

**Parallel Panel Session B1  
HTA for Resources Allocation Decision: Are Key  
Principles Relevant Globally?  
Singapore, 22 June 2009**

# **Application of Key Principles to HTA activities in Taiwan**

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# Reference

- **Using** The International Group for HTA Advancement's : **Key principles for the improved conduct of health technology assessments for resource allocation decisions as the criteria to analyze Taiwan's HTA Division in CDE.**

**International Journal of Technology Assessment in Health Care, 24:3 (2008), 1–15.**

Michael F. Drummond, J. Sanford Schwartz, Bengt Jönsson, Bryan R. Luce, Peter J. Neumann, Uwe Siebert, Sean D. Sullivan

# HTA, rapidly evolving process

- HTA is a dynamic, rapidly evolving process, **embracing different types of assessments** that inform real world decisions about the value of new technologies, interventions, and practices.
- In these HTAs the consideration of both costs and benefits, in **an economic evaluation is critical**.

## In Taiwan:

- HTA only apply to **new drugs** application for reimbursement purpose in **National Health Insurance** program
- **Did not** mandatory require the local pharmacoeconomic evaluation for the submission

The 15 principles are organized into  
four sections :

- (i) “Structure” of HTA programs;**
- (ii) “Methods” of HTA;**
- (iii) “Processes for Conduct” of HTA;**  
**and**
- (iv) “Use of HTAs in Decision Making.”**

# I、Structure of HTA Programs

**Principle 1: The Goal and Scope of the HTA Should Be Explicit and Relevant to Its Use**

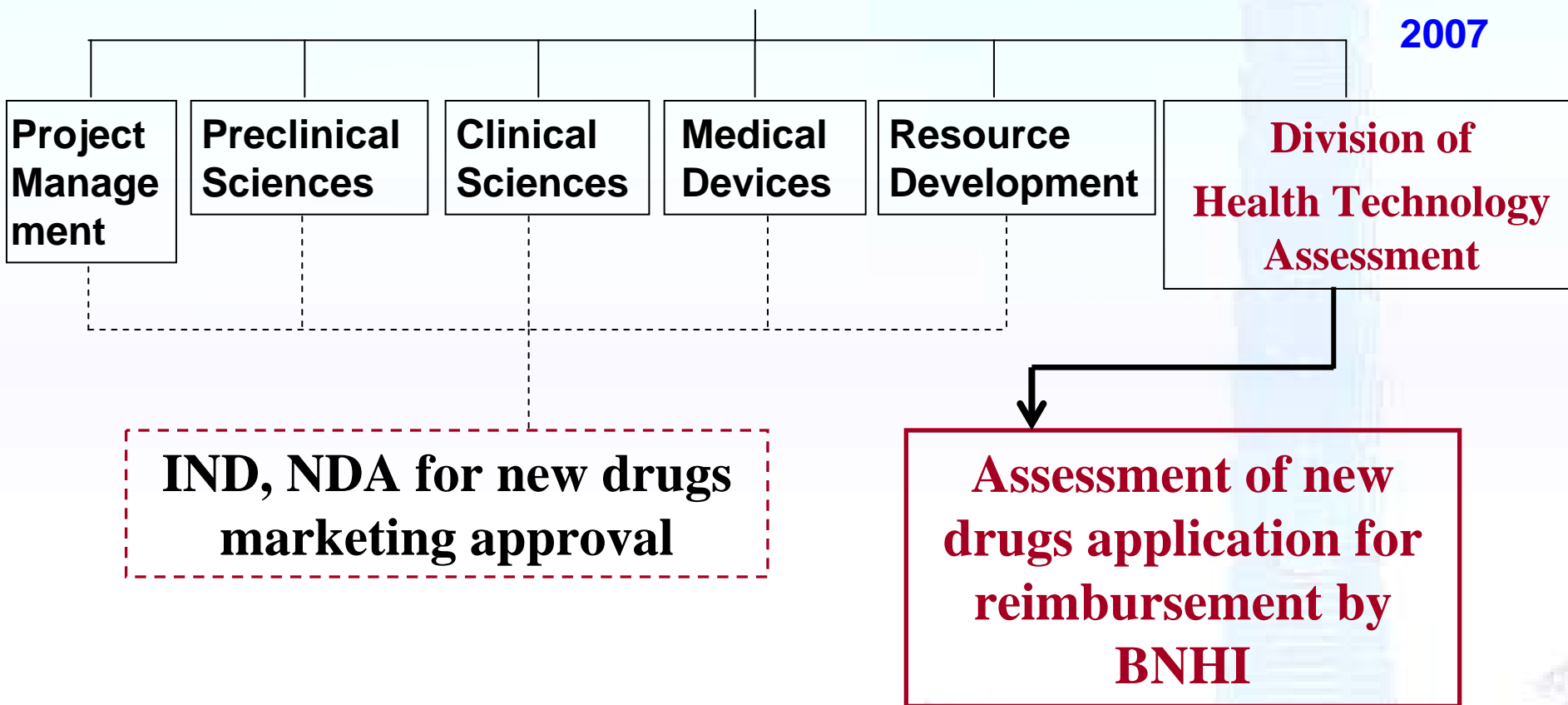
# Introducing a new drug in the health care system in Taiwan

