



Parallel Panel Session D2

Adapting HTA for Use in Other Jurisdictions

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Adapting HTA for Use in Taiwan

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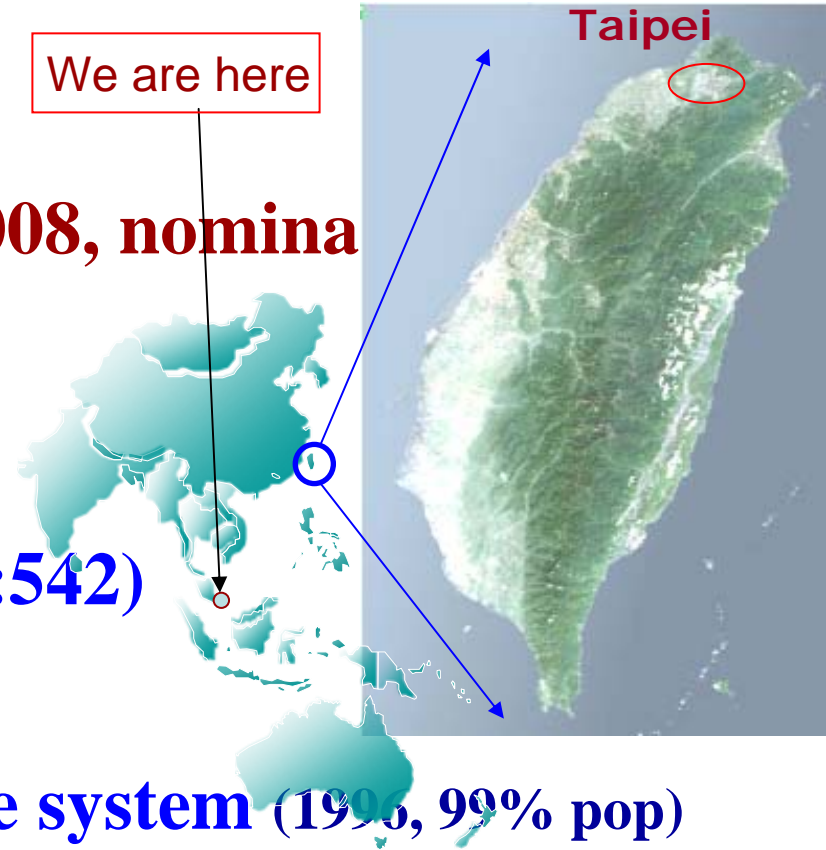
Outline

- Overview of Taiwan's health system
- Reasons for adapting HTAs for use in Taiwan
- Overview of the drug reimbursement process
- Challenges faced
- Success- 47 cases assessed the first year

Purpose: Provide an example for those who wants to start a HTA agency from a small scale and gradually grow up

Taiwan

- **Land Size: 36,190 km²**
- **Population: 23 million**
- **GDP per head: US\$17,950 (2008, nominal)**
- **NHE as 6.5% GDP**
- **Elderly (> 65 y) : 10.2%**
- **Private hospitals : 85% (total:542)**
- **Private clinics: 98%**
- **Single-payer health insurance system (1996, 99% pop)**
- **65% health care expenditure on ambulatory care**
- **Rx dispensed in Hospital, keep the difference**
- **Drug expend. 25% of total healthcare expenditure**





