

How do Culture, Values and Institutional Context Shape the Methods and Use of Economic Evaluation?

-- Taiwan Scenario

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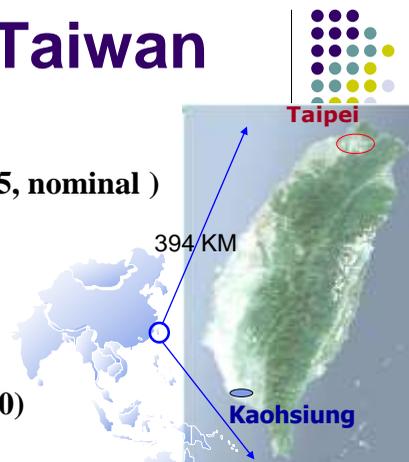
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Taiwan Society for Pharmacoeconomics and Outcomes Research (TaSPOR)



Taiwan

- Land Size: 36,190 km²
- Population: 23.5 million
- **GDP per capita: US\$22,469** (2015, nominal)
- **NHE as 6.19% GDP** (2014)
 - NHIA account for 52.5%
 - **Out-of-pocket: 35.8%**
- Elderly (> 65 y) : 12.2% (2015)
- Private hospitals : 85% (total: 540)
- Private clinics: 98%
- **National Health Insurance Scheme** (since 1995, 99.5% pop)
- Pay monthly premium
- **Comprehensive coverage:** ER, hospital inpatient and ambulatory care, primary care, Chinese Medicine, Dental
- Using global budget, FFS and partial DRG on reimbursement ₂

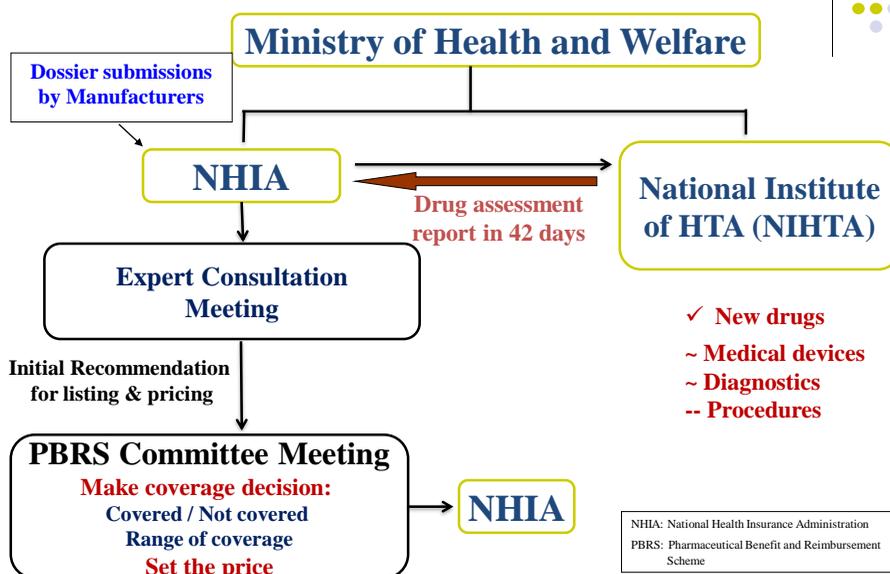


Introducing a new drug to the health care system in Taiwan



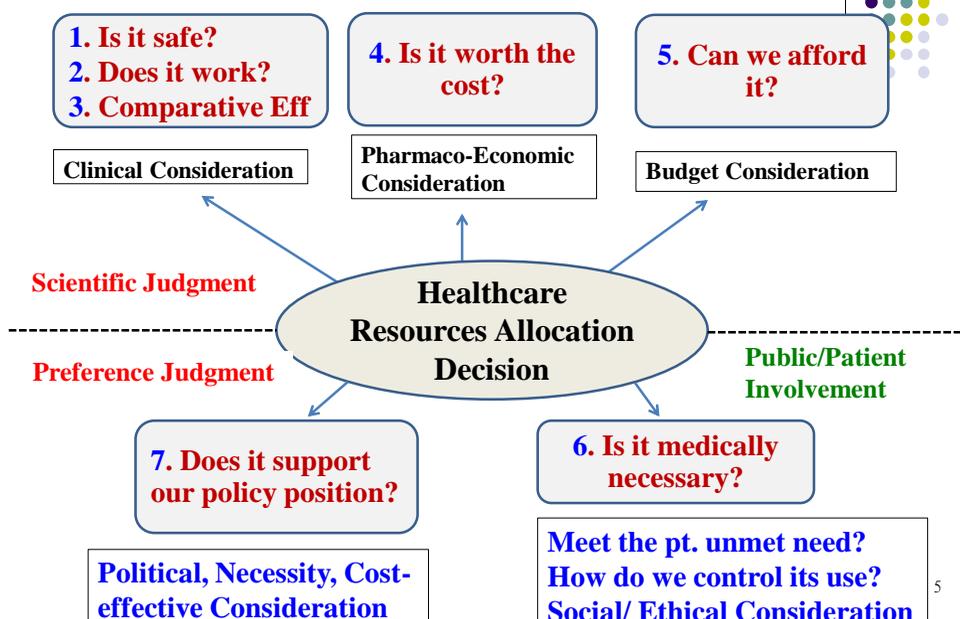
- Step 1: **Marketing approval**
 - *Technical Review*: **CDE** (Center for Drug Evaluation, 1998)
 - *Appraisal* : **DAC** (Drug Advisory Committee, TFDA)
 - *Decision* : **Taiwan Food and Drug Administration, Ministry of Health and Welfare (MHW, 2013)**
- Step 2: **Reimbursed by the National Health Insurance program** (start 1995)
 - *Assessment* : **HTA/CDE** (start 2008)
 - *Recommendations* : Expert Consultation Meeting 2013 (previous Drug Benefit Committee, 1996~2012)
 - *Appraisal*: **PBRs Committee Meeting** (2013, since 2nd gen. NHI)
 - *Decision* : **National Health Insurance Administration, MHW**³

