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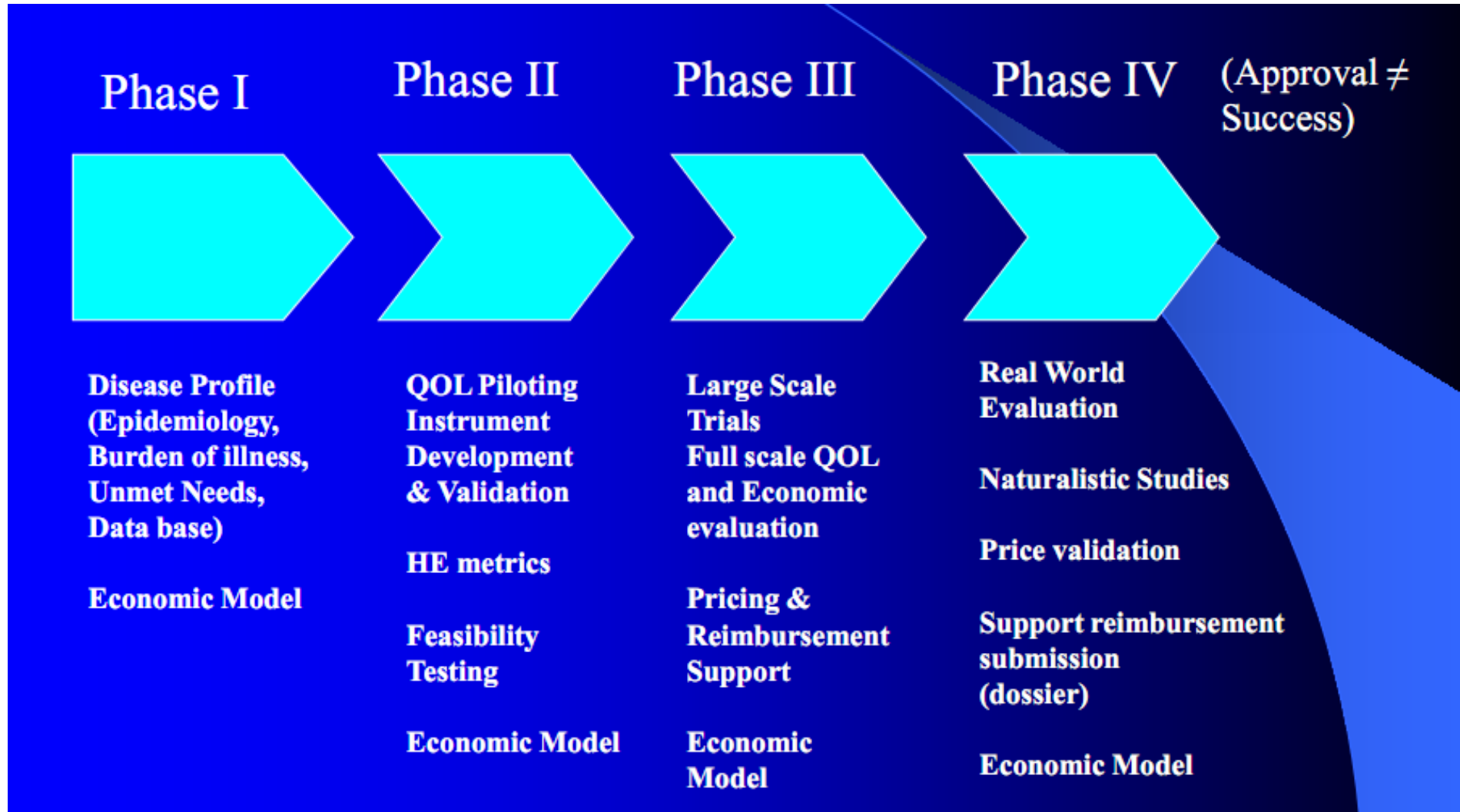
The Use of Health Economic Data in Maximizing Health Outcomes - a Global Perspective