- Step 1: **Marketing authorization**
  - *Technical Review*: **Center for Drug Evaluation (CDE, 1998)**
  - *Decision* : **Bureau of Pharmaceutical Affairs, DOH**
- Step 2: **Reimbursement by National Health Insurance program**
  - *Assessment* : **HTA/CDE (starting Jan. 2008)**
  - *Appraisal* : **Drug Benefit Committee (DBC, BNHI)**
  - *Decision* : **Bureau of National Health Insurance, DOH**

**Center for Drug Evaluation (CDE)**  
**An Independent Juridical Person,**  
**Non-governmental Organization**

1998

Dec.  
2007



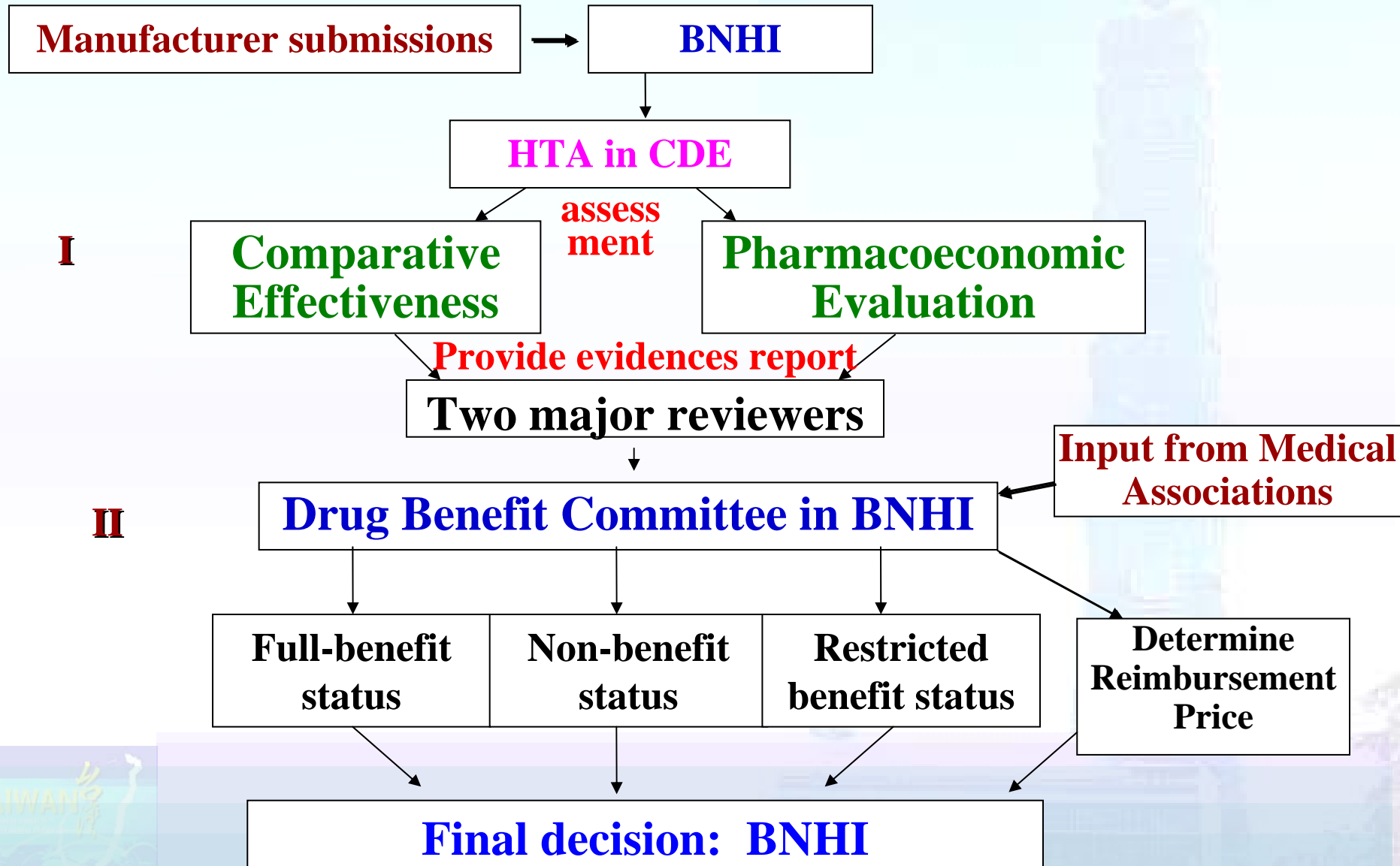
**IND, NDA for new drugs marketing approval**

