



## **Pricing developments in the Asia Pacific – does comparator-referenced pricing have a future?**

**Educational Symposium: Monday 5<sup>th</sup> September 2016**

**ISPOR AsiaPacific conference, Singapore**

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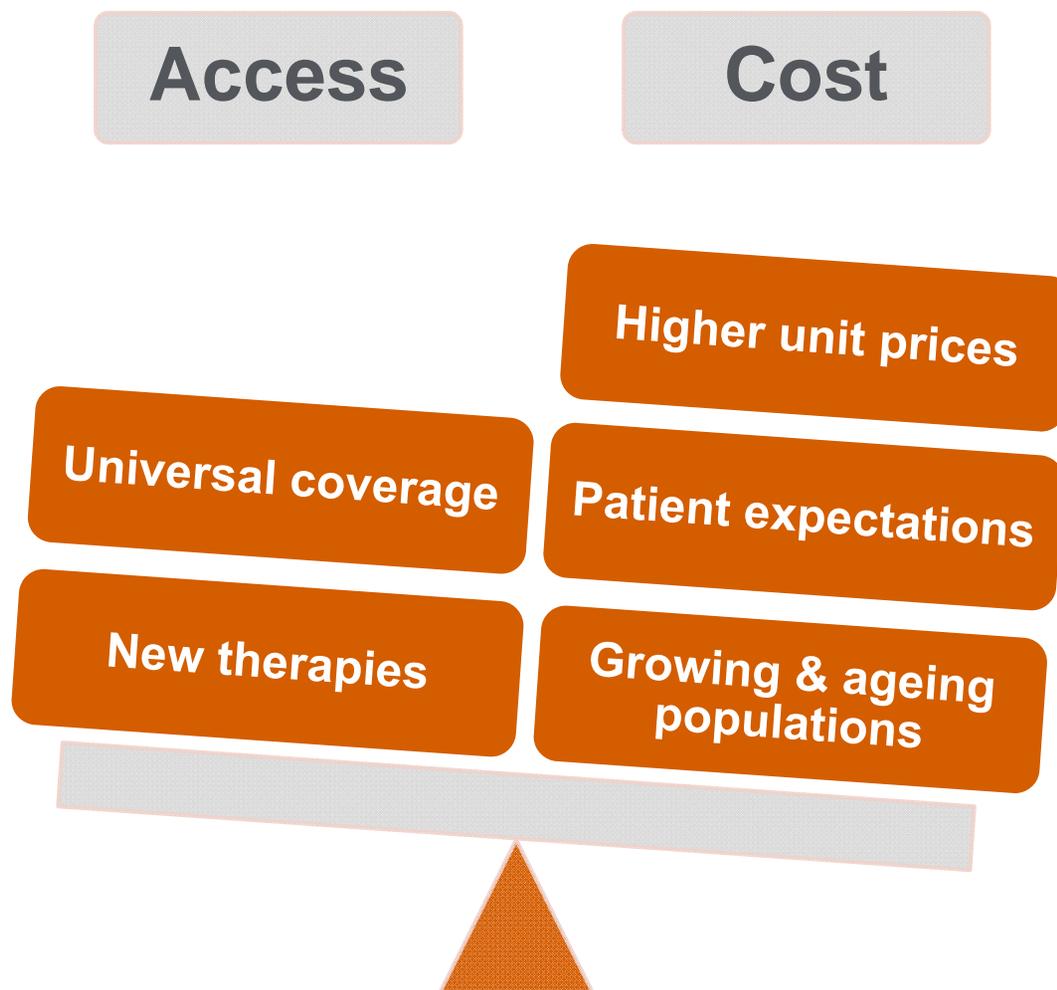
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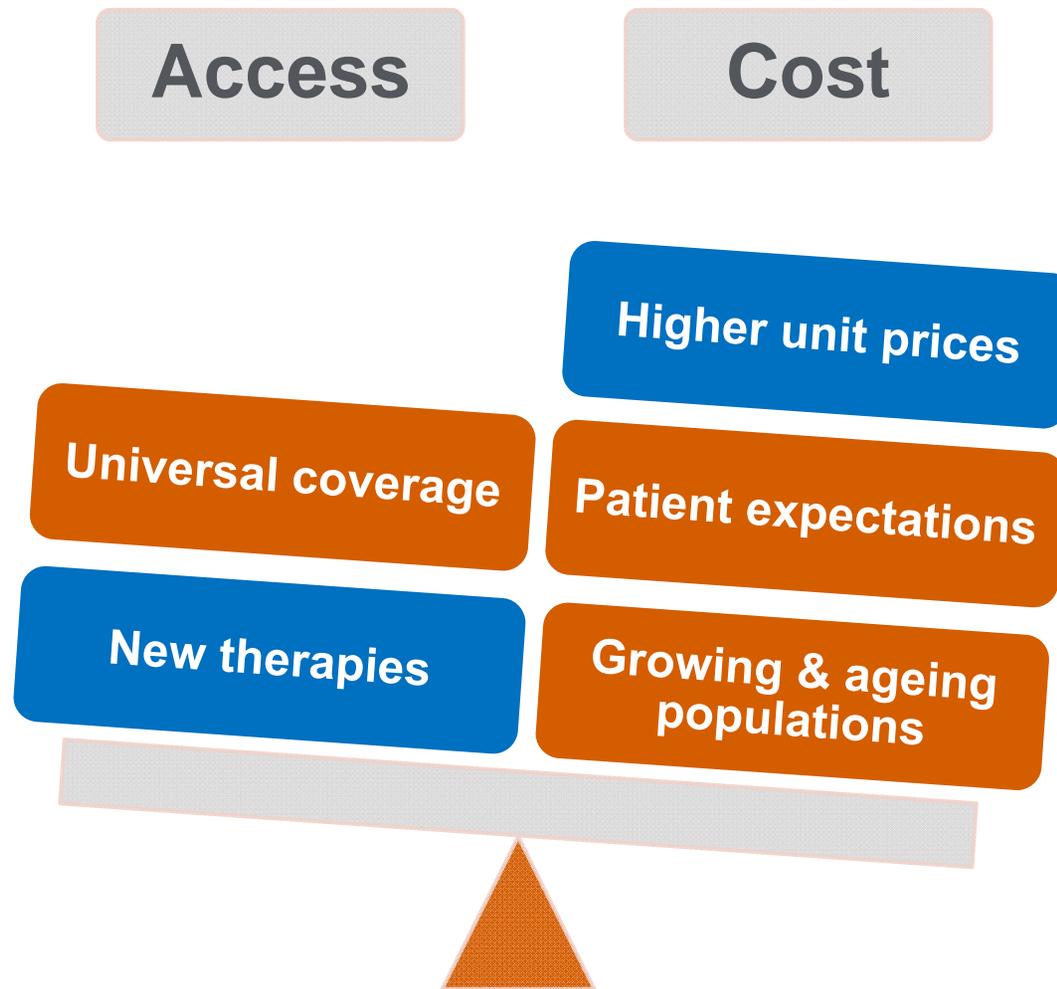
# Pricing in AsiaPacific: quest for sustainability

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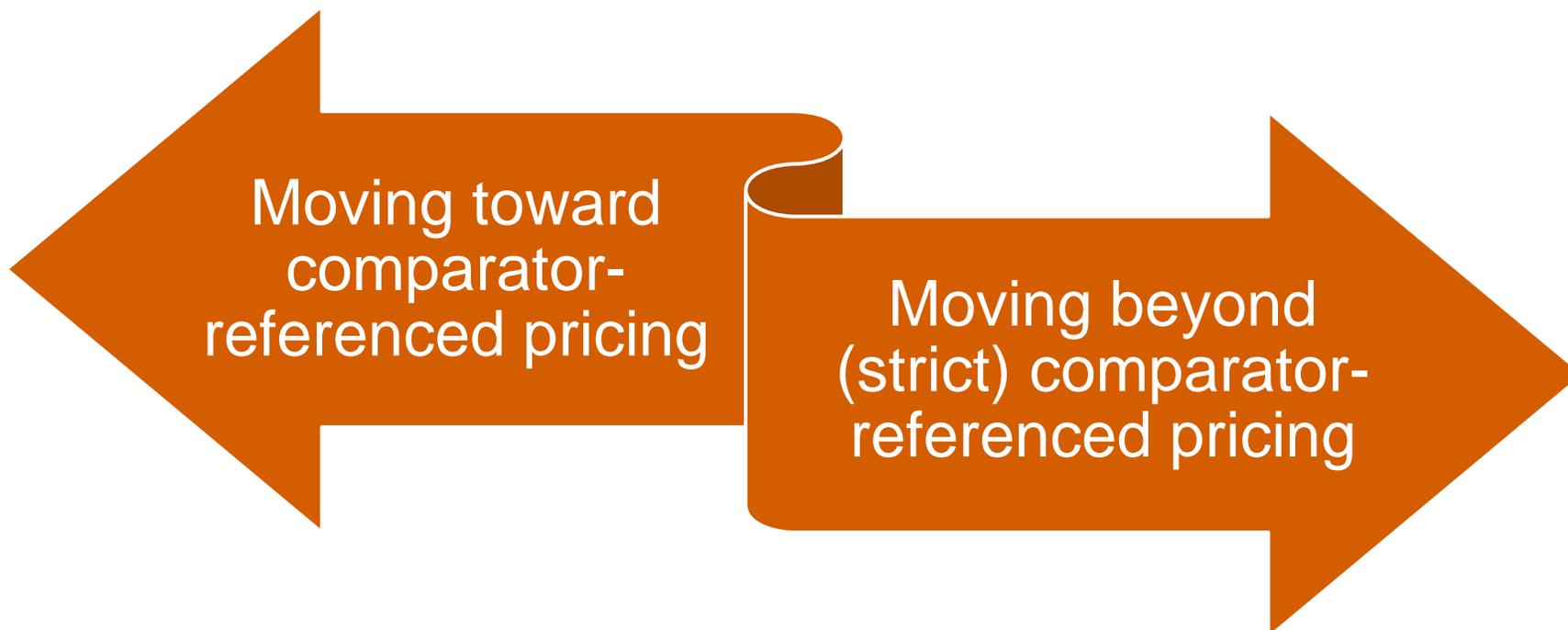
# Pricing in AsiaPacific: quest for sustainability

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# Are we all headed in the same direction?

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# Comparator-referenced pricing

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## **DEFINITION in broad terms:**

- *Comparator is the treatment most likely to be replaced*
- *Both costs and benefits are considered relative to the comparator*

## **Underlying principles:**

- ✓ *HTA evaluation uses the real (effective) price for the new drug*
- ✓ *this becomes the resultant price of the new drug*
- ✓ *this price is known, if/when new drug becomes a comparator itself*

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# **Pricing developments in Asia Pacific: does comparator-reference pricing have a future?**

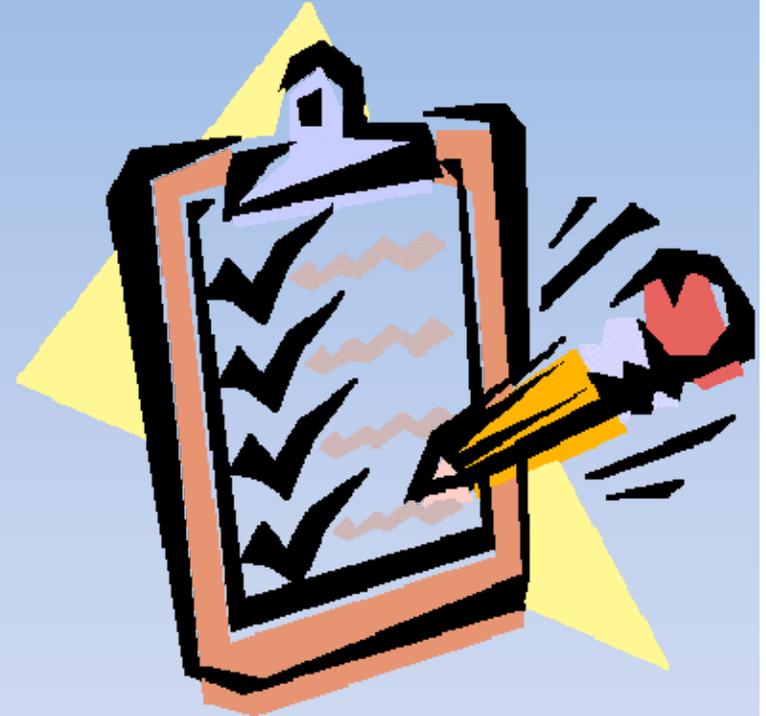
## **A view from a current user**

**Andrew Mitchell**  
**Strategic Adviser, Evaluation**  
**Australian Government Department of Health**



# Overview

- Application of principles
- Some consequences
- Some management options





## Health policy principles (1)



- ***Same*** health outcomes should require ***same*** costs for new proposal
  - same price for new medicine
- ***Improved*** health outcomes can justify ***increased*** costs for new proposal
  - increased price for new medicine