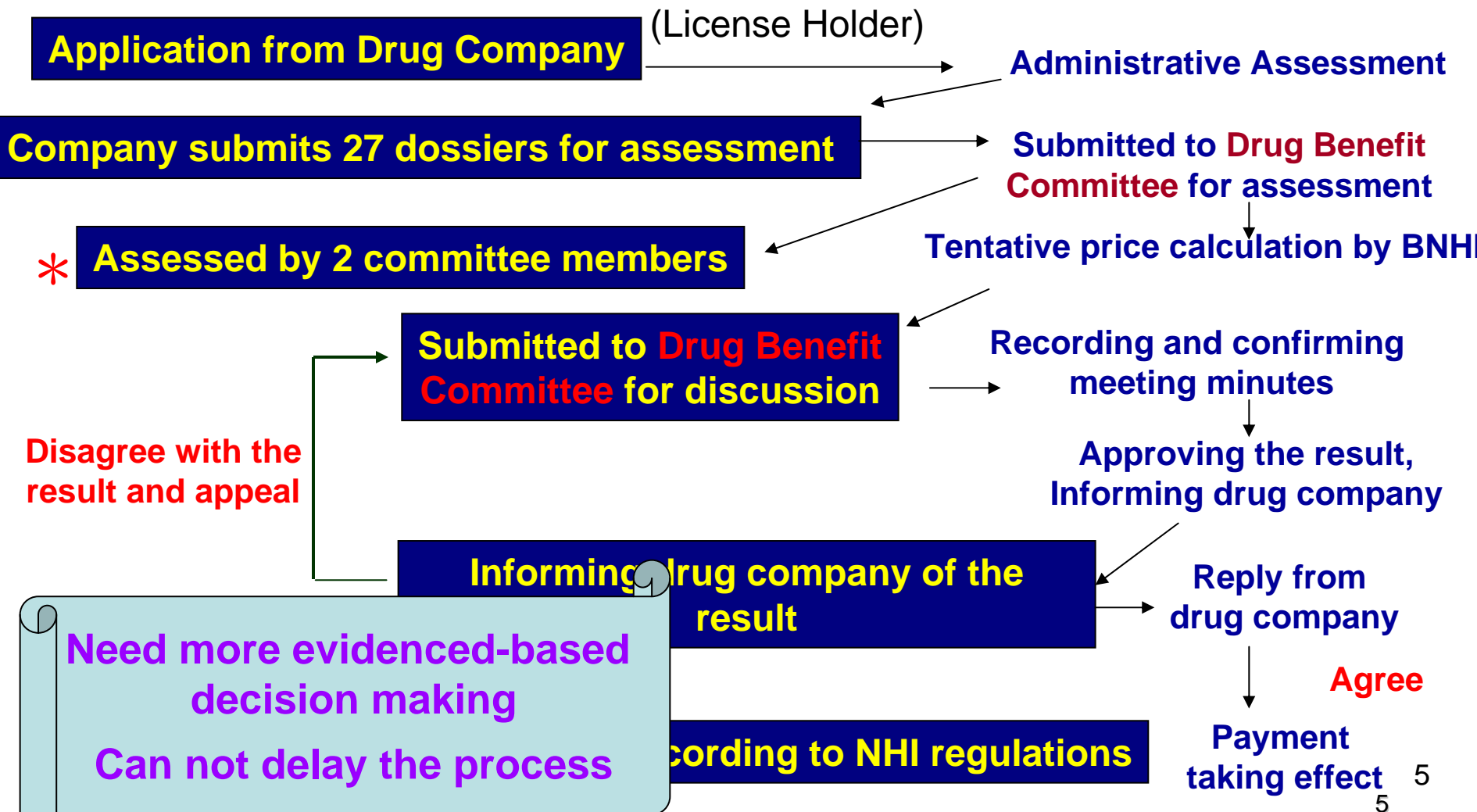
Introducing a new drug in the health care system in Taiwan

- Step 1: **Marketing authorization**
 - *Technical Review*: **CDE** (Center for Drug Evaluation, 1998)
 - *Decision* : **Bureau of Pharmaceutical Affairs, DOH**

- Step 2: **Reimbursed by the national health Insurance program**
 - *Assessment* : **HTA/CDE (starting 2008)**
 - *Appraisal* : **DBC** (Drug Benefit Committee, BNHI)
 - *Decision* : **Bureau of National Health Insurance, DOH**



Previous New Drug Pricing and Reimbursement Process in BNHI (before 2008)