**Assessment of new drugs application for reimbursement by BNHI**

## Principle 2: HTA Should Be an Unbiased and Transparent Exercise

- **10 staffs**
- **Budget: US\$ 0.75 million/year**
- **Commissioned and funded by Department of Health, not from BNHI: unbiased and independent**

# Two-stage drug review process



# Need more transparency

- The HTA report sends to **two major reviewers** on this case assigned from the DBC Committee as a reference to make their own 1~2-page report.
- The HTA report does not send to the manufacturer for comment at present.
- **However**, a decision by BNHI was made to send the conclusions part of the report to the manufacturer some time this year.

## Principle 3: HTA Should Include All Relevant Technologies

- Health technologies include **drugs, devices, procedures, diagnostics, and treatment strategies**. The range of relevant technologies relates to the breadth of the budget that the decision maker is seeking to optimize.
- However, in many of the countries where HTA has been linked to reimbursement or coverage decisions, it has **focused on drugs alone**.

  
**This is true in Taiwan**



# Principle 4: A Clear System for Setting Priorities for HTA Should Exist

- No jurisdiction assesses all health technologies, although some of **those focusing on drugs do assess all new products and formulations** before listing for reimbursement (e.g., Australia, Canada, Sweden.) **including Taiwan**

- ✓ **New chemical entity**
- ✓ **New indication**
- ✓ **New route of Adm.**
- ✓ **New combination**

## II 、 Methods of HTA

**Principle 5: HTA Should Incorporate  
Appropriate Methods for Assessing  
Costs and Benefits**

# **BNHI announced that**

## **Do not put more burden on drug industry at the beginning stage**

- **Keep the same contents on current Dossier prepared by manufacturers**
- **Did not ask for systematic review of effectiveness information**
- **Did not ask for PE information or conduct local PE study**

# New Drug Appraisal Process

## 1. Topic Selection and Prioritizing

- Manufacturers initiated new drug submission for reimbursement

## 2. Project Scoping

- ✓ Listing
- ✓ Set up reimbursement guideline
- ✓ Pricing (X)

## 3. Evidence Gathering

- CADTH(Canada), NICE(UK), PBAC (Australia)
- SMC, Cochrane, INAHTA, CRD (York),
- Micromedex, MD consult, PubMed, EMBASE

# New Drug Appraisal Process

## 4. Scientific assessment of evidence (HTA/CDE)

- Summarize comparative effectiveness and PE evidences collected, conduct budget impact analysis
- Provide report with conclusions

## 5. Appraisal of reports by **DBC** in BNHI

- 24 members meet every month
- HTA/CDE report, reports from two committee member, price info and calculation by BNHI
- Make listing, coverage and pricing **recommendations**

## 6. Dissemination and Implementation

- Positive listing
- Monitored by peer review group on medical charts

# “Methods” of HTA

- **Principle 6: HTAs Should Consider a Wide Range of Evidence and Outcomes**
- **Principle 7: A Full Societal Perspective Should Be Considered When Undertaking HTAs**
- **Principle 8: HTAs Should Explicitly Characterize Uncertainty Surrounding Estimates**
- **Principle 9: HTAs Should Consider and Address Issues of Generalizability and Transferability**