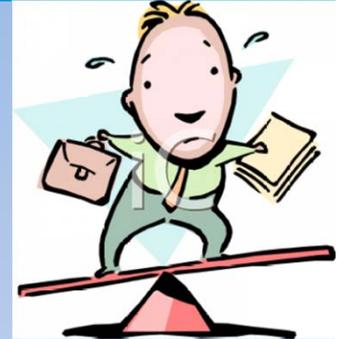
## Health policy principles (2)



- **Better** use of other health care resources may generate worthwhile cost offsets
  - increased price for new medicine



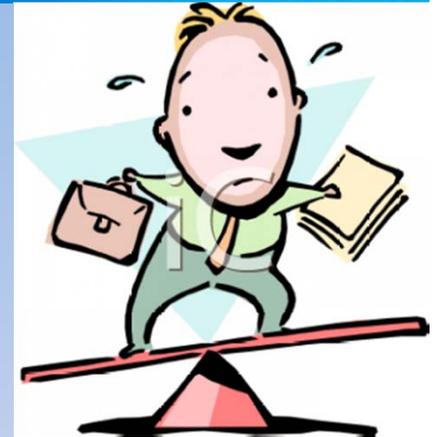
# Systematic consideration of cost-effectiveness



- 1990s: Australia became the first jurisdiction in the world to systematically consider the cost-effectiveness of new medicines
- Improved health outcomes
  - net clinical benefit = benefits > harms
  - QALYs = extension of life x quality of life
- Consequential changes in provision of health care resources



# Incremental cost-effectiveness ratio



$$\text{ICER} = \frac{\text{Costs}_{\text{new}} - \text{Costs}_{\text{old}}}{\text{Outcomes}_{\text{new}} - \text{Outcomes}_{\text{old}}}$$



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# Basic application of

- Pharmacoeconomics
- Cost-effectiveness analysis
- Health technology assessment



# Experience

- Primary objective met
  - helps justify new subsidy decisions
- Secondary consequence
  - sets a ceiling price
  - better value to the payer if price is lower





# Some consequences

- Separating known and unknown costs
- Separating known and unknown health outcomes
- A need to negotiate on other aspects of value from a health policy perspective

YOU ARE FREE TO CHOOSE,  
BUT YOU ARE NOT FREE  
FROM THE CONSEQUENCE OF  
YOUR CHOICE.

A UNIVERSAL PARADOX

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# Managing unknown costs



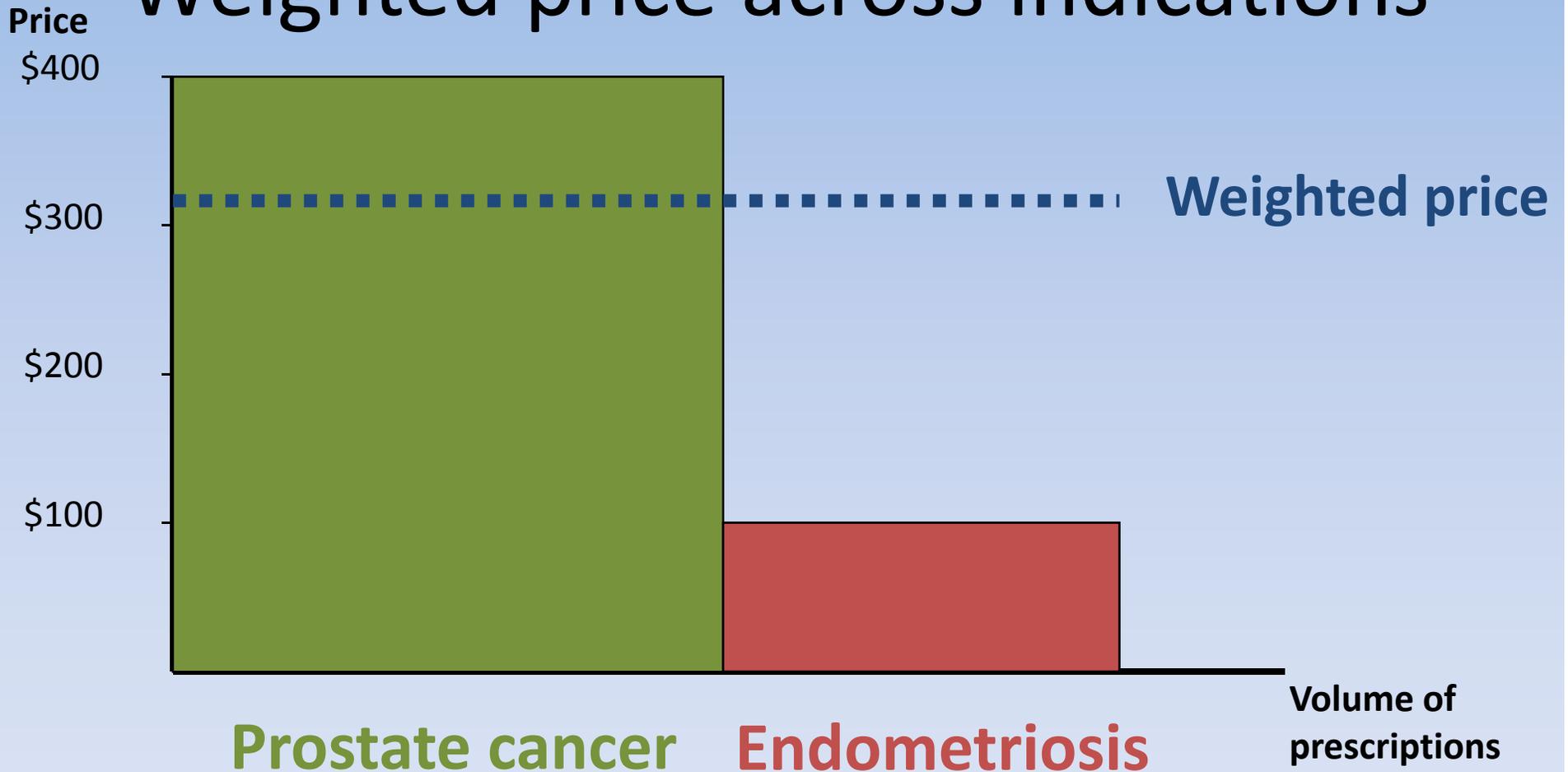
- Mostly about budgetary implications
- Risk-sharing arrangements (RSAs)
  - agree expected annual expenditure over 4 years
  - agree extent of rebate to be paid for any expenditure over a year's expectation **then**
  - measure expenditure each year **and**
  - pay agreed rebate for any expenditure beyond expectation



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# Weighted price across indications

