protect public health, and confirmed the legitimacy of the broad use of the flexibilities available in TRIPS to promote access to medicines

Other Initiatives

+ Malaysian Competition Commission

- Looking at unfair pricing/anti competitive in trade practices
- Market monopoly

+ Medicines Pricing Mechanism

- Value-based pricing (links drug price of a drug to cost-effectiveness)
- Price negotiations based on clinical value, delivers prices that truly reflect a drug's value
- Active negotiation for fair pricing based on economy of scale quantity -Joint Ministries Tendering Process



**Towards Fair Pricing
for Better Access to
Medicines**

Way Forward Strategies

+ Regulatory Framework to Improve Access to high-cost drug

- Accelerate process for generics/ biosimilars registration. This provide alternatives with cheaper price
- Create price competition with innovators

+ Transparent Patient Access Scheme/ Managed Entry Agreement

- Method to enable patients to gain access to innovative- high cost drug
- Potential for schemes should not be a burden to both provider and industries. Need early engagement with both parties (early dialogue, discussing on schemes and tailoring schemes that suits MOH settings)

+ Joint Price Negotiation

- Joint price negotiation as a country or region would offer opportunity to participate in collective, multinational transactions that enhance negotiation power

+ Transparency in Medicines Pricing/ Fairer Pricing System

- Proposal to regulate medicines prices

+ Redistribution of Budget

- An efficient reallocation of budget is necessary to make funding available for expensive treatment

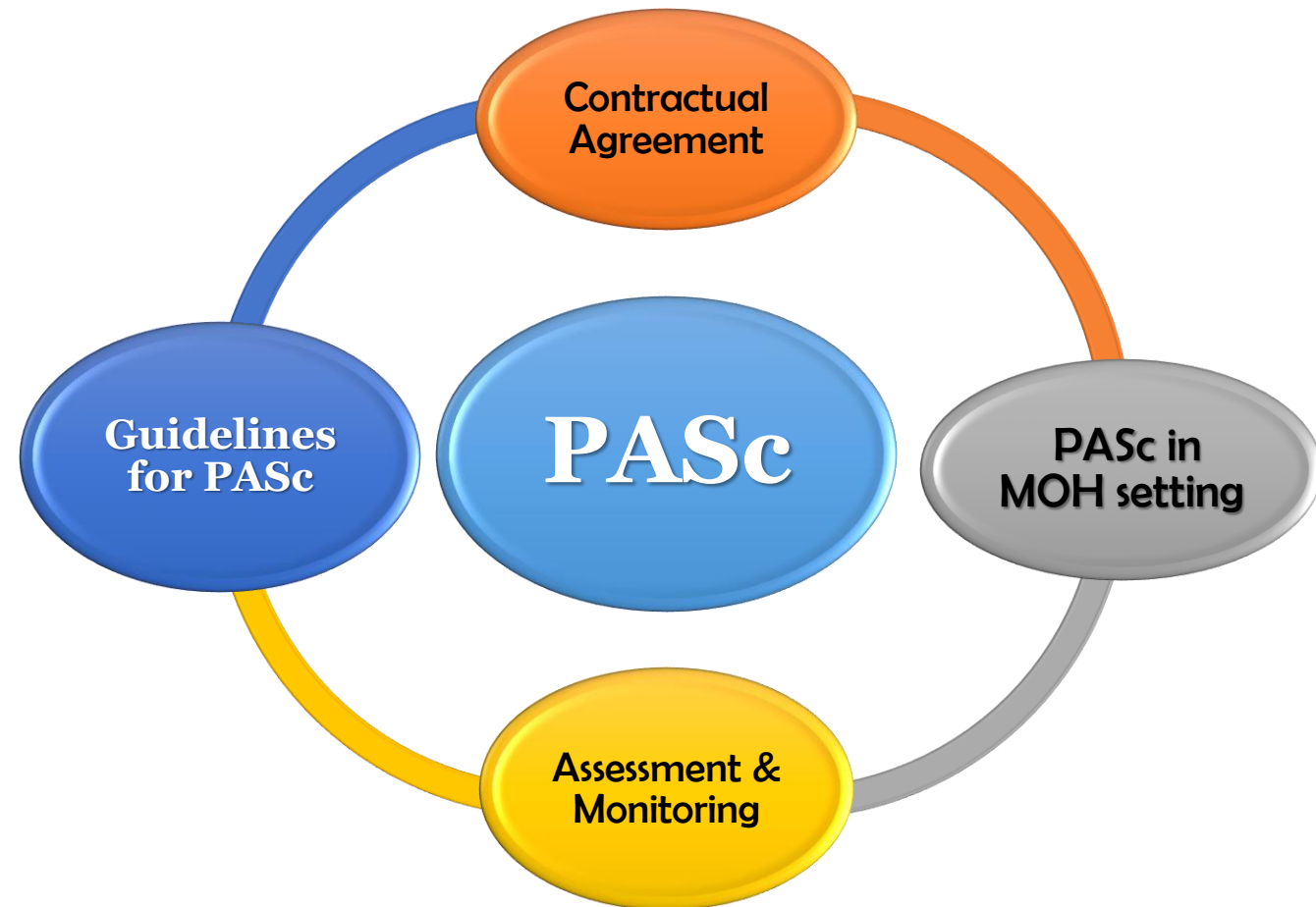
+ Enhancing Value-Based Medicine Concept in Selection of Medicines