HTA Process in Taiwan (starting 2013)



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Payers Considerations



Pricing and Reimbursement Guideline (1)

- **Category 1 new drug:** (Breakthrough innovative product)
- **Must meet one of the following criteria :**
 - Have new mechanism of action
 - The first drug for a specific disease shown to have good effectiveness
 - Via head-to-head comparison or indirect comparison indicates substantial improvement of the therapeutic value than the current listed comparator
 - Shown to be cost-effectiveness
- **Pricing principle**
 - **Set at median price** of international ten ref. C
 - Have efficacy and safety clinical trial in Taiwan with a reasonable scale, **add 10%.**

* UK, Germany, Japan, Swiss, US, Belgian, Australia, France, Sweden and Canada

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Pricing and Reimbursement Guideline (2)



- **Category 2 new drug :**
 - **Category 2A :**
 - Compare to the current best comparator shown to have **moderate improvement** of the therapeutic value
 - **Category 2B :**
 - Compare to the current best comparator shown to have **similar** therapeutic value

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Pricing principle for Category 2 new drugs



- **Pricing principle :**
 - median of International ten is the ceiling price
 - **methods :**
 - The lowest of the international ten
 - Prices at the original country
 - International price ratio
 - Dosage regimen ratio
 - Combination product: sum of single drug price times 70% or one single drug price

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Bonus principle for Category 2A new drugs



- Have efficacy and safety clinical trial in Taiwan with a reasonable scale, **add 10%**.
- Have pharmacoeconomic study in Taiwan, **add the maximum of 10%**.

No ICER threshold established yet
Recommended 1.4~2.1 GDP/QALY
around **US\$30,000~US\$47,000/QALY**

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Equality	Equity	Liberation
		
<p>In the first image, it is assumed that everyone will benefit from the same supports. They are being treated equally.</p> <p>Sameness</p>	<p>In the second image, individuals are given different supports to make it possible for them to have equal access to the game. They are being treated equitably.</p> <p>Fairness</p>	<p>In the third image, all three can see the game without any supports or accommodations because the cause of the inequity was addressed. The systemic barrier has been removed.</p>

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DAA for hepatitis C reimbursement decision in Taiwan (Four brands on the market)

	Harvoni ® Tab (90mg ledipasvir, 400mg sofosbuvir)	Viekirax ® Tab (12.5mg ombitasvir, 75mg paritaprevir, 50mg ritonavir)	Daklinza ® 60mg Daclatasvir
Daily dose	#1 QD	#2 QD + #1 BID	#1QD + #1 BID
Duration	3 months	3 months	6 months
Cure rate	94~99%	91%~100%	82~92%
Self pay cost/course	~NT\$1,250,000 (~US\$39,062)	~NT\$1,490,000 (+Exviera: Dasabuvir)	~NT\$330,000 (+Sunvepra) (~US\$ 10,000)
NHIA will negotiate drug cost/course, plans to have an independent budget for this category of drug treatment for ten years (Aug. 2016). Treat 10,000 patients/year, budget: US\$ 80 million. (1US\$=32NT\$)			

4th: Sovaldi

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Drug Treatment for Patients with Rare Diseases



- **Rare Disease and Orphan Drugs Act** since the year 2000 advocated by Taiwan Foundation for Rare Diseases
- **Rare Diseases and Drugs Council** decided 210 rare diseases, 92 drugs and 40 nutritional foods
- NHIA created special fund to cover all, free of copayment (**2013 annual budget US\$ 93 million**)
- The diagnosis, treatment, drugs, nutritional foods to sustain life, and medical devices for daily living, if not covered yet, can be subsidized (80~100%) by the National Health Promotion Administration

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<http://www.tfrd.org.tw/english/>

Conclusions



- Economic evaluation is not fully utilized to make reimbursement decision
- However, the culture is to fully support those in needs
- The value of drugs and therefore the reimbursement price is still based on the comparative effectiveness and confounded by budget impact to the payer.