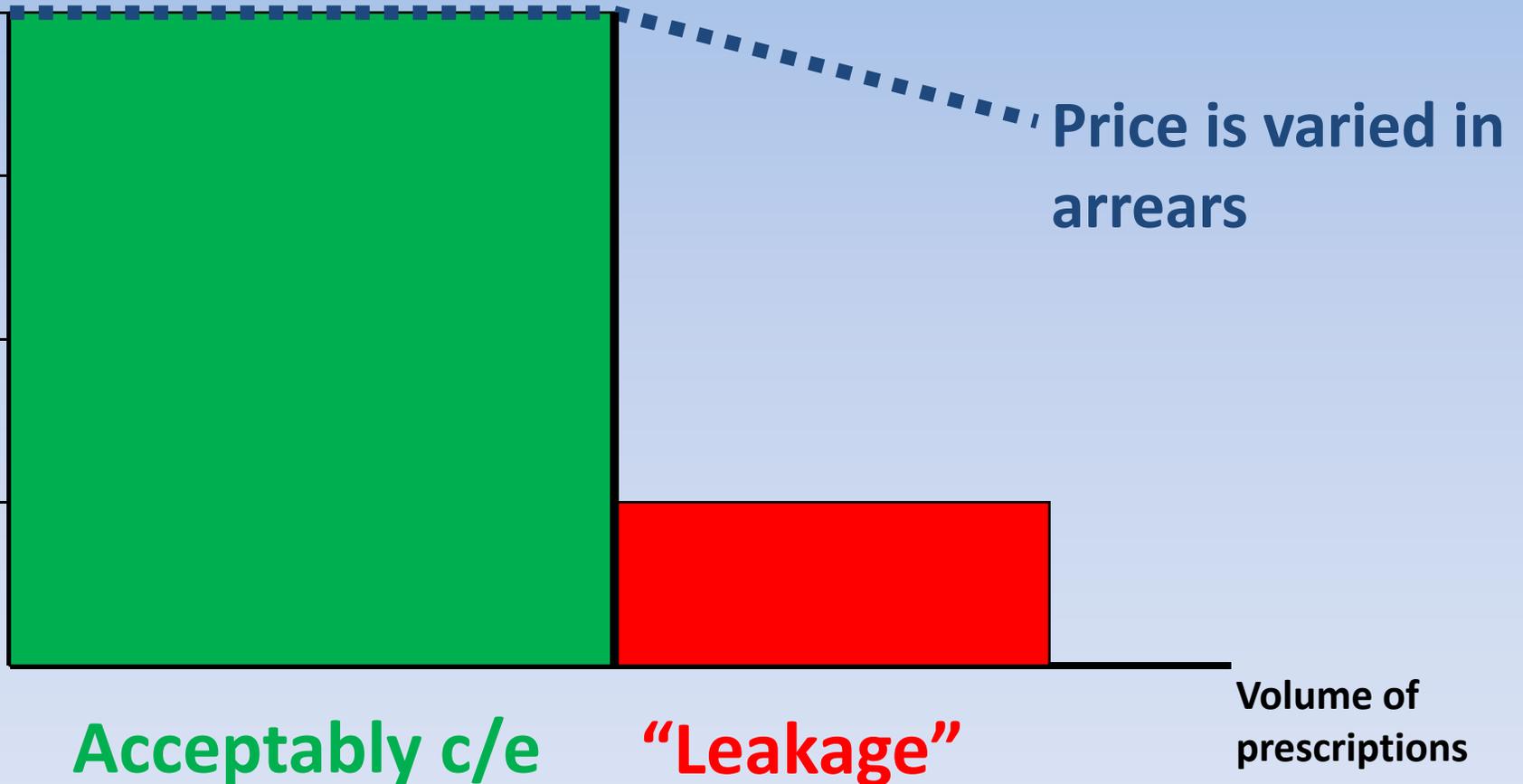


**Goserelin: an early example of pricing across indications**



# Managing risk by varying price

Price  
\$X

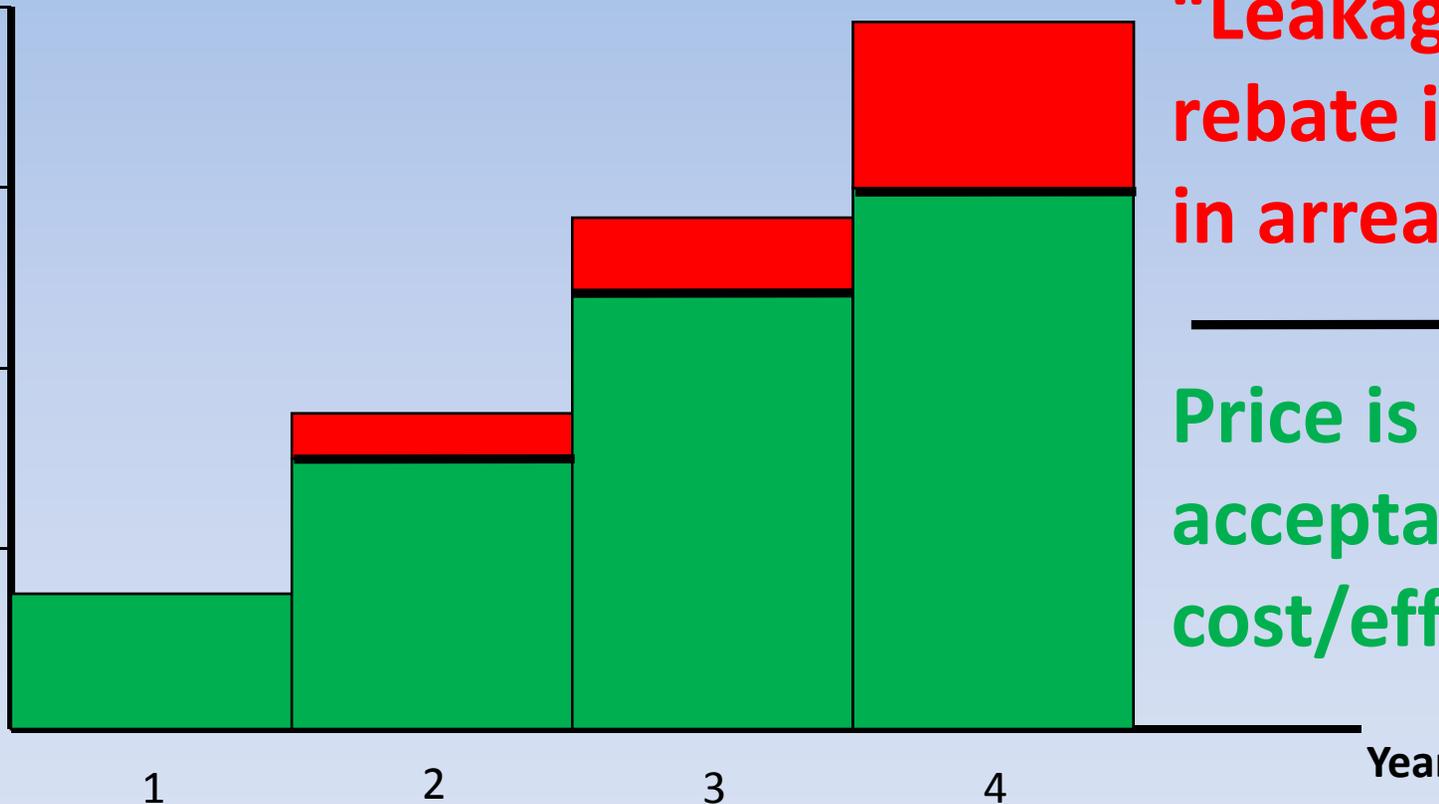


## Price volume agreement



# Managing risk by paying rebates

Expenditure  
\$X



**“Leakage”:**  
rebate is paid  
in arrears

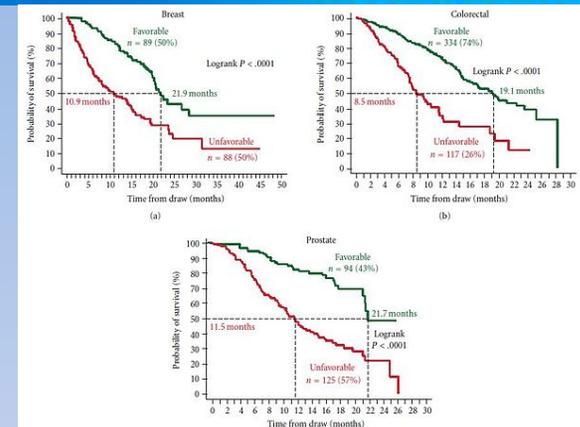
————— Cap  
Price is  
acceptably  
cost/effective

**Risk-sharing arrangement**



# Managing unknown health outcomes

- Mostly about immature trial evidence
- Managed Entry Schemes (MESs)
  - agree primary health outcome
  - agree generated new evidence will be more convincing **and**
  - agree discounted price in the meantime **then**
  - reconsider at end of MES and adjust accordingly





# Managing pricing flexibility

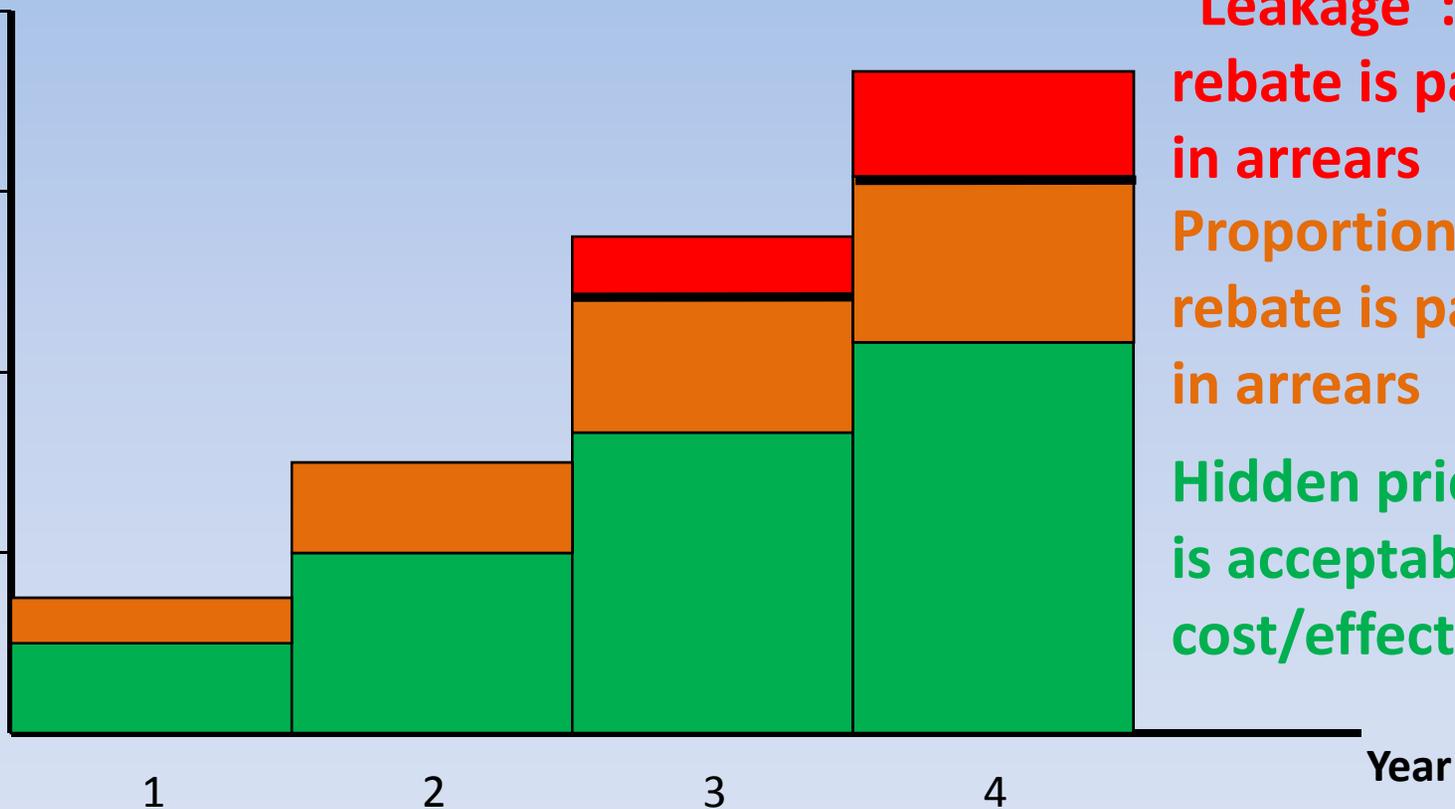
- Lower price if kept confidential
- Special Pricing Arrangements (SPAs)
  - agree lower price
  - agree pivots recommendation from “no” to “yes”
  - agree kept confidential *then*
  - list in the Schedule of Pharmaceutical Benefits with note identifying existence of SPA

**CONFIDENTIAL**



# Adding Special Pricing Arrangements

Expenditure  
\$X



**“Leakage”:**  
rebate is paid  
in arrears  
Proportional  
rebate is paid  
in arrears  
Hidden price  
is acceptably  
cost/effective

**“Published versus effective” price agreement**



# Conclusions



Australian “comparator-referenced pricing” gives incentives rewarding

- *improved health outcomes*
- *better use of health care resources*
- *confidence in the best available evidence*