## 台灣藥物經濟評估方法學相關指南

(Guidelines of Methodological Standards for Pharmacoeconomic Evaluations)

1.0版本 (草案)

95/12/14

民國九十五年九月衛生署核准研究經費，支持建立藥物經濟研究的相關評估指南。研究主持人譚延輝博士定義為建立台灣藥物經濟評估方法學指南，重點在執行藥物經濟學評估時的方法學指南。此研究邀請學術界代表陳恆德醫師、楊銘欽副教授，中央健康保險局代表黃黎明、杜安瑋，以及製藥界代表程馨、洪在華、王宥人，一起組成工作團隊，從認識加拿大指南、美國 AMCP 指南，到寫成台灣的指南草案，經兩次研討與一次公開說明會與擴大專家會議，完成這一份台灣藥物經濟評估方法學指南的第一版本。

### 第一章、簡介

健康照顧介入活動的經濟評估，主要在描述、分析與比較兩種或多種介入活動之間的成本與所得到的結果。若此經濟評估是在探討藥品及醫療器材，就應使用“藥物經濟評估”這個名詞，即使對照組是完全沒治療，或使用非藥物療法。但經濟評估也可運用到其他不同醫療科技的介入，包括診斷科技或醫療處置等。

一個藥物經濟評估可定義出一個藥物產品是否具有多增加的價值，也就是與目前使用的對照組比較，可能有多增加的金錢上利益及/或健康療效上的好效果。因此提供出證據，來證實醫療保險單位提供該新藥給付或改變目前藥物給付條件的正當性。很重要的一個觀念是：符合成本效益可能代表健康療效上會增加，但同時也會增加藥物的財務預算；或者能達到相同的健康療效但使用較少的醫療資源。因此，增加醫療科技的成本效益可能會也可能不會降低醫療的花費，但實質上可看到每單位花費會導致更高的健康療效之衝擊。藥物經濟評估之目的是提供實證(evidence-based)資訊，給決策者做適當決定的參考；是經由增加決策者更多信任、有根據的資訊來做出明智的決定，同時讓醫療保險資源能做最有效率的分配。

台灣藥物經濟評估方法學指南，是期望建立一套執行藥物經濟評估的方法學標準。經此標準所執行藥物經濟評估的結果，會被醫療保險單位認為是可值得相信的結果。例如：當藥廠有一新藥產品，擬於台灣執行經濟

# Guidelines of Methodological Standards for PE Evaluation

published on December 2006

by TASPOR

(Taiwan Society for PE and Outcomes Research,

Taiwan Chapter of ISPOR)

[http://www.taspor.org/2\\_2](http://www.taspor.org/2_2)

## III 、 Processes for Conducting HTA

### Principle 10: Those Conducting HTAs Should Actively Engage All Key Stakeholder Groups

- such an open process **will enhance transparency** and **trust** in the process as stakeholders develop a greater understanding of the criteria and standards used.

#### **Taiwan did not fulfill this principle**

- **No patient group involved**
- **No manufacturer's comments**
- **Summary of meeting minutes published on the website of BNHI in April, 2009**

## **“ Processes for Conducting HTA ”**

- **Principle 11: Those Undertaking HTAs Should Actively Seek All Available Data**
- **Principle 12: The Implementation of HTA Findings Needs to Be Monitored**

# Format of the Assessment Report

1. Product information
2. Current status of disease management
3. Availability of assessment report from international society?
  - CADTH/Canada**  **PBAC/Australia**  **NICE/UK**
  - Cochrane,  INAHTA,  CRD (York),  SMC
  - Micromedex,  MD consult,  PubMed,  EMBASE
4. Summary of the comparative effectiveness
5. Summary of the economic evaluation
6. Taiwan situation: suggest comparators, target population, Taiwan epi. data, budget impact
7. Conclusions