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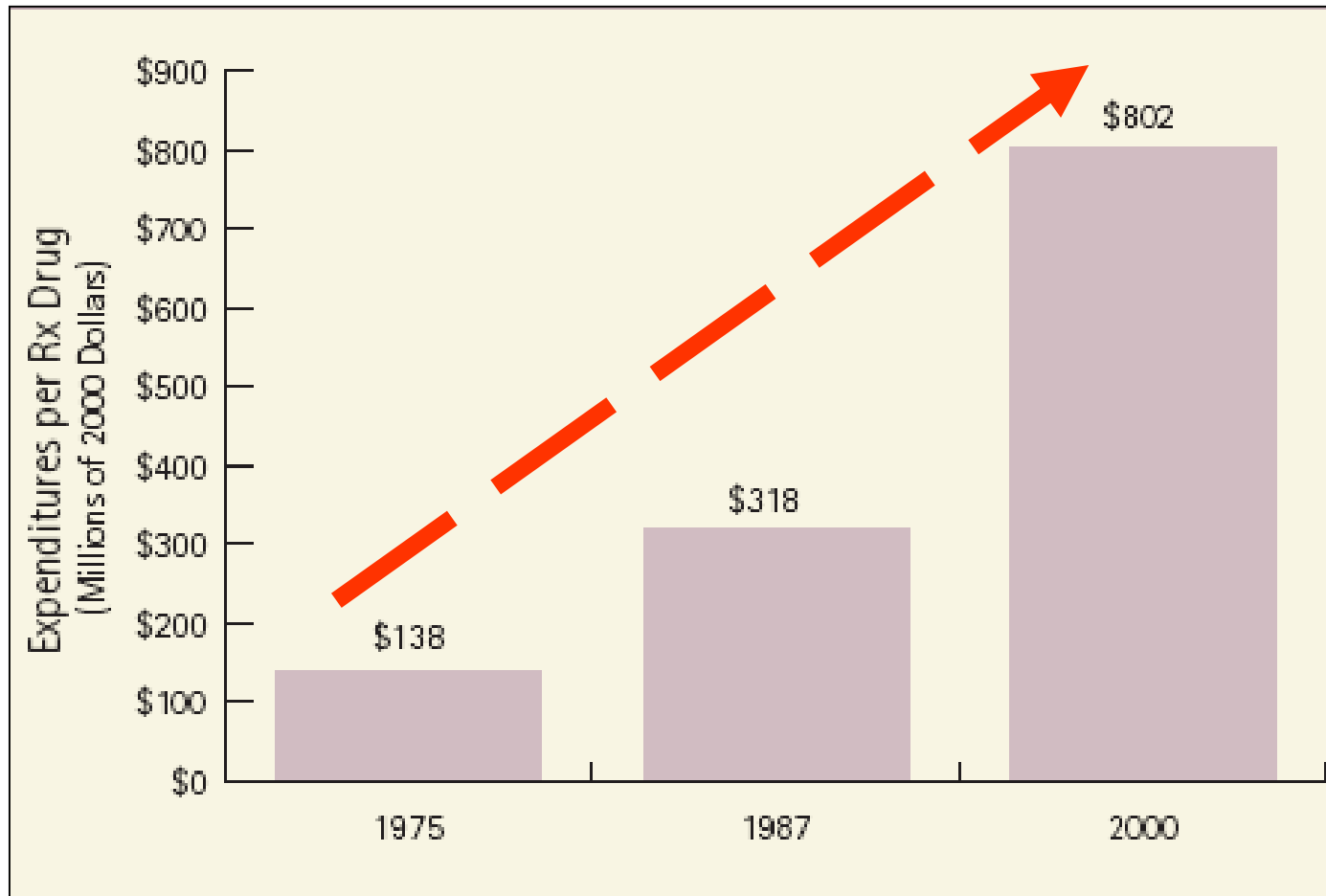
Outline

1. Background
2. Global situation of HE data utilization in health care decision-making
3. Application of HE data: EVALUATION of new medicines through Health Technology Assessment (HTA) and IMPROVING ACCESS to new medicines through pricing and formulary listing
4. Take home messages