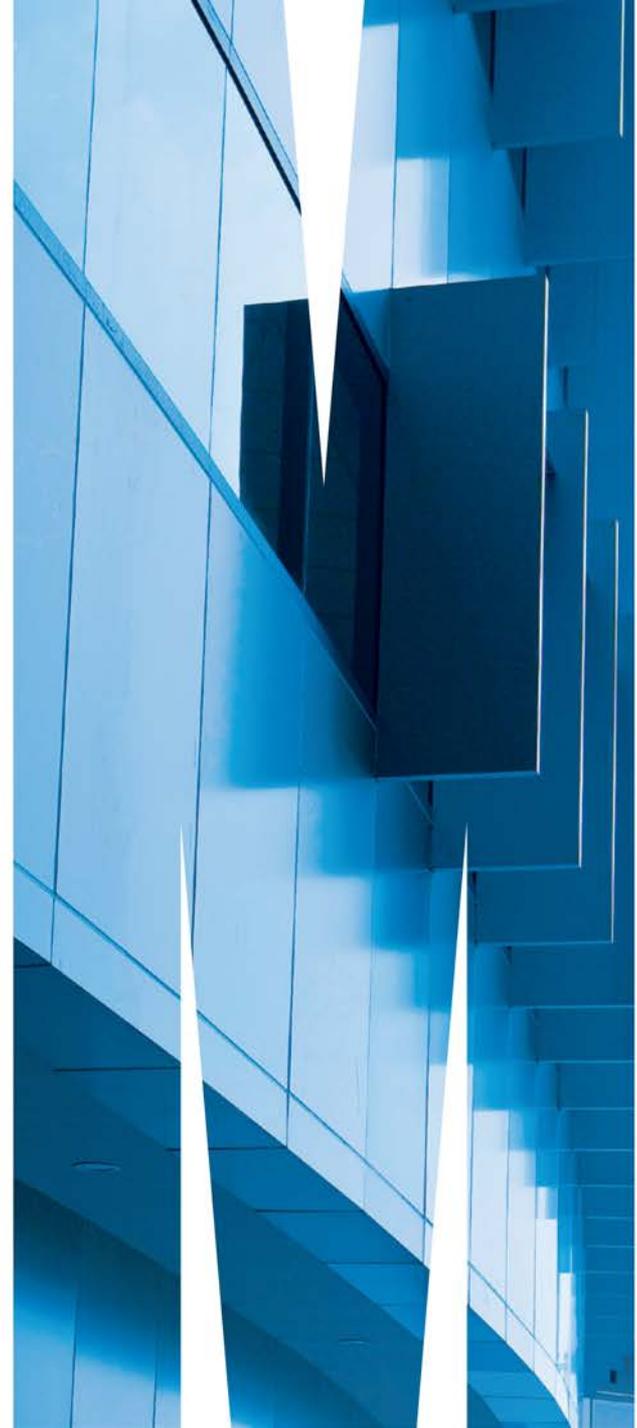
Australian HTA manages and values

- *transparency*

# *Pricing developments in the Asia Pacific – does comparator-referenced pricing have a future?*

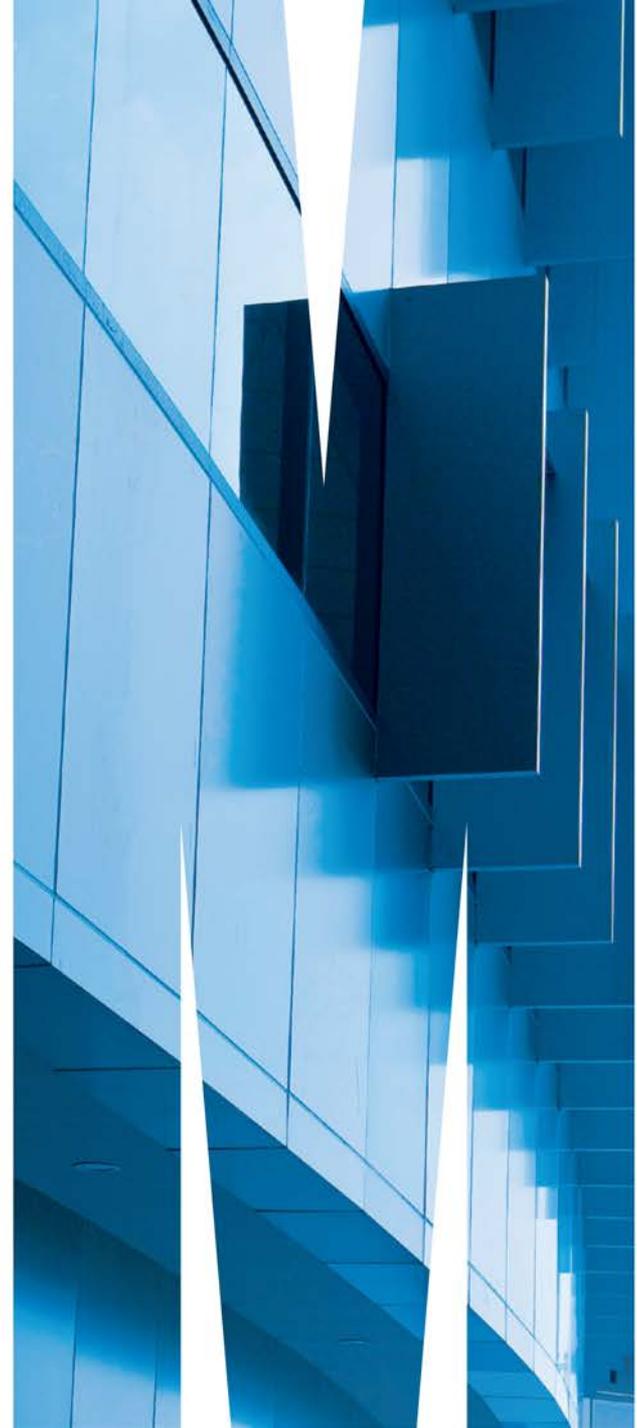
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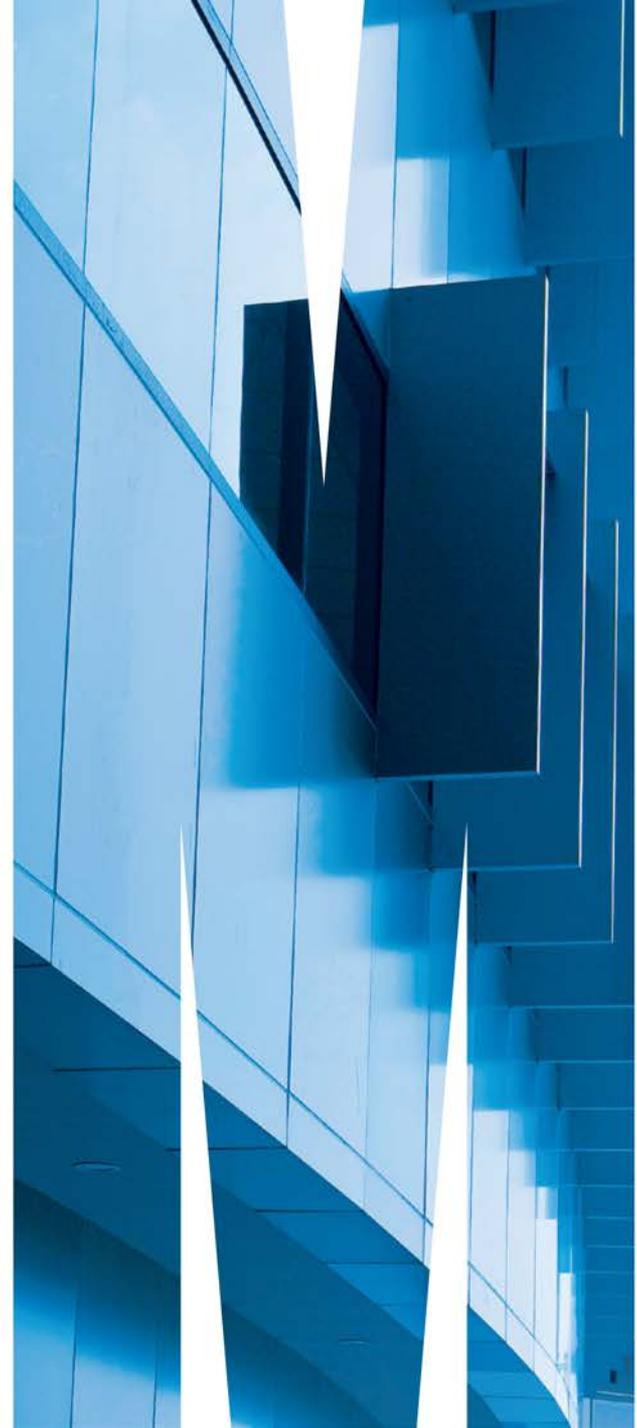
## Outline

- Recent trends of development in HTA in Asia
- Comparator-referenced pricing from an academic point of view
- Capacity building in HTA



# China

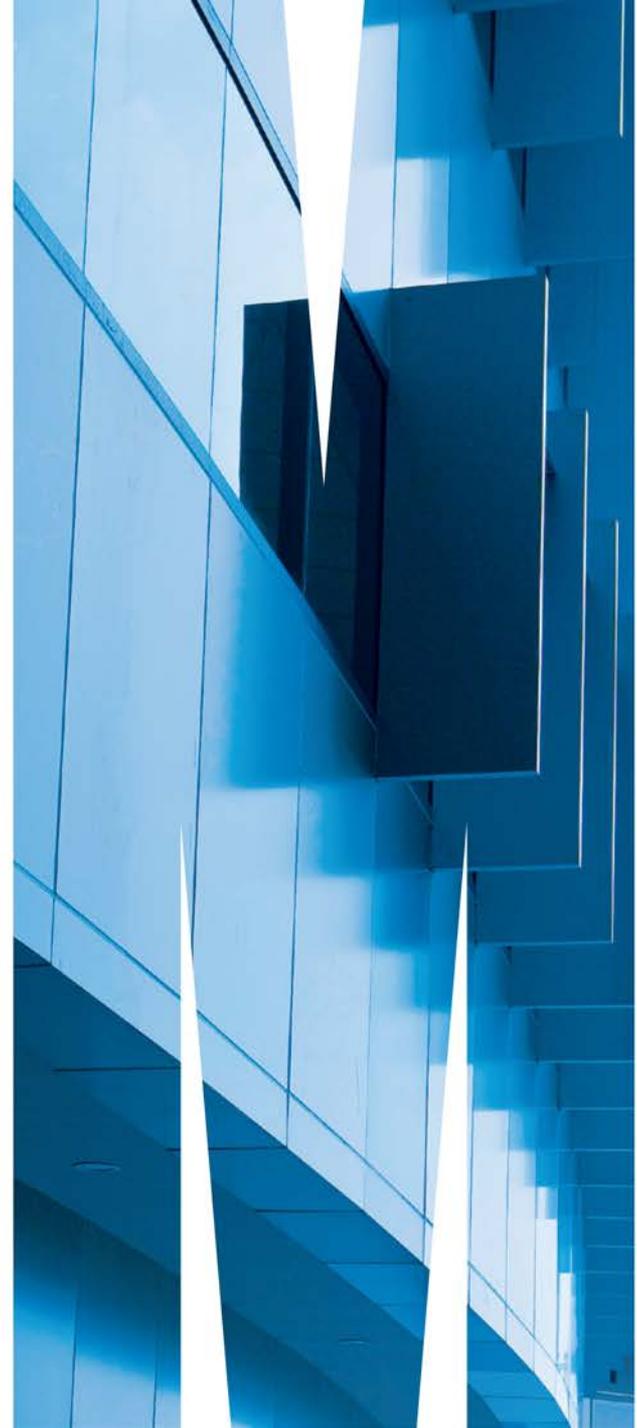
- Universal coverage of health insurance as a major part of health care reform
- HTA still in process of development
- Application of HE data used occasionally, a trend of increase observed
- Stable and rapid economic development which provides the financial conditions necessary to operate and sustain an evidence-based system of decision making



Korea

- Threshold: implicit 1 GDP

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# HTA system in Korea



develop  
new technology



Committee for HTA



The Ministry for  
Health Welfare  
and Family  
Affairs



use new  
technology



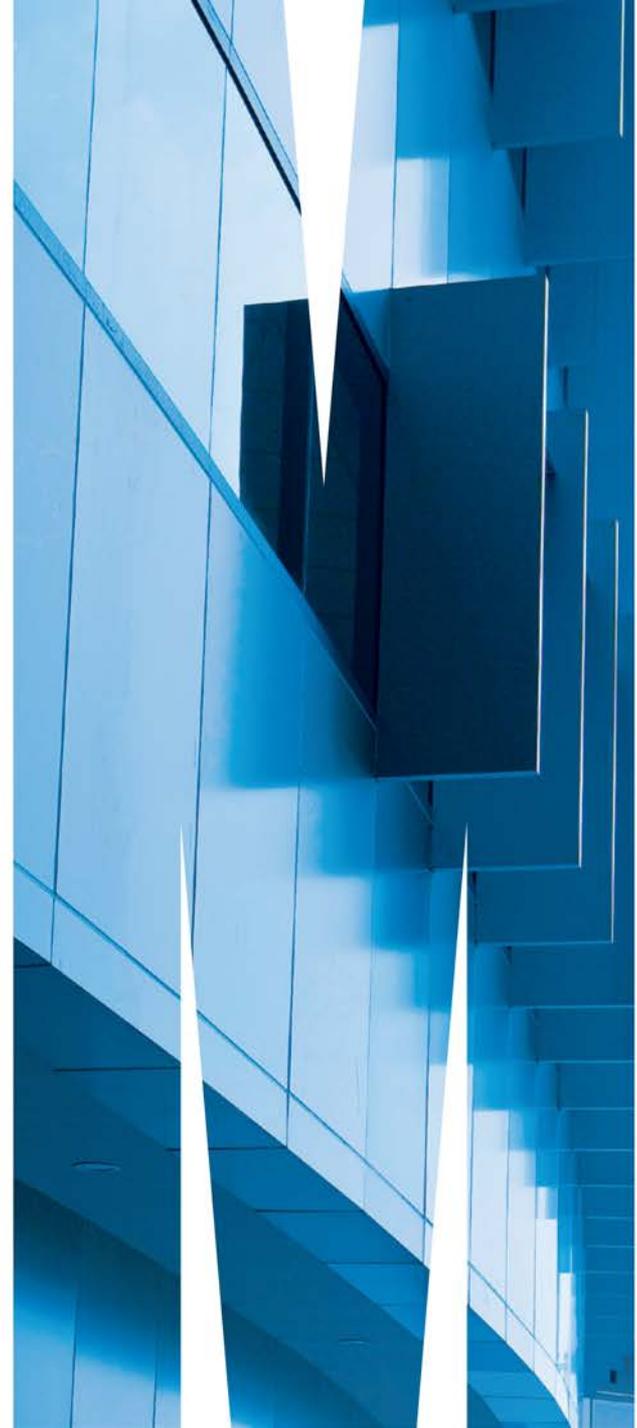
review Cost-  
effectiveness



## Taiwan

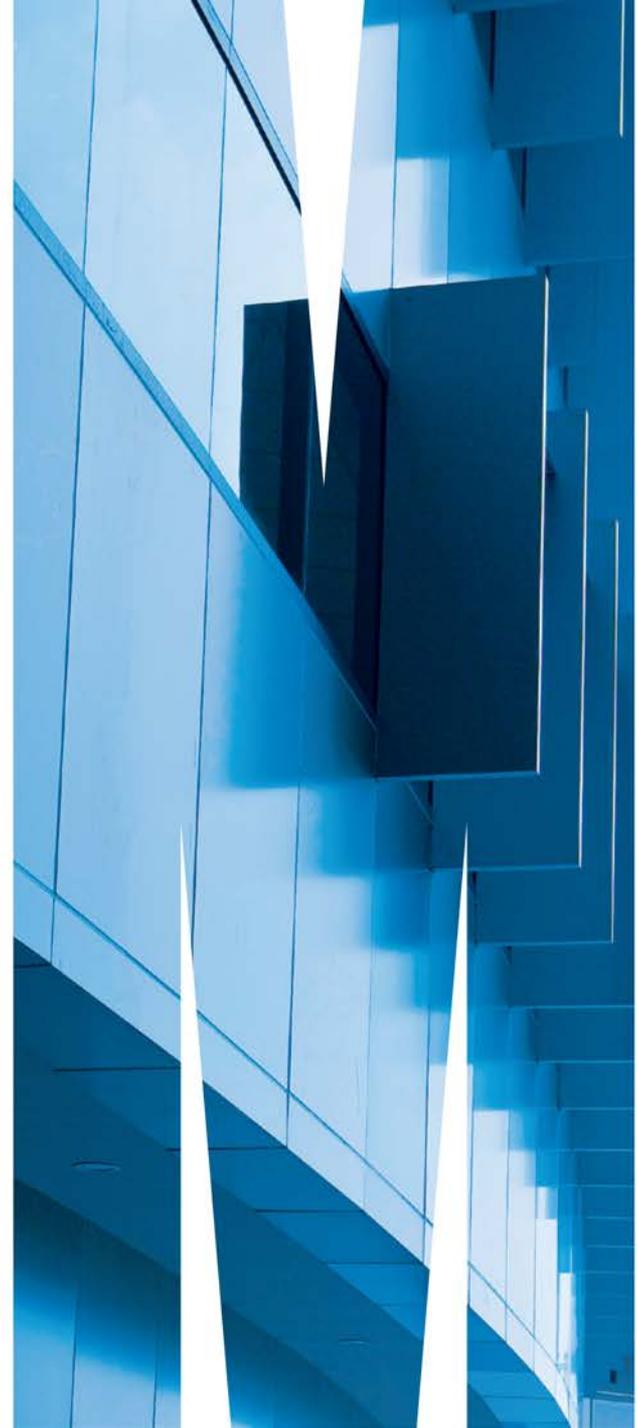
- In January 2011 HTA became an official requirement for new drugs, new medical devices, and all kinds of new surgical and medical procedures approval processes for reimbursement by the NHI program
- The pricing principle is to set at median price of ten reference countries and if efficacy and safety can be established through clinical trials conducted in Taiwan with a reasonable scale (at least 80 people in phase III trial), a bonus mark up of 10% is allowed
- Very well developed capacity

