



HTAi 2009 6th Annual Meeting in Singapore -- Plenary 3  
Globalisation and HTAi – Issues and Needs in Relation to HTA

# Issues and Needs in Countries with Recently Established HTA in Asia

**Tony, Yen-Huei Tarn, MS., PhD.**

**Director**

**Division of HTA**

**Center for Drug Evaluation (CDE)**

**yhtarn@cde.org.tw**

**<http://www.cde.org.tw/>**



# Outline

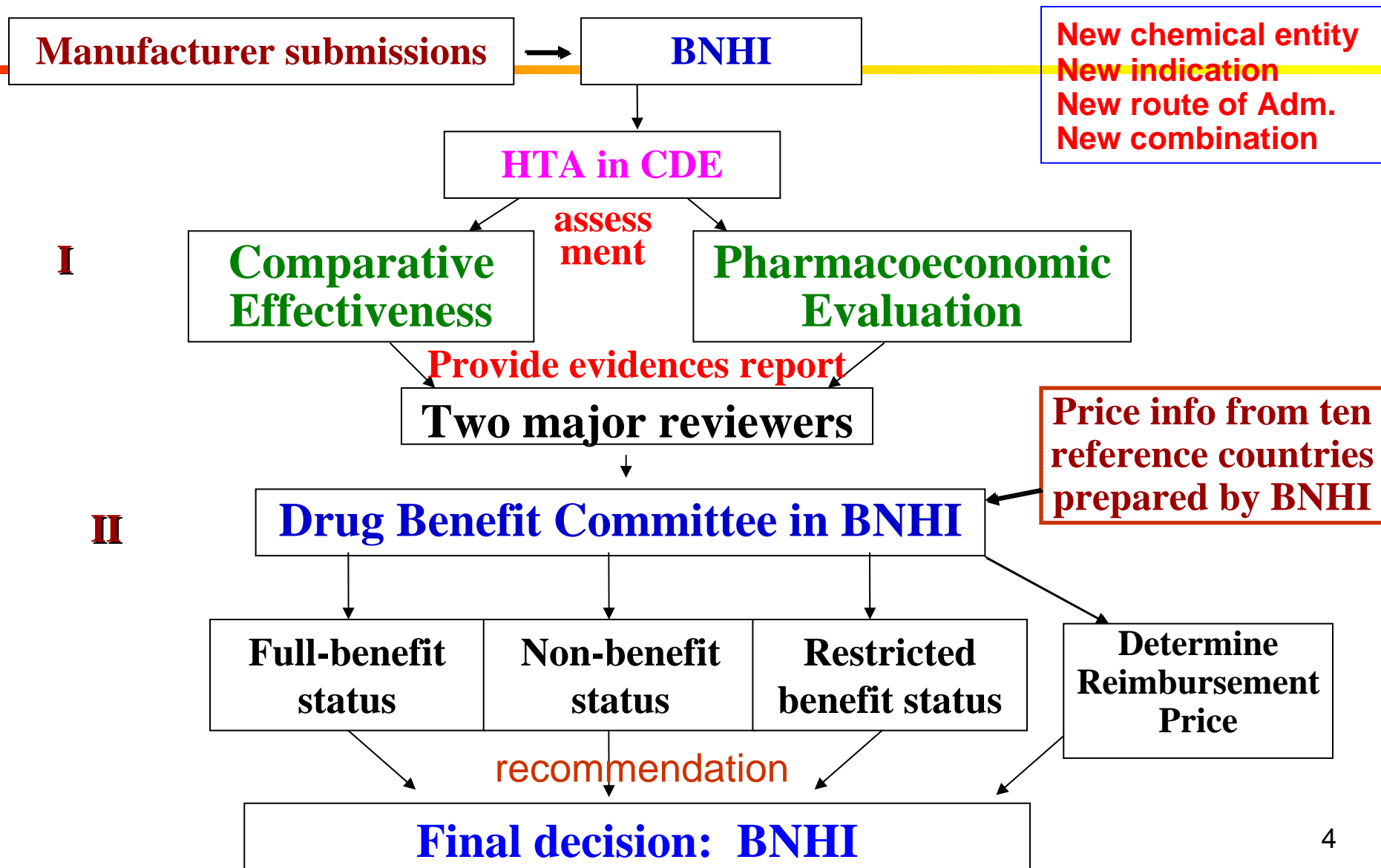
- **2008 starting HTA in Taiwan**
  - **Issue I: the transparency**
  - **Issue II: the speed**
  - **Issue III: pricing**
  - **Issue IV: the definition of breakthrough, innovation, substantial improvement**
- **2006 starting HTA in Thailand**
- **2007 starting HTA in Korea**
- **Needs**