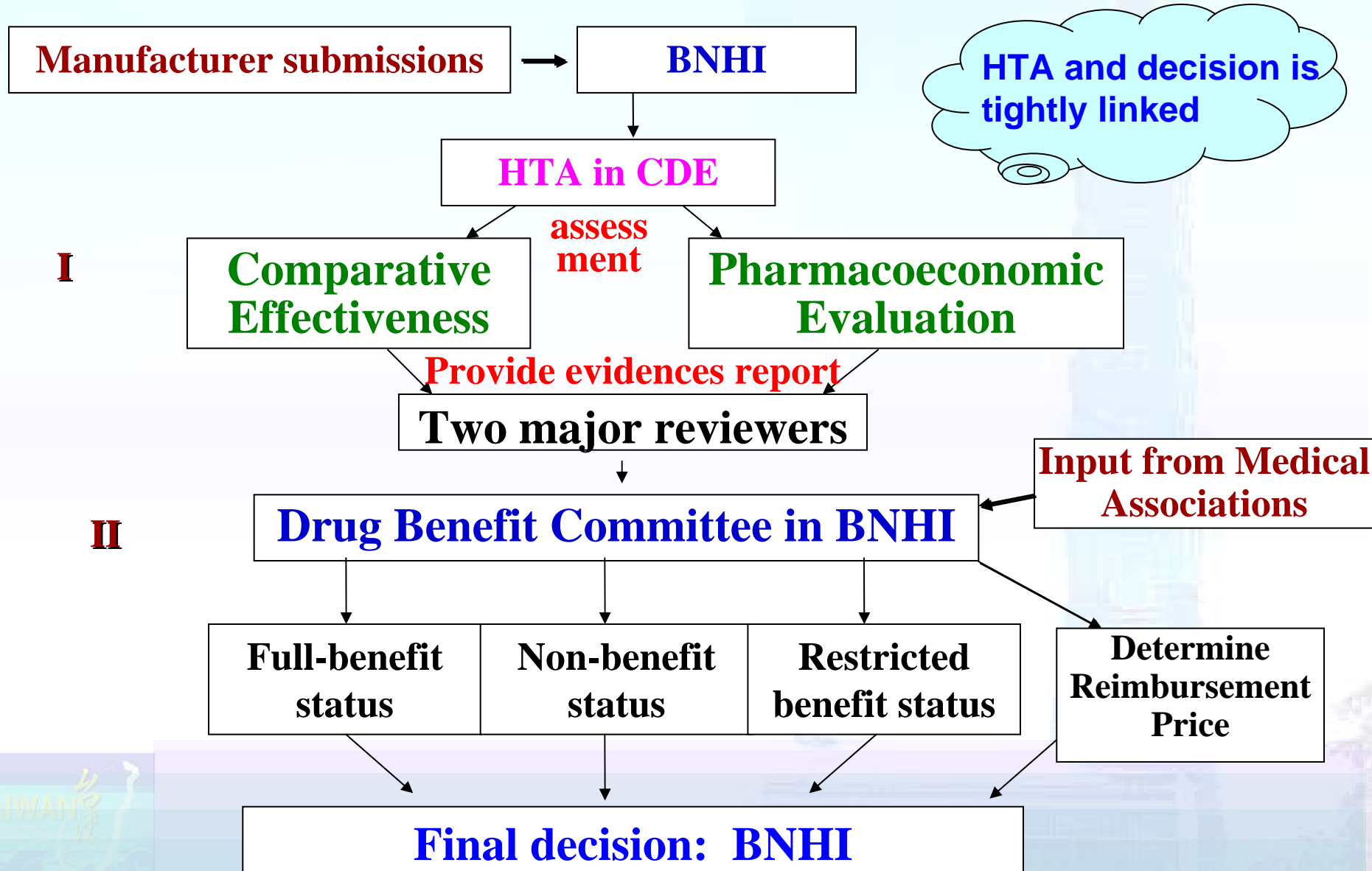
## **IV. Use of HTAs in Decision Making**

- **Principle 13: HTA Should Be Timely**
- **Principle 14: HTA Findings Need to Be Communicated Appropriately to Different Decision Makers**
- **Principle 15: The Link Between HTA Findings and Decision-Making Processes Needs to Be Transparent and Clearly Defined**

# Process Timeline

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

# Two-stage drug review process



# Future Developments in Taiwan

- **Design new submission format** (breakthrough innovative)
  - Ask for supporting comparative effectiveness summarized information
  - Detailed budget impact analysis
- **Design dual tract system for breakthrough and substantial improvement products**

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

  - Provide incentives for local PE study
- **More transparency**
- **Discuss decision making rules-- thresholds of ICER.**

Thank you for your attention!