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# Japan

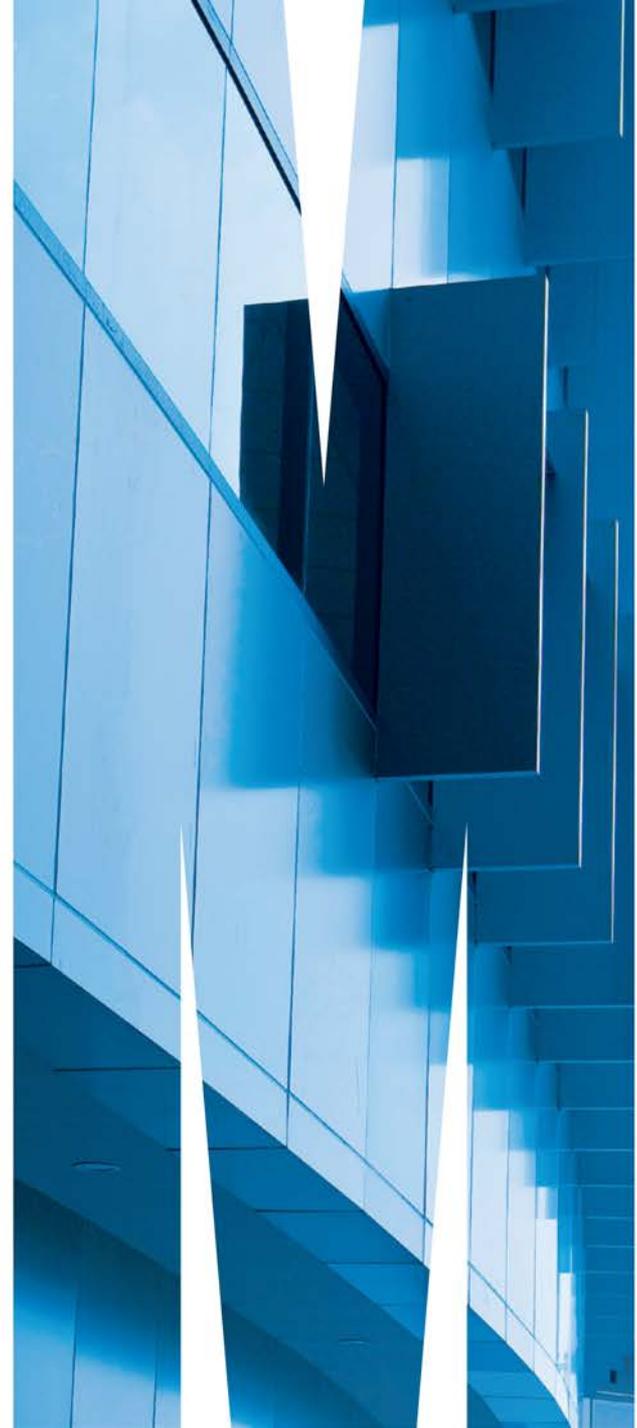
- Early 1990s recommendation for using HE data to new drug applications
- Demand for HE data began to surge in recent years due to the huge economic burden on government
- In April 2012, the Ministry created a new committee named “Cost-Effectiveness Evaluation Committee”
- Health economics assessment is only part of the overall HTA,
- Long term goal: capacity building



# The Philippines

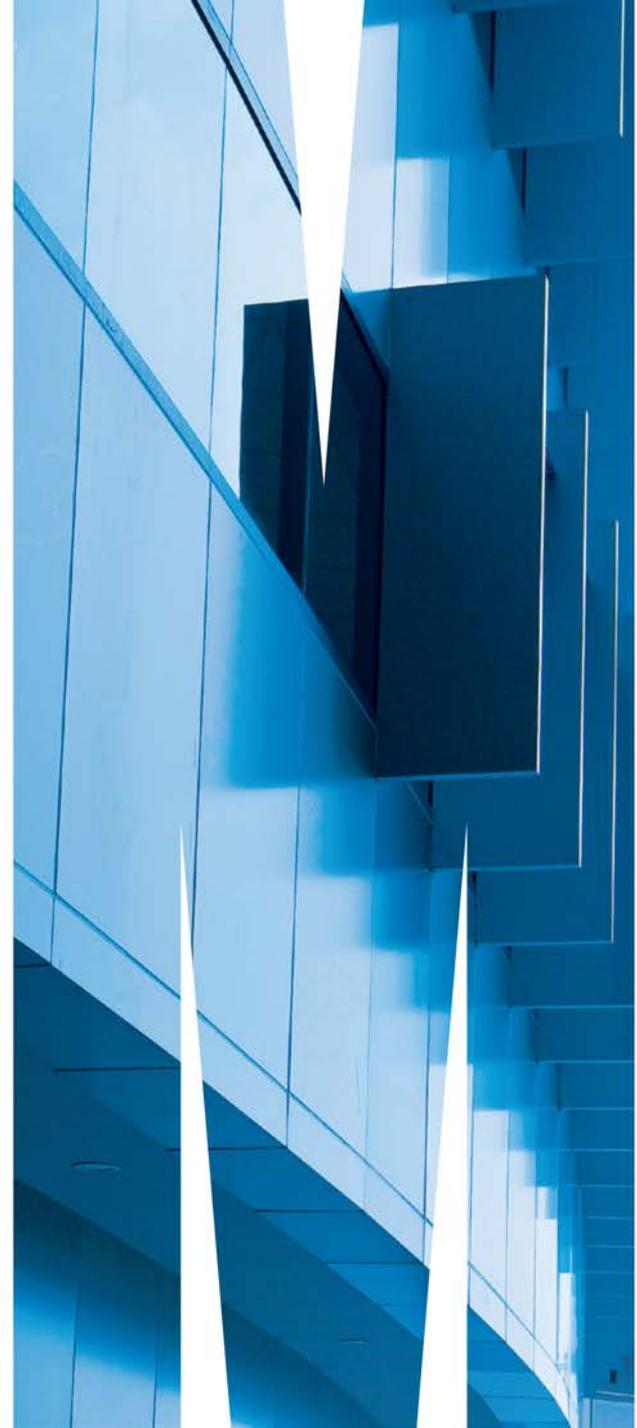
- A committee of HTA was established in 1999 for development of reimbursement policies
- HTA committee is also responsible for the appraisal and dissemination of clinical practice guidelines as well as for the evaluation of the effectiveness and safety of medical and surgical procedures
- Capacity building is a main concern

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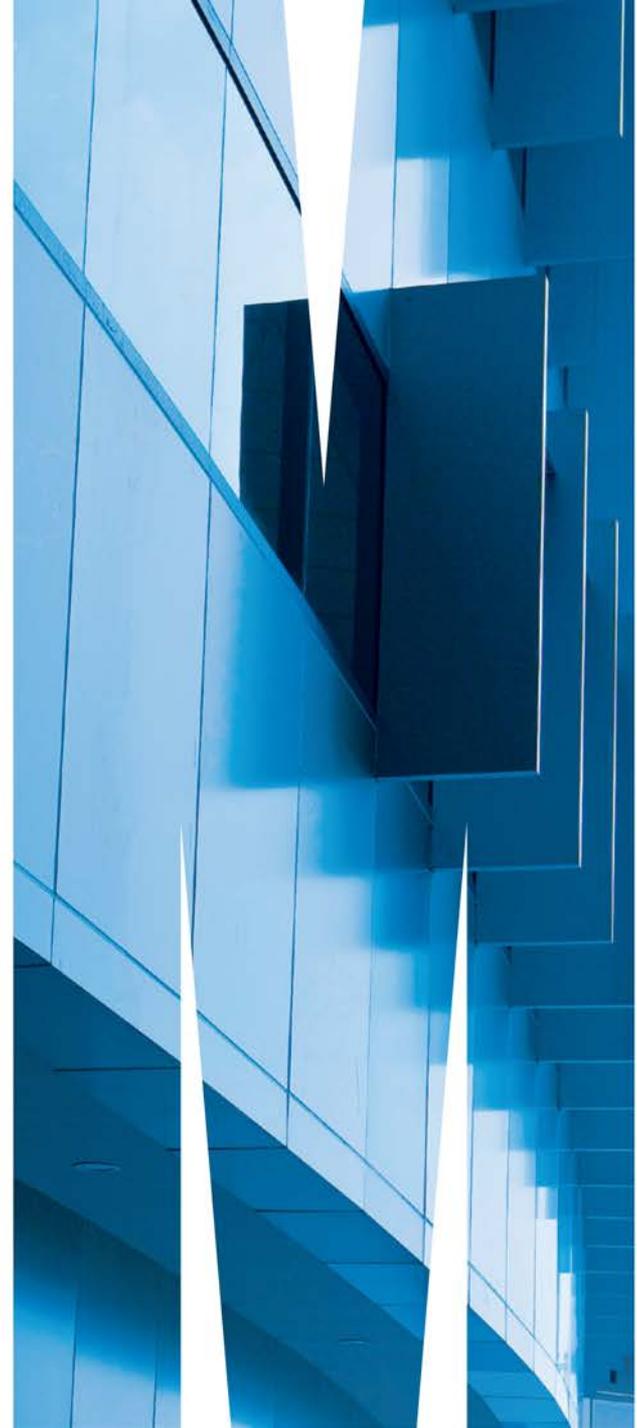
## Thailand

- Since 2007, government has been sponsoring the Health Intervention and Technology Assessment Program (HITAP) for developing HTA to ultimately guide resources allocation decisions
- There is a national guideline for HTA and a guideline for HTA process intended to achieve good governance.
- Current health policy stresses the need for institutional capacity building to provide pharmacoeconomics evidence to guide decision making



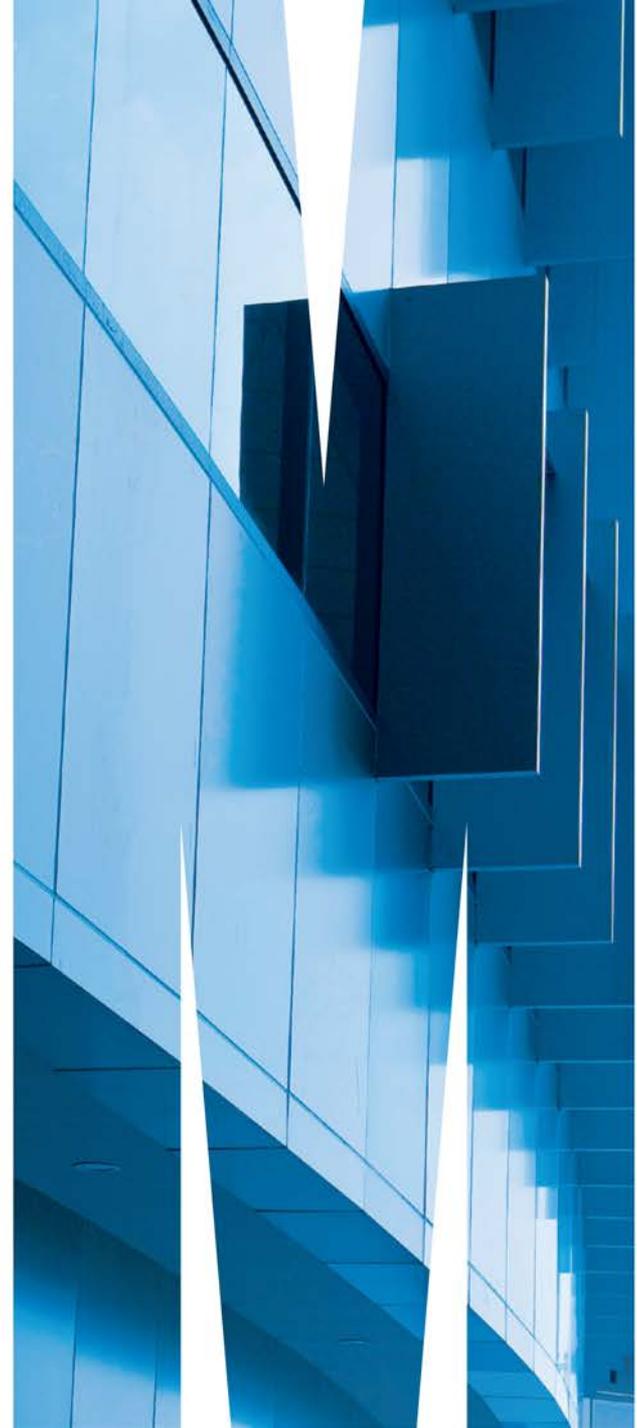
## Singapore

- Ministry of Health has an expert panel Drug Advisory Committee responsible for recommendations of drugs to be included in the Standard Drug Lists (subsidized)
- Committee takes into consideration relevance and the cost-effectiveness of the medicament in its recommendations but MOH makes the final decision including other considerations such as budget impact, clinical value and policy priorities
- PE Evaluation and Drug Utilization (PEDU): an HTA Branch created by the Ministry of Health to evaluate the cost-effectiveness and budget impact of new drugs