# Taiwan

- **Bureau of National Health Insurance, BNHI**
  - **Single payer, cover 99% of the pop.**
- **Appraisal: Drug Benefit Committee, 1996**
  - **24 members, monthly meeting**
  - ✓ **Relative Effectiveness**
  - ✓ **Budget Impact Analysis**
  - ✓ **CUA/CEA\_PE study**
  - ✓ **Ethical/Law/Social/Political Impact (ELSI)**
- **Assessment: HTA Division/ CDE, 2008**



# Two-stage drug review process





# **Do not put more burden on drug industry at the year 2008**

- Keep the same contents of sub. dossier**
- Did not ask for systematic review of effectiveness information in dossier**
- Did not ask for PE information or conduct local PE study in dossier**

**2007, BNHI**

**Local PE study still optional for submission**

**If submitted, no guarantee higher price**



# Issue 1: the transparency

- The HTA report completed within 42 days from CDE **did not** ask for comments from the manufacturer who made the submission.
- The scheduling of the DBC meeting and reasons of the reimb. decision are not open to the public
- No patient group participate in the appraisal process

**Significant political pressure exist in 2008**



# **Dec/31/2008, National Drug Policy Meeting held by DOH**

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## **One conclusions related to this issue:**

- BNHI agrees to be more transparent**
  - ◆ DBC minutes summary put on the web in April**
  - ◆ Conclusion part of the HTA report send to manufacturers sometime this year**

# Issue 2 : the speed (calendar days)

Timeline		BNHI	Timeline	CDE
0	0	Receive application from Manufacturer		<b>Case send to CDE</b>
		↓ <b>10 days check</b>	+1	1
+ 10	<b>10</b>	Accepted, notify to send 30 copies of dossiers		
		↓ Received 30 copies		Receive 3 c by HTA/CDE
+34	<b>44</b>	Send to two major reviewers select from DBC committee members	+42	43
		↓ <b>7 days review</b>		<b>Conduct assessment within 42 days and back to BNHI</b>
+16	<b>60</b>	Prepare all meeting documents		
		↓ <b>21 days prior to meeting, bound all information</b>		
+30~ 60	<b>90~ 120</b>	<b>DBC monthly meeting</b>		HTA evaluators also attend the meeting



## Issue 2 : the speed

- At minimum, 120 days for the first DBC meeting and 88% of new drugs reach price determination in 2008
- For some cases, the **price** decided by the DBC can not be accepted by the manufacturers
- The **range of coverage** may need suggestions from Medical Societies

**All of these may prolong the pricing and reimbursement decision of the new drugs and was complained by the industry**

# Issue 3: price, major concern by industry

## New Drug Pricing Analysis (2005-2006)

	Approved prices vs. application prices	Approved prices vs. median prices of ten reference	Approved prices vs. lowest prices of ten reference
<b>Total Average</b>	<b>0.73</b>	<b>0.56</b>	<b>0.78</b>
<b>By Manufacturer</b>			
Foreign manufacturer	<b>0.78</b>	<b>0.63</b>	<b>0.86</b>
Local manufacturer	<b>0.53</b>	<b>0.31</b>	<b>0.50</b>
<b>By Drug Category</b>			
Category I (Break)	<b>0.79</b>	<b>0.83</b>	<b>0.93</b>
Category II (Me-too)	<b>0.73</b>	<b>0.57</b>	<b>0.77</b>
Category III (Line-ext)	<b>0.87</b>	<b>0.53</b>	<b>0.86</b>



# Role of HTA for Decision

- **Provide evidences to support:**
  - **Listing**
  - **Range of Coverage**
- **How about Pricing?**