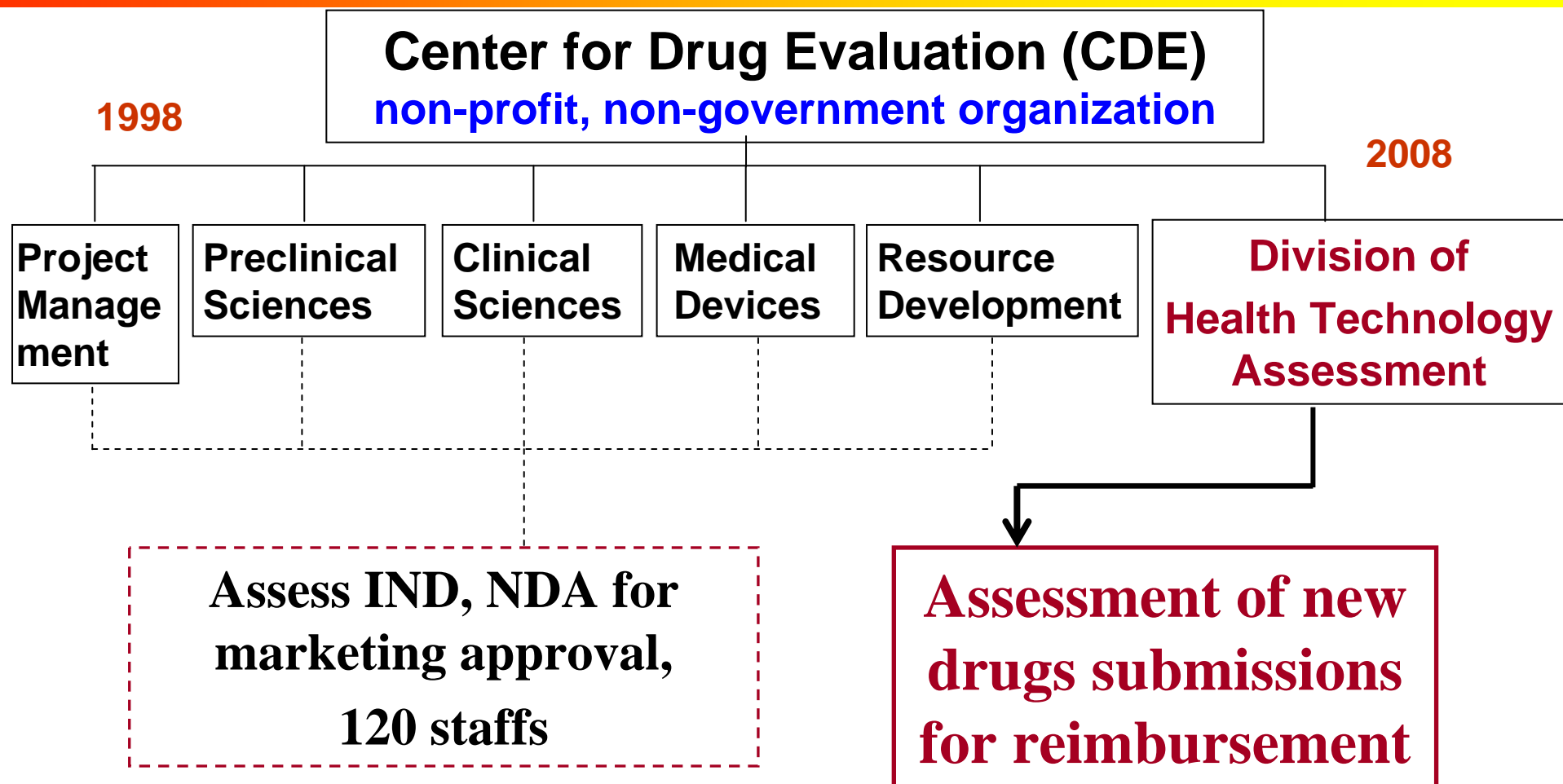


2007 Progress in Taiwan

- **February 2007**, Minister of Health decided to establish a HTA group inside Center for Drug Evaluation (CDE)
- **June 2007**, **HTA Task Force** created in CDE
- **October 2007**, Positioning of HTA in relation to BHNI by **Deputy Minister of Health**.
 - ◆ **HTA**: Advisory role, provide evidences of comparative effectiveness and cost-effectiveness, not involve with price determination
 - ◆ **BNHI**: Take HTA evidences as part of the information for listing and reimbursement decision.
- **Dec. 20, 2007** HTA division approved by the **Board of CDE**