# Malaysia

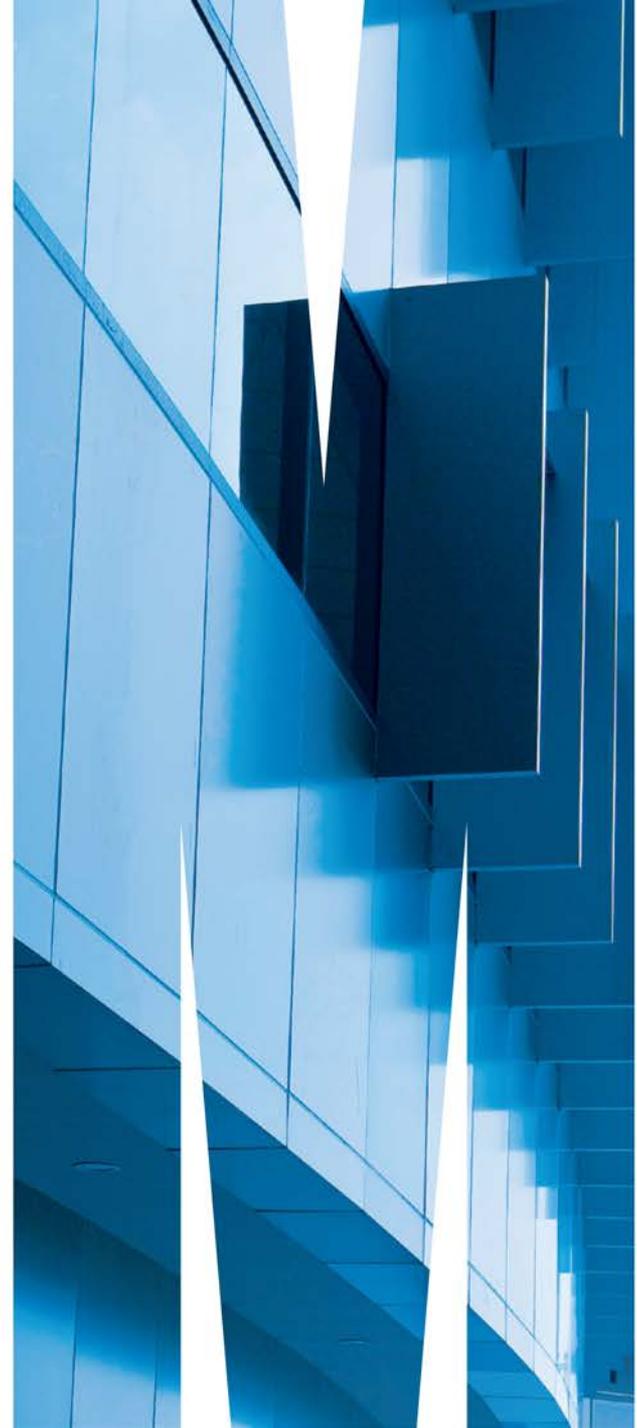
- HTA has a role in the health care system in Malaysia under the Health Technology Assessment Section (MaHTAS)
- Since 2001 the MaHTAS has the responsibility to develop and implement national evidence-based Clinical Practice Guidelines
- PE guideline developed in 2011, formal requirement for PE data (mainly budget impact) for new drugs implemented in 2016
- Threshold: 1 GDP
- Building of capacity is imminent



## India and Pakistan

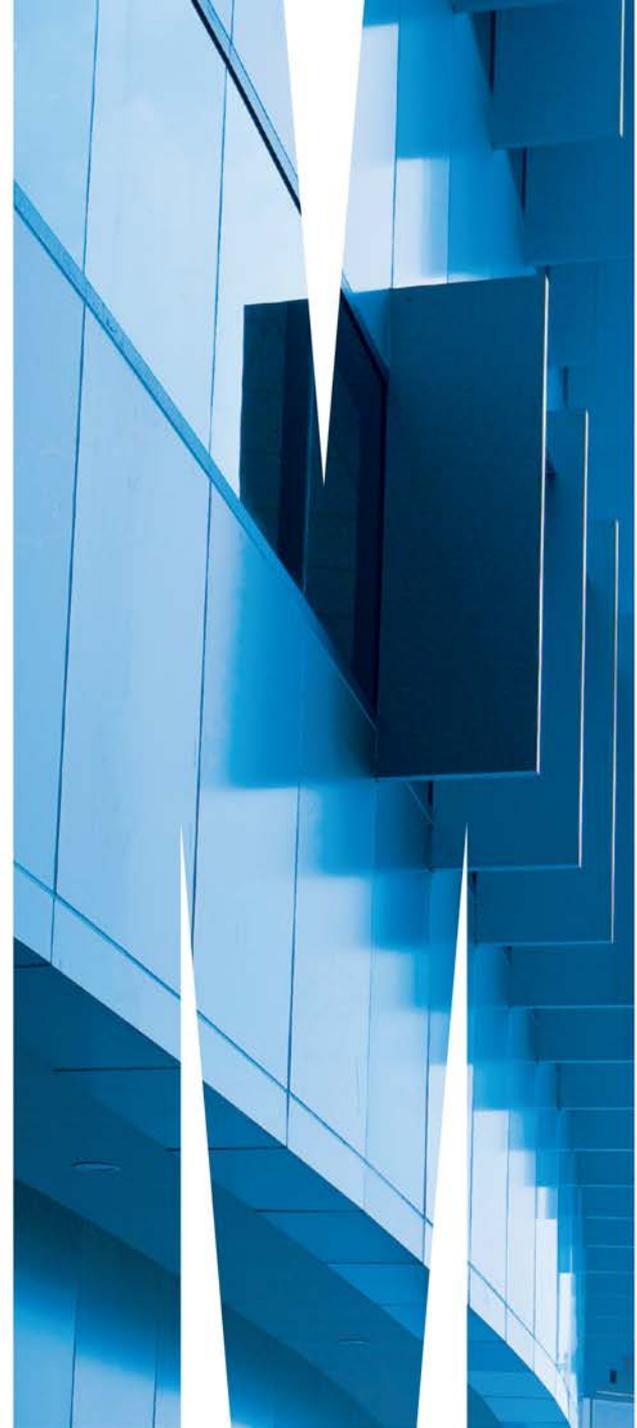
- Evidence-based decision-making is still developing
- Awareness for HE data is growing
- Research at university level began to appear at international level in last 2-3 years
- Much capacity building is needed

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## Indonesia

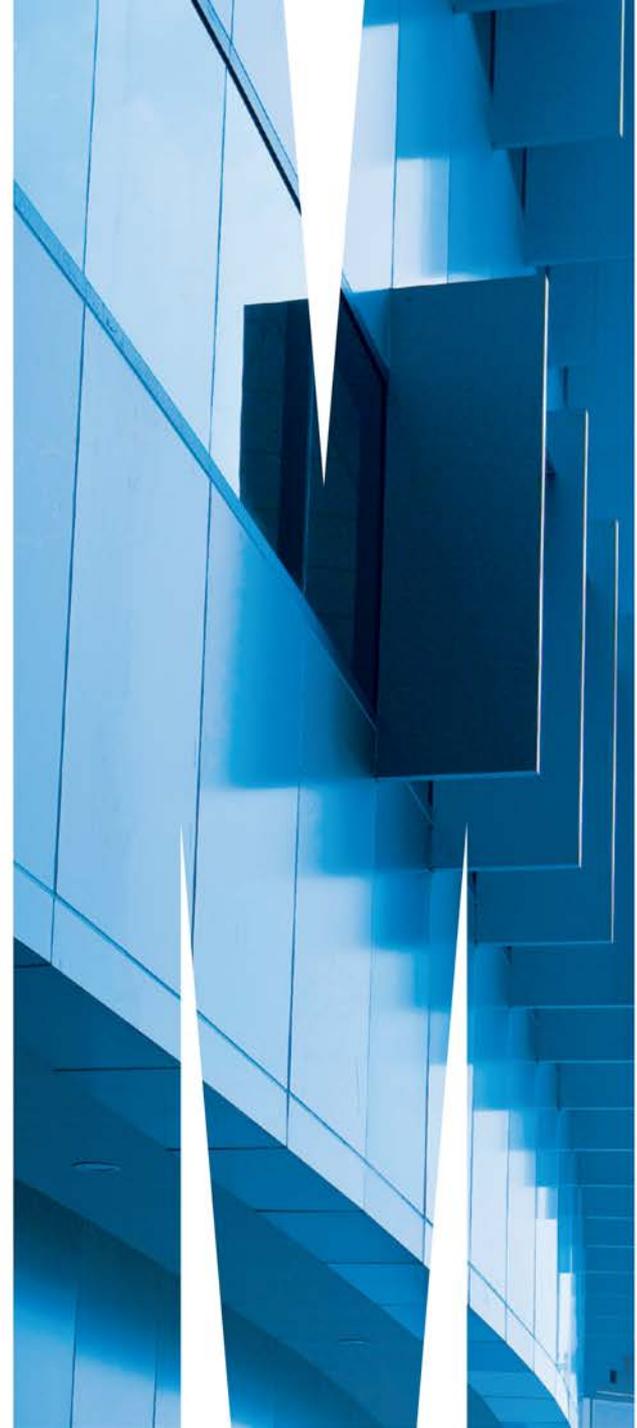
- The Indonesia's UHC/JKN was launched on 1 January 2014 to initially cover around 120 M population who are already engaged in various social health insurance (SHI) schemes under one fund-management agency called Health-BPJS. The targeted all population coverage is around 250 M people to be covered by 2019. With the targeted coverage, JKN will be the the world largest SHI.
- HTA not widely applied due to lack of capacity



# Mongolia

- The capacity in the Ministry of Health is too weak to generate strong economic and health outcomes that are evidence-based
- Contain health care costs by regulating prices of medicines, training of health manpower and use of high-cost medical equipment in hospitals.
- Apply cost-effectiveness criteria in defining health insurance benefits.