- Promoting Evidence-Based Medicine and focus on patients' values/ utility values

Patient Access Scheme (PASc)

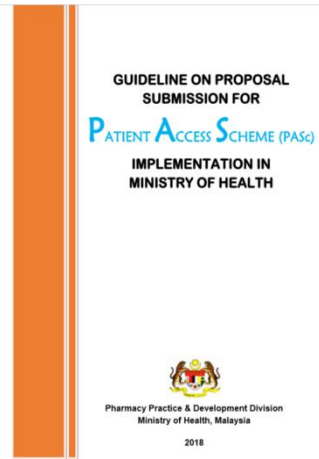
- PASc is a scheme proposed by pharmaceutical companies and agreed upon by the Ministry of Health (MOH) in order to **improve access to medicines** which are likely to have **high budget impact** either due to high treatment cost per patient and/or large volumes of use.

- ✓ **BECAUSE** - Need to make new drugs available to patients in order to balance the interests of patients, clinicians, manufacturers, and other stakeholders
- ✓ **DESPITE** - Presence of a significant degree of uncertainty at the time of making formulary decisions
- ✓ **WHILE** - Ensuring the **long-term financial sustainability** of healthcare systems



General Issues with the Proposed PAsc

- Some of the medicines proposed showed an **additional budget impact to MOH** even though the price is reduced with the scheme
- The **risk was not shared equally between payer and supplier** due to
 - i. upfront purchase by the payer – MOH needs to buy a certain volume upfront to be eligible for the bonusing scheme (buy 1, free 1)
 - ii. uncertainty in patient numbers
- **Patient Access Scheme (PAsc) Guideline - June 2018**



- This guideline sets out the process for submission, evaluation and approval of PAsc in MOH health facilities.
- The main part of this guideline is written for pharmaceutical companies who intend to propose PAsc for medicines to be used within MOH health facilities.
- These requirements are designed to **standardise submissions** by pharmaceutical companies and **minimise variability** in the quality of proposals submitted.

Alternative business models

World Health Organization



FAIR PRICING FORUM
2017 Meeting Report
Amsterdam, The Netherlands
11 May 2017

“Achieving fairer pricing for new medicines will challenge the current model of market-driven R&D. To enable government risk-sharing, it was proposed that public funders might be able to support the clinical trial phase in health care systems. Such risk-sharing models could potentially result in lower prices. It was suggested that governments should attach conditions to research funding so that the public funding is explicitly taken account of in pricing discussions and the results are made publically available.” *Report on the Fair Pricing Forum 2017, Beurs van Berlage, Amsterdam, the Netherlands, 11 May 2017*

Collaboration among MOH, DNDi, Pharco Pharmaceuticals and a local pharmaceutical manufacturing

company- A clinical trial on sofosbuvir/ravidasvir combination treatment for hepatitis C using medicines produced by Egyptian drug manufacturer Pharco Pharmaceuticals was run by DNDi and co-sponsored by the Malaysian Ministry of Health, in ten sites in Malaysia. Agreements signed in 2016 and 2017 enabling the trials and patient scale-up in Malaysia set out a target price of US\$300 for a 12-week treatment, an almost 100% drop from existing treatment prices in Malaysia.-Source DNDi

Malaysia to make drug to treat Hepatitis C

KUALA LUMPUR: Treatment for Hepatitis C will get a significant boost in the country with a drug to be produced locally. Deputy Health Minister Dr Lee Boon Chye said the drug, ravidasvir, would be produced in a joint venture between Pharmaniaga (M) Bhd and Pharco Corp of Egypt.

“We need to foster new collaborations across different stakeholders, which includes some of our civil society organisations and patient groups, in upscaling our national Hepatitis C response,” he said at the 4th National Hepatitis Conference 2019 here yesterday.

Source:<https://www.thestar.com.my/news/nation/2019/03/08/malaysia-to-make-drug-to-treat-hepatitis-c/#0AocAbidIzktuHFr.99>



MINISTRY OF HEALTH
MALAYSIA

DNDi

Drugs for Neglected Diseases initiative

Summary



- Currently, the value of drugs and MOH purchase price is still based on comparative effectiveness, quantity threshold and confounded by budget impact to the payer.
- Given the increasing demand for expensive new technologies and limited financial resources, **value based approaches play an important role** in formulary decisions.
- **Transparency in Medicines Pricing/ Fairer Pricing System**
 - **Fair medicines price** should play a key role in increasing the affordability of medicines and the sustainability of healthcare system
- Nevertheless, access to medicines can also be improved through **various entry schemes, eg patient assisted program**
 - However these programs are complex, burden of monitoring to the facilities, accountability is questionable and not sustainable to payer.
- **Risk-sharing of market-driven R&D models** could potentially result in fairer affordable prices for new innovative high cost drug.



Thank you