Organizational Structure of CDE





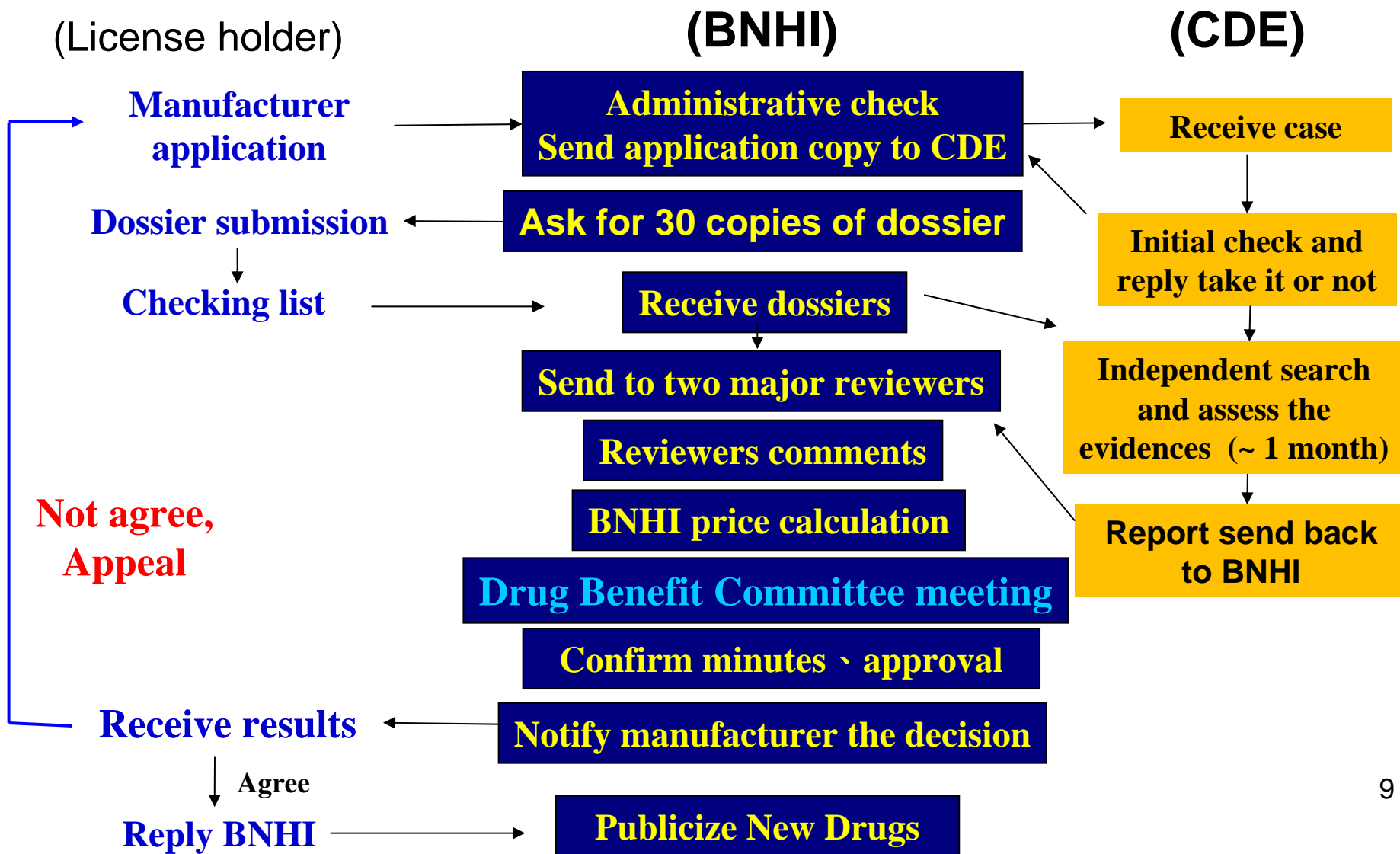
HTA Division (2009)

- **10 staffs**
- **Budget: US\$ 0.75 million**
- **Commissioned and funded by Department of Health, not from BNHI: unbiased and independent third body**
- **Internal 42 days assessment on one case, consult external expert if necessary**
- **Two reviewers on one case**
- **One reviewer has ~3 cases/month**
- **Two products:**
 - **Assessment report of new drug**
 - **Research report on temporary assignment**