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# Comparator-referenced pricing

- HTA-based to ensure “value-for-money”
- Reimbursement is likely if ICER is within the acceptable range
- Setting of prices by manufacturers will follow the range of ICER threshold. Chance of abuse?
- Strengths: more scientific and more flexible, addresses not only price but also the appropriate indications and patient subgroups, evaluates the relationship between additional value and additional costs (i.e. cost effectiveness)
- Concerns: HTA agency does not have a mandate to implement its recommendation, hence access problem can arise; study design can be adjusted to favour a new drug, pricing up to threshold
- Limitations:
  1. More costly and more resource intensive, hence difficult to be used on every pharmaceutical
  2. Recommendations can be restrictive to certain indications and patient subgroups only
  3. Favourable assessment outcomes do not automatically guarantee reimbursement

# What is the right price-tag?

- 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.
- launch vs. current price
- Product names, packaging and dosage forms also contribute to pricing decisions
- 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

# Capacity building

- General concepts and basic theories
- Decide on whether taking a focused or general approach
- For HTA, focused approach will be specific aspects of HTA, e.g. pricing strategies, cost-effectiveness, setting of priorities. For general approach, they can do complete HTA on selected categories of drugs
- Select a topic (e.g. oncology, diabetes etc) and a study method (modeling, database analysis etc)

# Challenges for embarking on Post-graduate training in HE

- Career prospects unclear
- Scope of research in HE and HTA is very wide
- Focused approach: too specific in one aspect
- General approach: not enough overall depth
- Insufficient qualified supervisors
- Data availability issue

## Regional collaboration in training

- Attachment of students to universities in other Asian countries for training in specialized areas in HE through MOUs
- Advantages:
  - producing graduates who have wider exposure
  - platform-building for exchange and enhance research collaboration between countries
  - enhance standard of knowledge and experience in the region

# Regional collaboration in training

- PhD students are usually focused in specific areas in HE
- Attachment of students to universities in other Asian countries for training in specialized areas in HE through MOUs
- Advantages:
  - cost-effective use of manpower for training
  - producing graduates who are relatively more comprehensive in experience
  - platform-building for exchange and enhance research collaboration between countries
  - enhance standard of knowledge and experience in the region

# Looking ahead

- Over the last decade, HTA has been implemented in a number of Asian countries
- However, a number of obstacles are not without concern
- These include: lack of trained human resources, limited availability and accessibility of reliable local cost data, inability to turn research output into policy and practice
- Possible solutions: improved infrastructures—including electronic medical records, outcomes database
- Clarity, fairness, flexibility and transparency are important
- Alternative access schemes such as outcome-based agreements , MEAs, risk-sharing should be further explored

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*Comparator  
referencing pricing –*  
The Industry  
Perspective

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## Challenges for Industry

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1. What does comparator mean? Selection of comparator
2. Developing the required data vs. the 'right' comparator
3. Analysis of the comparative data – use of HTA.
4. Impact of comparator pricing on access – how does it relate to risk sharing?
5. The future opportunity

# Definition of comparator differs between countries

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Use of comparators in price setting and price maintenance vary in the Asia Pac region

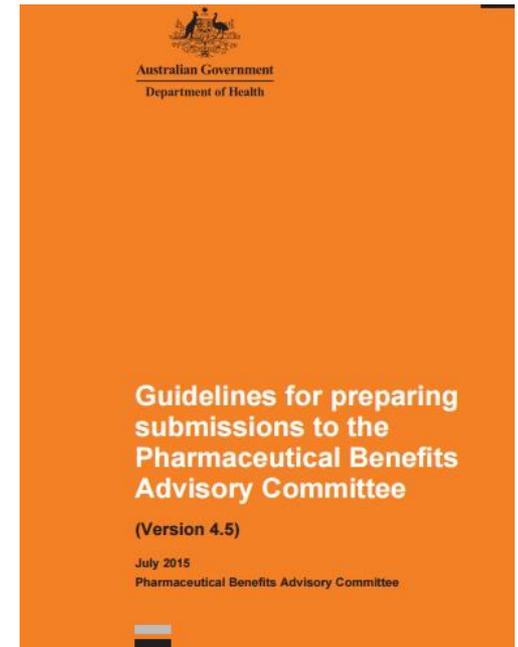
Australia:

*“most likely to replace” “lowest cost”*

Japan

**Is there any drug in the market which has similarity in the following aspects?**

- a. Indication and effects
- b. Pharmacological action
- c. Composition and chemical structural formula
- d. Dosing form, formulation category, formulation and administration



Different treatments available in each country and different standards of care.

# Developing the required data to meet needs for all countries is challenging

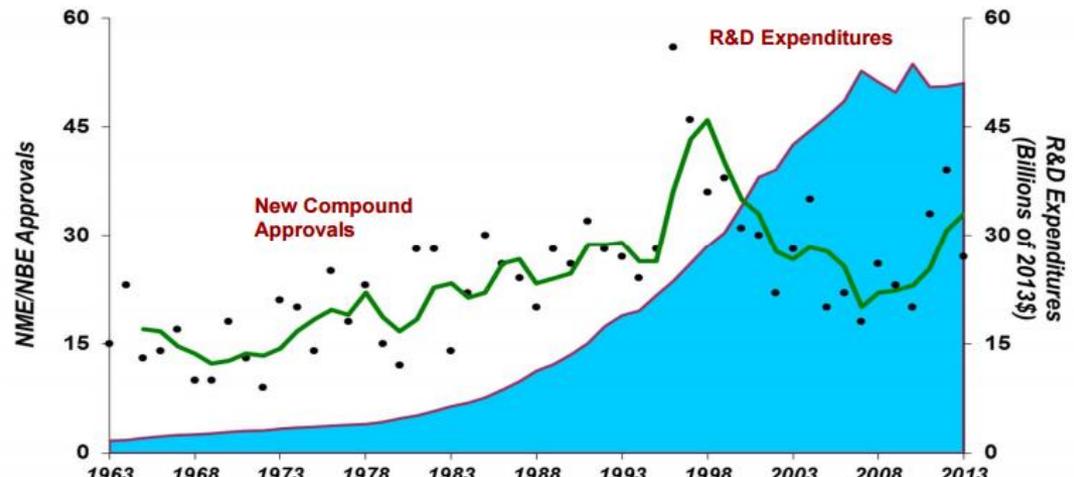
Developing evidence, running clinical trials against the most appropriate comparator is becoming more complex and costly:

- *Comparator for Regulatory maybe be different to reimbursement*
- *Comparator varies from one country vs. another not only because of treatment patterns but also due to pricing rules.*
- *SOC may change between starting the trial and filing P&R dossier*

*Consequence – delay to Patient access*

Sources: Tufts CSDD; PhRMA, 2014 Industry Profile

**New Drug and Biologics Approvals and R&D Spending**

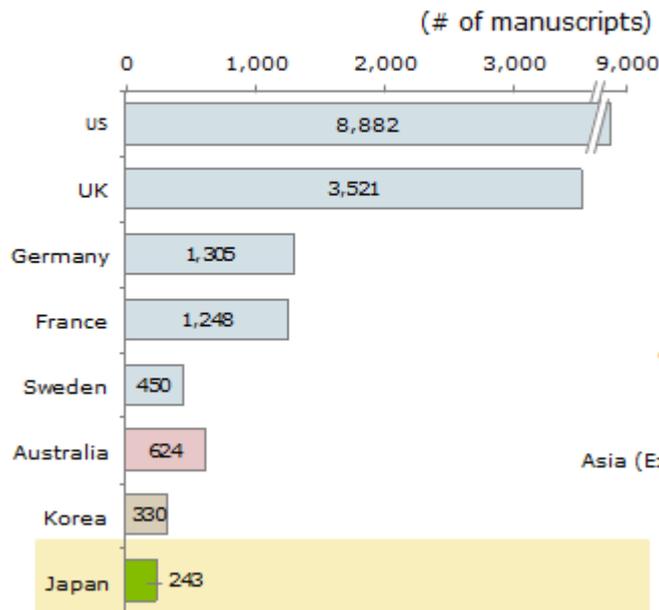


# Use of HTA methodologies - analyses vs. comparator

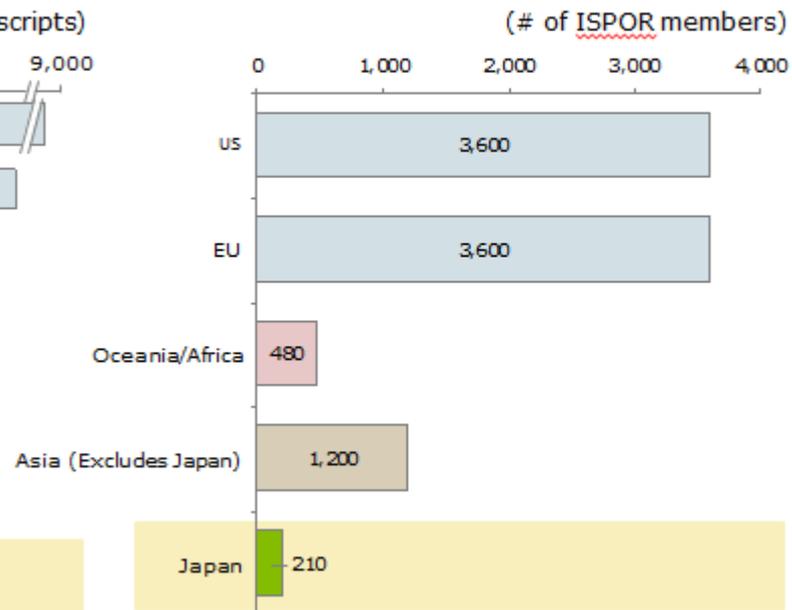
- *Lack of local data (e.g. standard costs) in majority of Asian markets for economic modelling*
- *Request for review of economic analysis developed for US/EU to assist with local decision making*
- *ICER threshold can vary by disease e.g. HCV and oncology*
- *Still limited experience with HTA in Asia*



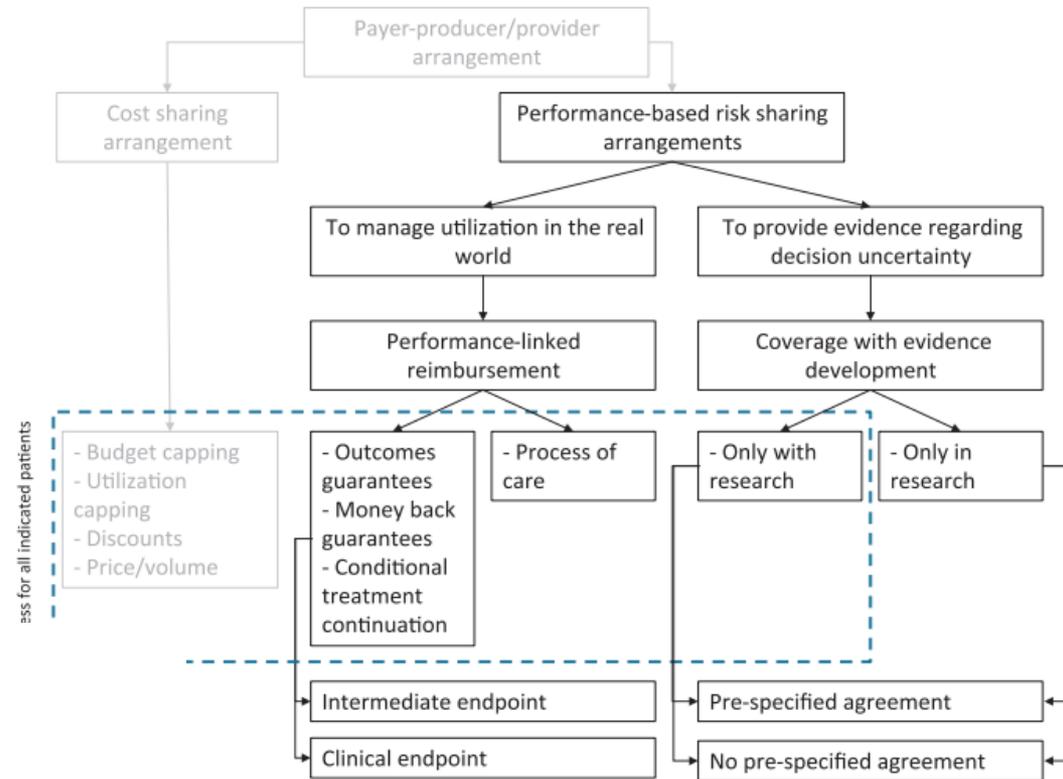
**Health Economic Manuscripts<sup>1)</sup>**



**ISPOR members by Region<sup>2)</sup>**

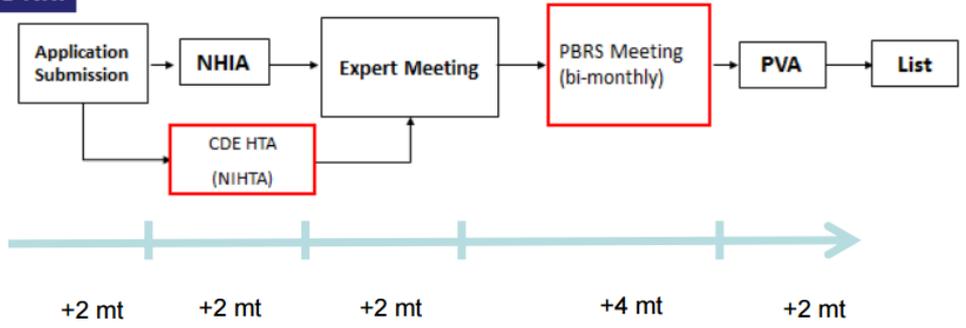


# Risk sharing arrangements – understanding varies across region



## New Product Listing in Taiwan Price & reimbursement process

2G NHI



# Limited experience with risk sharing outside of Australia

**Patient access schemes in the Asia-Pacific region by country, type and condition**

	Australia	South Korea	New Zealand	Total
<b>Types</b>				
Outcome-based	21	-	-	21
Evidence generation	3	-	-	3
Financially-based	33	3	5	41
Hybrid*	41	-	-	41
<b>Conditions</b>				
Cancer	29	-	2	31
Inflammatory Conditions	28	-	1	29
Infectious Disease	7	-	-	7
Pulmonary Hypertension	7	1	1	9
Other	27	2	1	30
<b>Technology</b>				
Pharmaceuticals	95	3	5	103
Medical devices	3	-	-	3
Subtotal	98	3	5	106