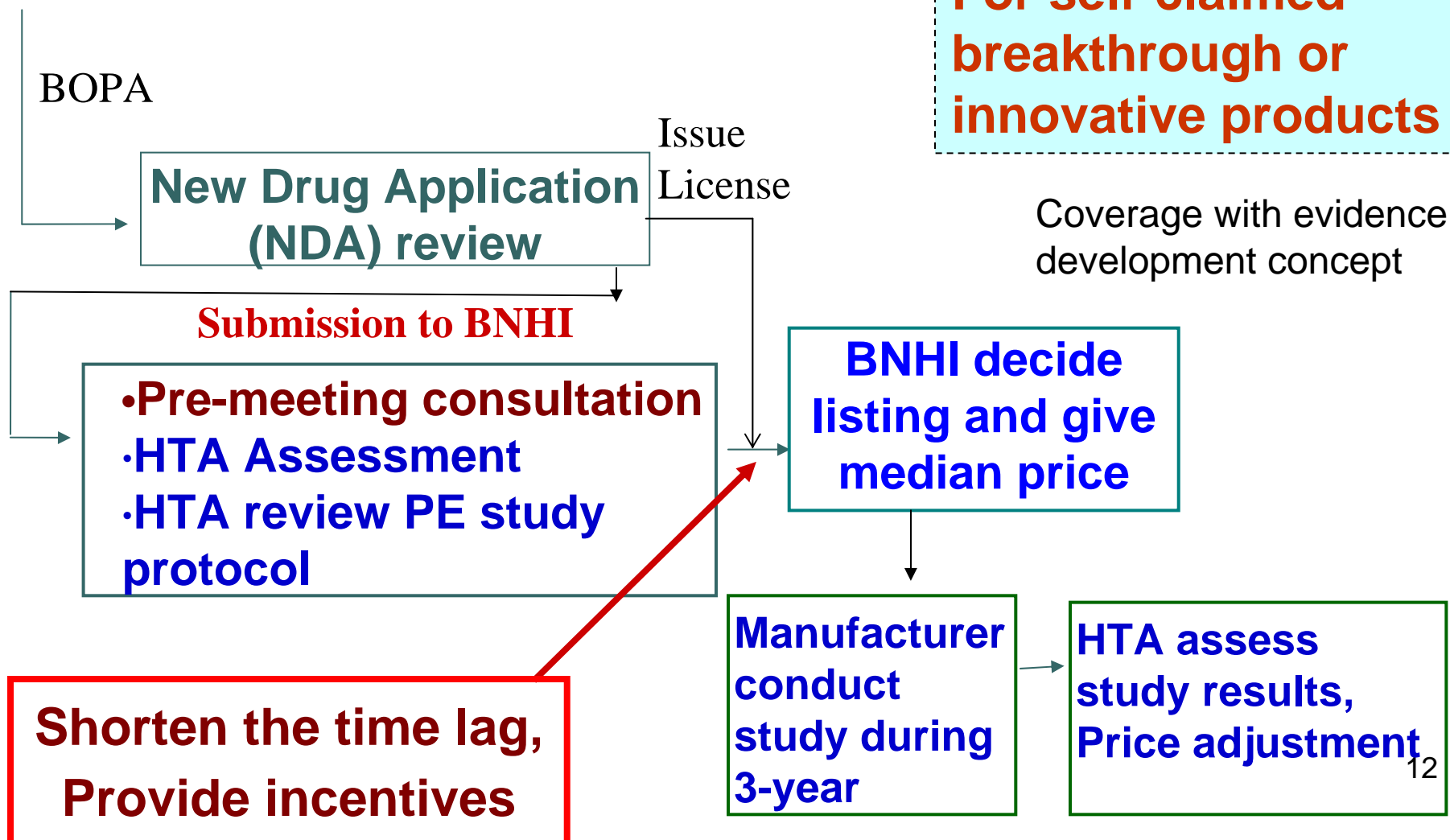
- ✓ **Can value-added information translate into higher price?**
- ✓ **If no local PE study, how?**



# Issue 4 : Parallel Submission

(Drug Information Journal, Vol. 43, pp. 319–323, 2009)