Use of Health Economics During Drug Development Cycle



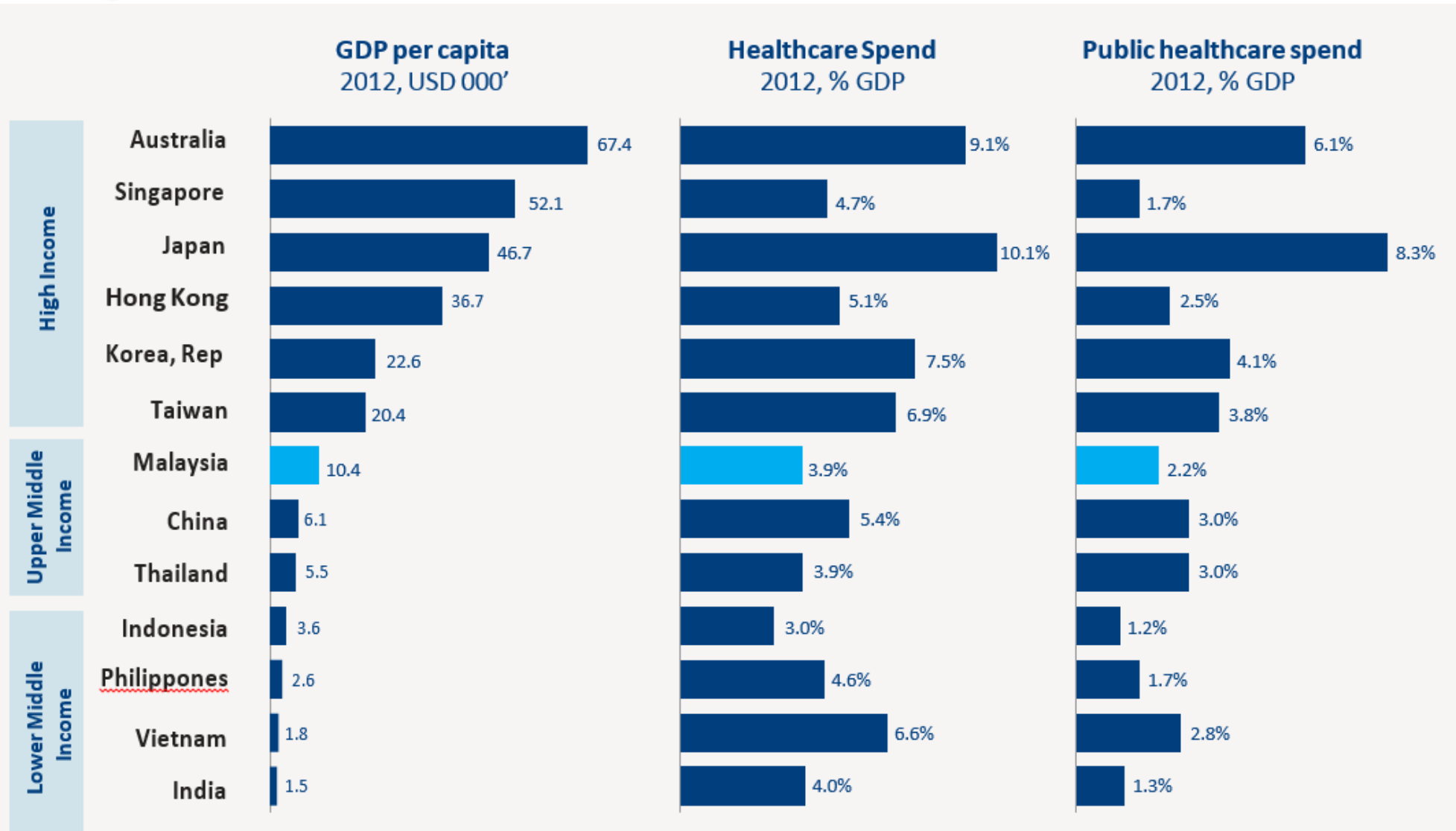
Cost of Developing a New Drug



**Latest estimation in 2015:
US 1.5 Bn**

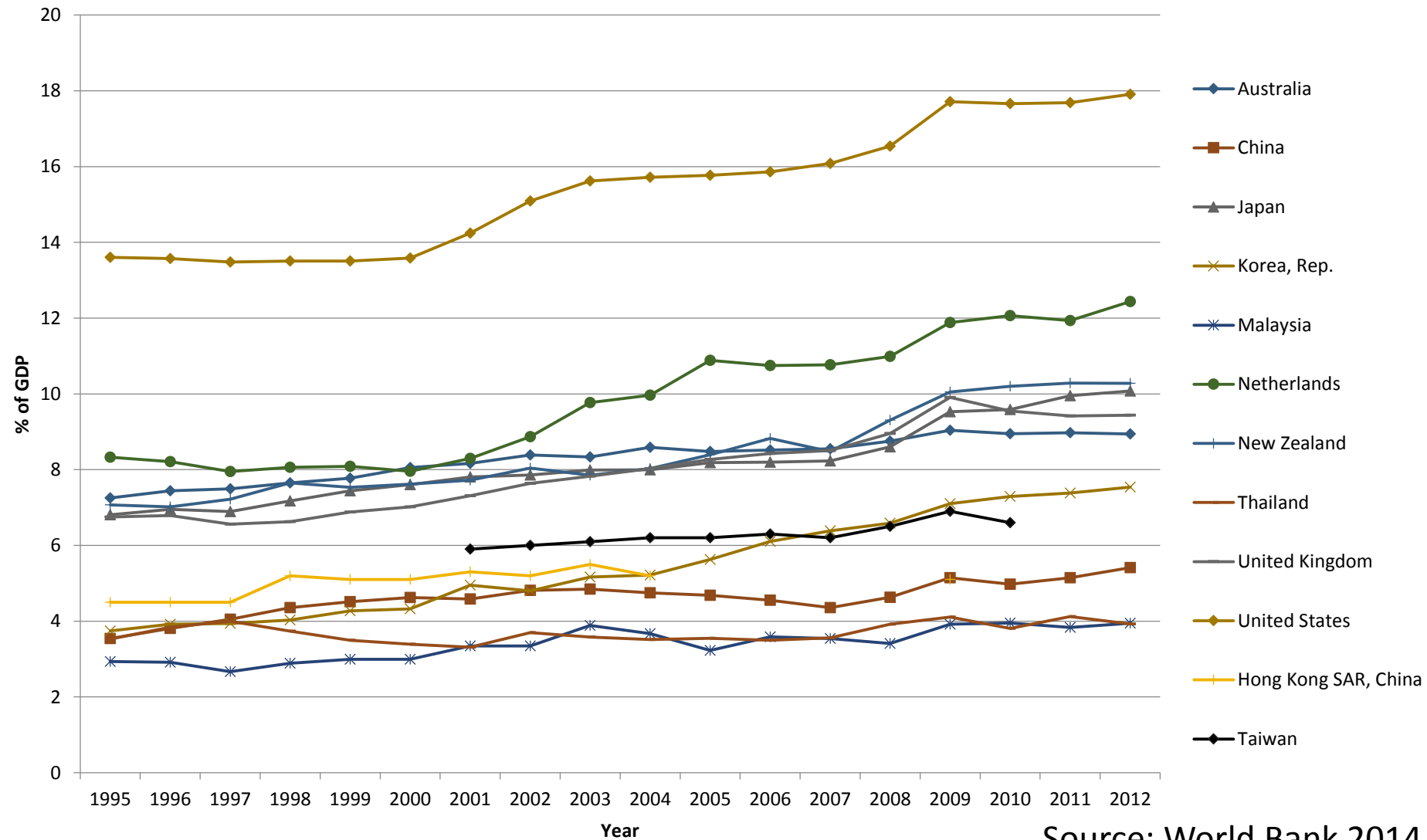
Source: J.A. DiMasi, R.W. Hansen, and H.G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics* 22 (2003): 151-185.

Comparison of macroeconomic status of Asia Pacific countries



Source: World Bank 2012 (latest available data), Hong Kong Census and Statistics Department, National Statistics Taiwan

Total Health Care Expenditures as Percentage of GDP



Source: World Bank 2014

Health expenditure, as a proportion of GDP, has exceeded economic growth in almost all OECD countries in the last 17 years.

Major contributing reasons to increasingly expensive health care

1. **Cost inflation** of new health technologies
2. **Aging population**, therefore changing epidemiology from traditional acute diseases to more chronic health problems i.e. a shift to NCDs
3. **Increased expectation** from public
4. **Under development of preventive care**, over reliance on secondary care

Health care resources utilized properly?

Statistical findings show that "patients in the highest-spending regions of the country receive 60 percent more health services than those in the lowest-spending regions, yet this additional care is not associated with improved outcomes."

(Fisher et al 2003)

Resources appear not being utilized in the wisest manner and not resulting in maximum benefits

Traditional Criteria in Assessing a New Drug

- Safety
- Efficacy
- Quality
- Unit cost

True VALUE of a drug is not assessed !

More recent criteria

- Safety
- Efficacy
- quality
- Cost-effectiveness (the 4th hurdle, Drummond 2004)
- Post-market re-assessment (the 5th hurdle, 2008)