\*Hybrid schemes involved both pricing arrangements and conditional treatment co

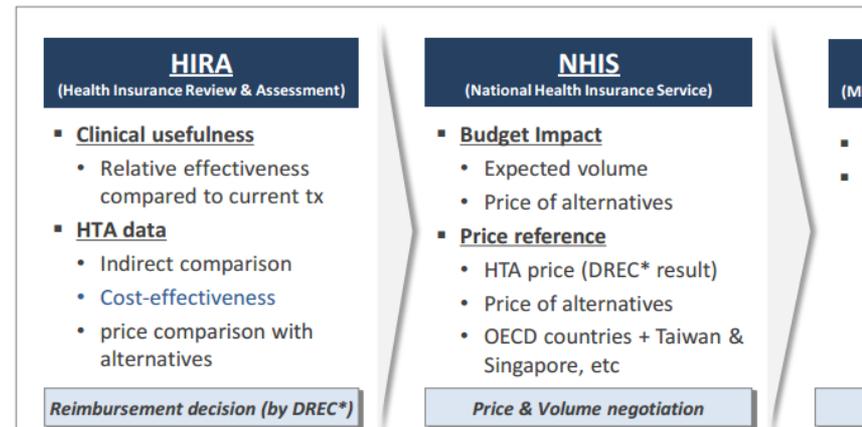
Very few countries and examples of risk sharing being integrated into HTA process - used to assist patient access.

Experience with risk sharing even price volume agreements are very limited in Asia – opportunity?

**New drug listing: 2-step system (HTA + Negotiation)**

[Step 1] HIRA : Reimbursement decision based on *Health Technology Assessment*

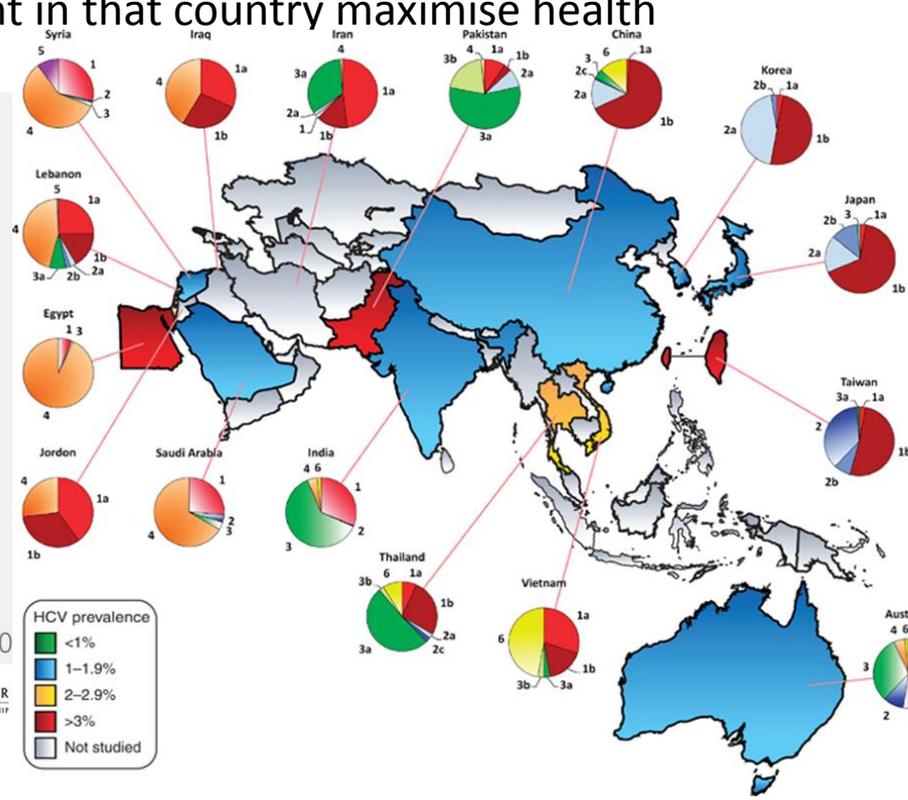
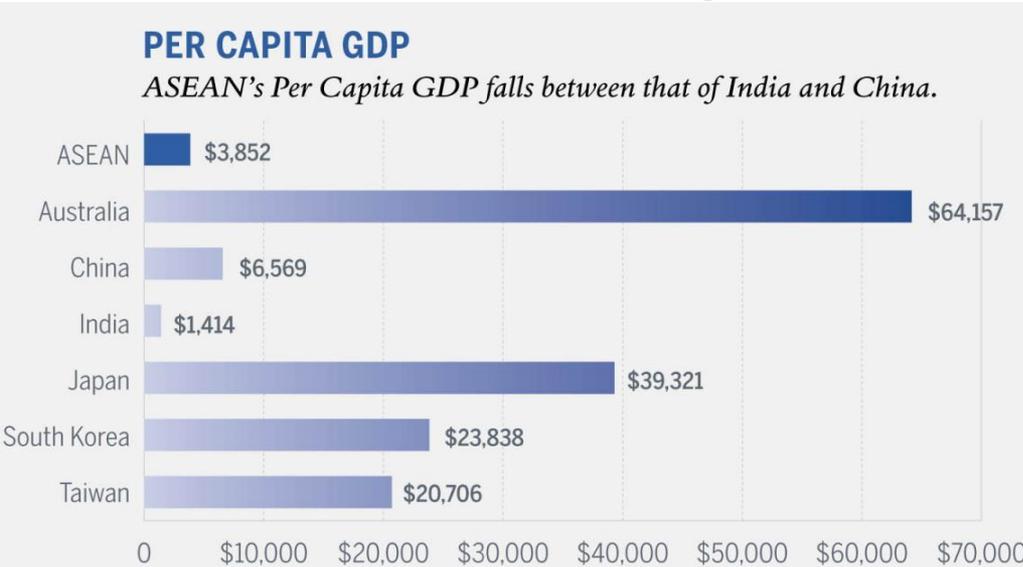
[Step 2] NHIS : *Price negotiation*



\*Drug Reimbursement Evaluation Committee

# The Future – affordability and pricing

How to set a price which helps the Government in that country maximise health outcomes for their set budget?

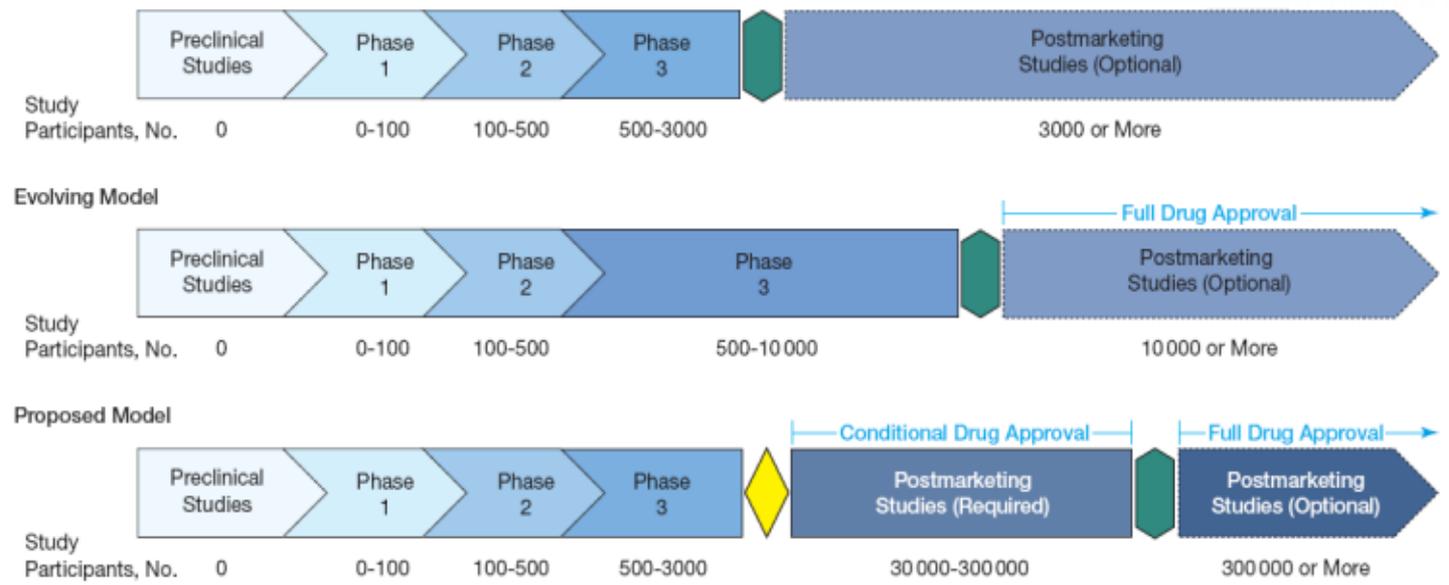
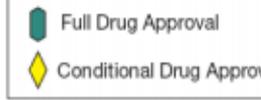
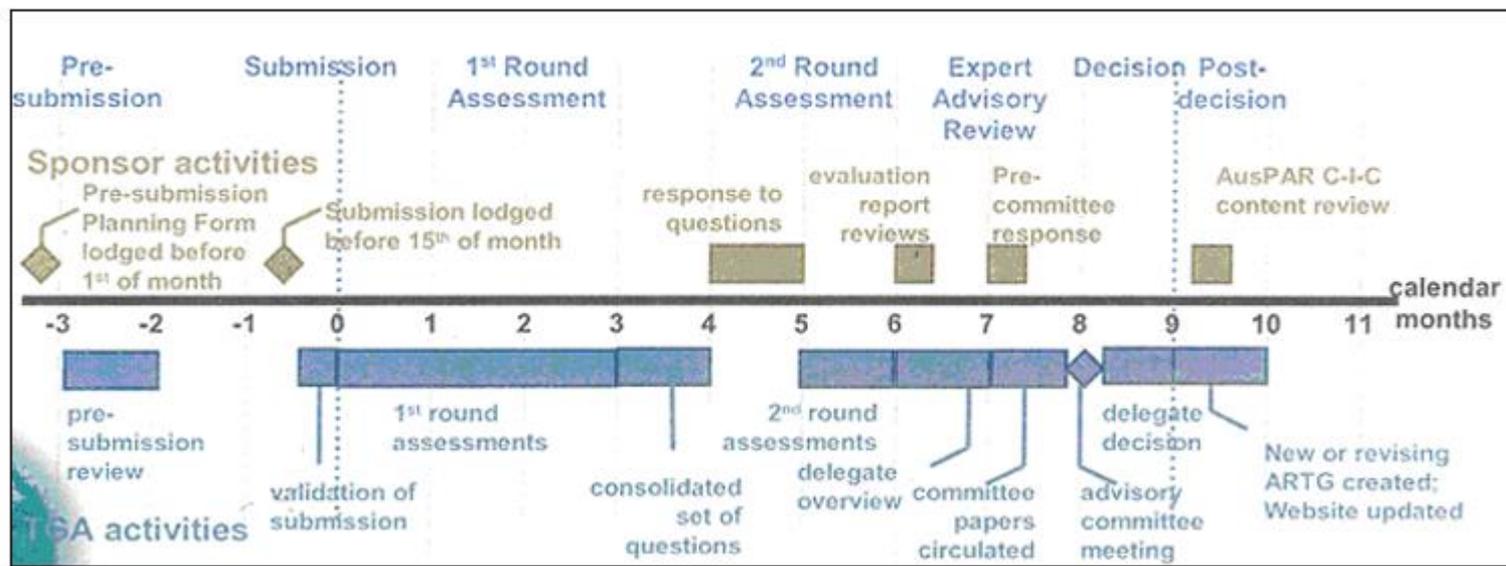


## Case study – HCV:

- For DAAs, HTA has not been the barrier to access, with almost 100% SVR “cure” the treatments are highly cost-effective but the problem is affordability

Affordability is vastly different across the region.

# The Future - accelerated registration process and parallel reimbursement processing



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