Manufacturer





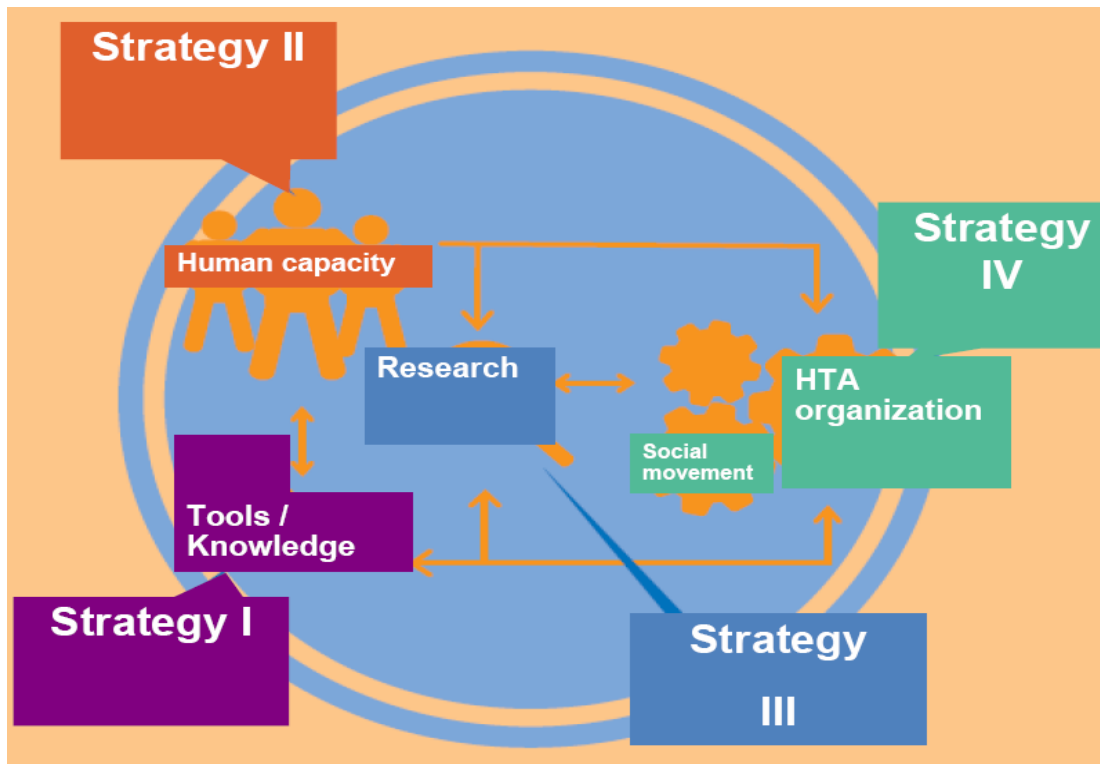
## **Issue 4 : definition of breakthrough, innovation, substantial improvement**

- **PMPRB in Canada, French -- categories**
- **But no clear definition to differentiate the substantial and moderate improvement**
- **It will hinder the categorization used for approval of parallel submission and the following price determination at the early stage**

**Need inputs from international society**

# Thailand

- Establishment of **HITAP** in 2006  
(Health Intervention and Technology Assessment Program)
- Vision: “Appropriate health interventions and technologies for Thai society”



Dr. Yot speech in  
Taiwan in 2008

# Staffs of HITAP in 2008

- 6 post-doctoral fellows
- 11 master degree researchers
- 4 Bachelor degree trainees
- 8 master/Ph.D. students **Total: 36**
- 7 Supporting staffs
- **Multi-disciplinary team:** medical doctors, pharmacists, nurse, public health specialists, economists, anthropologist, policy analyst, mass media specialists, statisticians, engineer, social scientists, geographer etc.
- Master/Ph.D. fellowships
- Support for staff-exchange program

# Challenges facing in Thailand, 2008

- **Resource constraints** from the **Universal Coverage policy**
- The need to have a transparent and participatory decision making by **civil society**
- **Economic evaluation** becomes a well-known tool among academics and some decision makers. The use in decision making is growing
- **Further improvement in HTA processes**, i.e. topic selection, appraisal, approval, and appeal, transparent, participatory, and accountable

# **Korea: Committee for New Health Technology Assessment**

- **Established in June 2007– Medical Law**
- **Annual Budget: US\$ 1,350,000**
- **75% financed from government**
- **20 members** from clinical medicine, health specialist, lawyer and consumer representatives **appointed by** Minister for Health Welfare and Family Affairs.
- **The Committee for HTA has five Subcommittees**
- **The Subcommittee consist of 248 members of medical doctors, dentists and oriental medical doctors, ...**

Applied for INAHTA membership in 2009

# Administration and research

- The HTA Department, Health Insurance Review and Assessment Service (**HIRA**), performs the necessary administration and research services.
- Review of Safety and Effectiveness, the HTA process takes approximately **six months**.
- HTA committee finally **concludes** the safety and effectiveness of a technology.
- By announcing the assessment results, the **inclusion** of useful technologies under National Health Insurance **coverage** may be encouraged



# Needs in these countries

- **Capacity building, manpower and methods.**
  - **Budget impact analysis**
  - **Indirect comparison**
  - **Local phase IV PE study design**
  - **Methods of risk sharing, pay-for-performance**
  - ...
- **Assure quality of assessment conducted**
- **Experiences and reports sharing**
- **Consultancies to advice on further improvement by international community**



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**Thank you for your attention!**