Cost vs Value

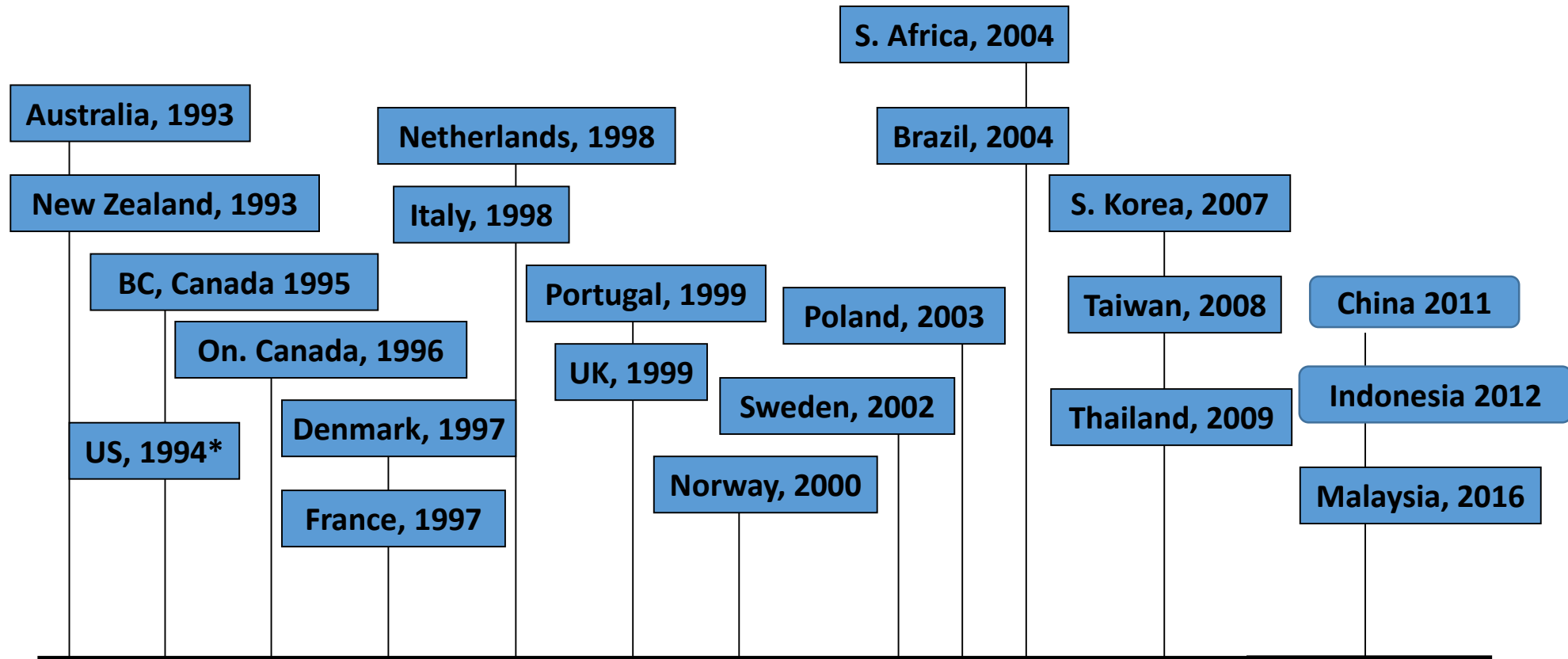
Cost

- Fixed
- Easy to count
- visible

Value

- Uncertainties exist
- Difficult to estimate
- Difficult to demonstrate
- Humanistic consideration included
- Examples: quality-of-life, overall effect on the society, impact on the management guideline etc

Use of Health Economic (HE) data in health care around the world



Adoption of HE Evaluation in Europe and N America: A Snapshot

COUNTRY	AGENCY	TYPE	YEAR OF INITIATION
UK	NICE (National Institute for Health & Care Excellence)/universities	Independent (govt-funded)	1999
Canada	CaDTH (Canadian Agency for Drugs and Technologies in Health)/universities	Independent (govt-funded)	1994
Australia	PBAC (Pharmaceutical Benefits Advisory Committee)/universities	Independent (govt-funded)	1993
Germany	Institute for Quality and Efficiency in Health Care (IQWiG)	Independent (govt-funded)	2004
The Netherlands	Dutch Health Care Insurance Board (CVZ)	Independent (govt-funded)	2006
France	HAS (Haute Autorite De Sante)	Independent (govt-funded)	2005

Adoption of Health Economic Evaluation in Asia: A Snapshot

COUNTRY	AGENCY	TYPE	YEAR OF INITIATION
CHINA	Various University Centers	Funded by MoH	1994
MALAYSIA	Universities/MaHTA	Funded by MoH	1995
SINGAPORE	Research & Technology Assessment Department	Funded by MoH	1995
SOUTH KOREA	Health Insurance Review & Assessment Agency (HIRA) / National Evidence-based Healthcare Collaboration Agency (NECA)	HIRA (Govt-funded)	2006
TAIWAN	HTA Division-Center for Drug Evaluation (CDE)	Funded by govt	2006
THAILAND	HiTAP (Health Intervention & Technology Assessment Program)	MoPH	2007

Applications of HE data in health care decision-making

1. **EVALUATION** of new medicines by Health Technology Assessment (HTA)
2. **IMPROVING PATIENT'S ACCESS** to new medicines

Health Technology Assessment (HTA)

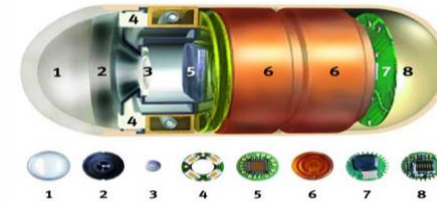
Objectives

To support evidence-based policy making for :

- **Evidence-based approach** to aid healthcare decision making
- **Identifying health technologies** that bring the greatest benefit to patients
- Ensuring **early access**, allowing **choice** among health technologies of value
- **Consistency** in decision making by benchmarking a threshold
- Assistance in **long term health care budgeting**
- Increase in **transparency and accountability** in decision making
- Enhancement of **drug pricing negotiation** process based on solid local data
- **Prioritization** of resource use

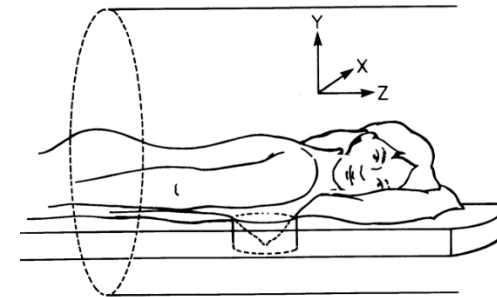
Health Technologies

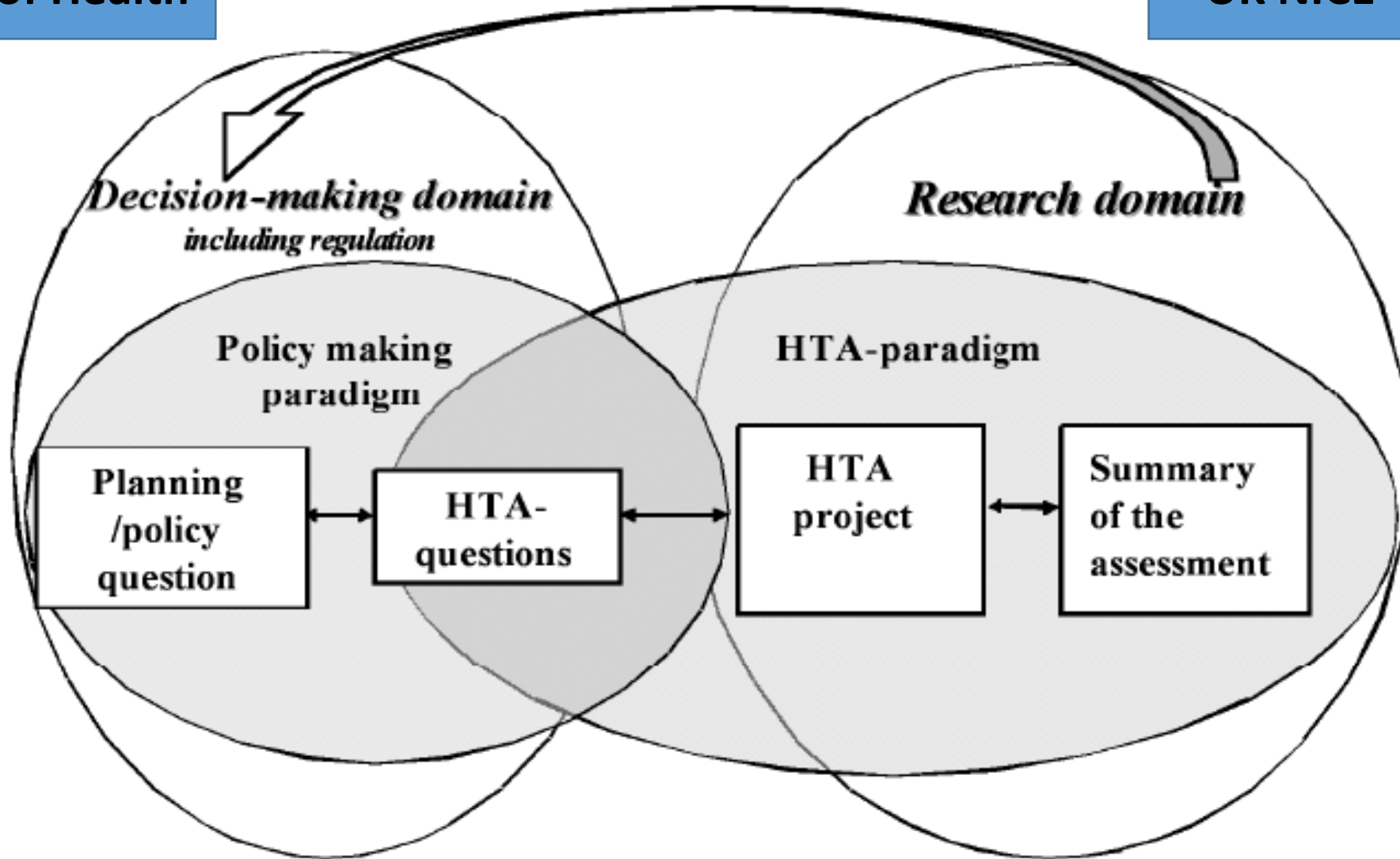
- Diagnostics: Virtual colonoscopy
- Devices: Computerized knee
- Procedures: Breast MRI
- Drugs: Biologics
- Services: Counseling



INSIDE THE M2A™ CAPSULE

1. Optical dome
2. Lens holder
3. Lens
4. Illuminating LEDs (Light Emitting Diode)
5. CMOS (Complementary Metal Oxide Semiconductor) imager
6. Battery
7. ASIC (Application Specific Integrated Circuit) transmitter
8. Antenna





Based on Kristensen FB et al. Seminars in Colon and Rectal Surgery ,2002; 13:96 – 103

So HTA is a science!

What is assessed in an HTA?

Technical properties	<ul style="list-style-type: none">• Performance characteristics maintenance, ease of use, etc.
Safety	<ul style="list-style-type: none">• Adverse events in a given situation
Efficacy	<ul style="list-style-type: none">• Can it work?
Effectiveness	<ul style="list-style-type: none">• Does it work?
Economic impact	<ul style="list-style-type: none">• Economic evaluations, budget impact analysis
Organizational /professional	<ul style="list-style-type: none">• Diffusion, utilization, skills, education
Social/ethical/legal	<ul style="list-style-type: none">• Challenge certain legal standards and/or societal norms

Incremental Cost-effectiveness Ratio (ICER) as thresholds of Cost-effectiveness

1. Based on QALY or LYG

- USA: US\$50,000/QALY (US100,000/QALY)
- Australia: A\$42,000-76,000/LYG (~1.26 - 2.3 Australia GDP per capita, George *et al* 2001)
- NICE: £20,000-30,000/QALY (~ 1.4 – 2.1 UK GDP per capita, Towse and Pritchard 2002)
- Canada: US\$87,800/QALY

2. Based on GDP per capita by WHO 2002 (thus affordability of the country considered)

- **ICER** : \$/Disability Adjusted Life Year (**DALY**)

< GDP : very cost-effective

> GDP but < 3 x GDP : cost-effective

> 3 x GDP : Not cost-effective

Applications of HE data in health care decision-making

1. EVALUATION of new medicines through Health Technology Assessment (HTA)
2. IMPROVING PATIENT'S ACCESS to new medicines



“Clinical trials are too slow, too costly, not reliable and not designed to answer the important questions”

- Robert Califf

Newly appointed FDA Commissioner



Delay in launch of new medicines

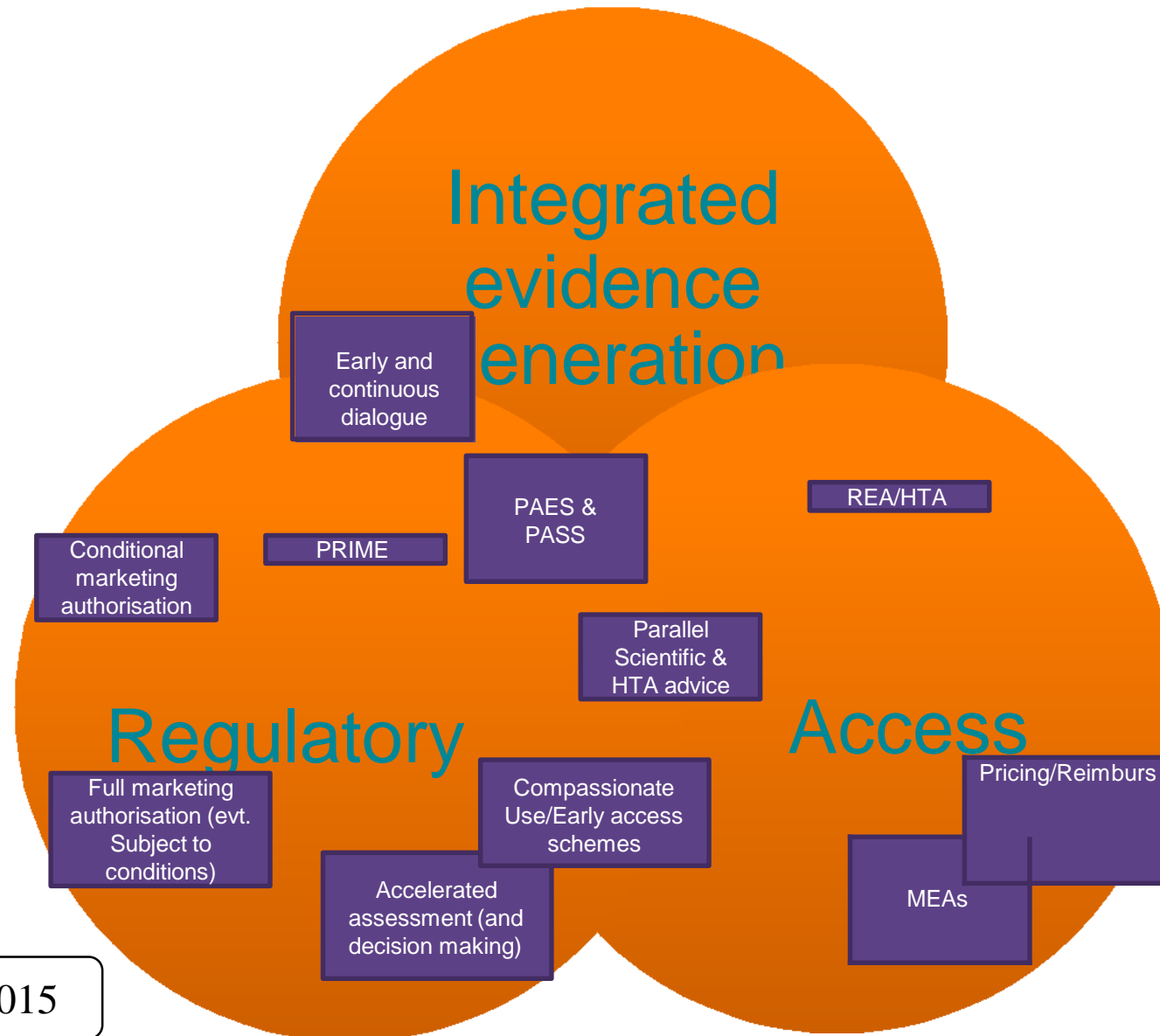
TA	Product	First Launch Year	Time of launch compare to first launch (months)							
			0	1-6	7-12	13-18	19-24	25-36	37-48	>48
Diabetes	JANUVIA	2006								
Anti-HIV	ISENTRESS	2007								
CV	PRADAXA	2008								
Oncology	SUTENT	2006								
Anti-Inf.	MYCAMINE	2005								
Respi.	ONBREZ	2009								

Source: IMS Knowledge Link



Early HTA would likely improve patient access

Early patient access: combination of existing and new tools within the current legal framework



Source: Bergstrom EMA 2015

Improvement in patient's ACCESS to new medicines

- Pricing of new medicines
- Listing of new medicines in formulary

Pricing strategies

- Traditional : Discounts, Price-volume agreement
- Reference-based pricing
- HTA-based pricing
- Value-based pricing

Reference-based pricing

- Drugs considered as similar are clustered
- A single level of reimbursement (i.e. the reference price) set for the whole cluster
- Reference price: usually based on the cheapest drug in the group or some average of existing prices

HTA-based pricing

- Reimbursement is granted if ICER from HTA is within the acceptable range
- Setting of prices by manufacturers will follow the range of ICER threshold
- Strengths: more scientific and more flexible, addresses not only price but also the appropriate indications and patient subgroups
- 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

Value-based pricing (VBP) scheme

- Price of a drug is based on the value it adds in each individual indication, as demonstrated by technology appraisals
- An accurately estimated threshold for ICER is therefore central to the whole policy
- In other words, in the presence of an accurate threshold, the reimbursed medicine will at least provide 1 additional QALY/LYG for the cost paid by the health care system/society

Formulary listing

- Managed Entry Agreements (MEAs)
- Performance-based/risk-sharing arrangements

Managed Entry Agreements (MEAs)

- An arrangement between a manufacturer and payer/provider that enables coverage/reimbursement of a health technology subject to specified conditions
- Categories:
 - managing budget impact through capping, discounting, number of doses etc
 - managing uncertainties relating to clinical and/or cost-effectiveness in real world environment e.g. retrospective reimbursement for non-responders
 - managing utilization to optimize performance e.g. targeted patient groups, appropriately trained professionals etc

Performance-based Risk-sharing arrangements

- Background: Always uncertainty at launch of a product about the ultimate real-world clinical and economic performance
- Scheme: A plan by which the performance of a product is tracked in a defined patient population over a specified period of time, amount/level of reimbursement is based on the health and cost outcomes achieved

Take home messages

- Health organizations around the world e.g. NICE, PBAC, CADTH etc have adopted the use of **HE** in their new drug evaluation and formulary listing **to maximize health outcomes**
- HE evaluation is recognized as an **evidence-based approach** to assist informed decision-making in optimising health care spending
- Utilization of HE data requires a **multidisciplinary approach** to evaluate efficacy, effectiveness, safety, economic, social, organizational, ethical and legal issues in relation to a new health technology