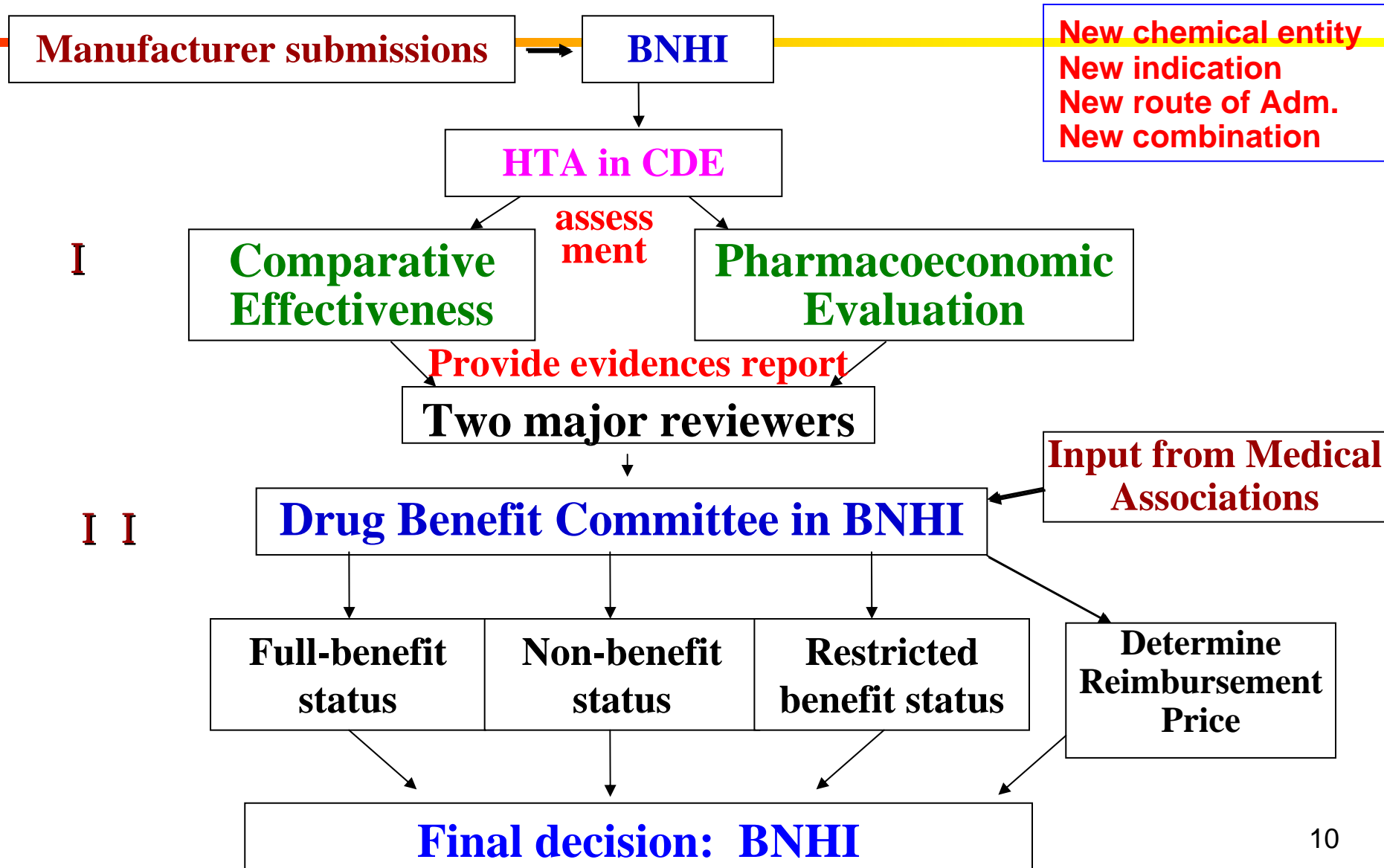
New Drug Pricing and Reimbursement

Process in BNHI (after 2008)





Two stages 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



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**
 - SMC** Cochrane, INAHTA, CRD (York),
 - 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



Search Canada, Australia, UK reports

➤ Public Summary Documents

- <http://www.cadth.ca/index.php/en/cdr/search>
- <http://www.health.gov.au/internet/main/publishing.nsf/Content/public-summary-documents-by-product>
- <http://www.nice.org.uk/guidance/index.jsp?action=ByType&type=6&status=3&p=off>
- http://www.scottishmedicines.org.uk/smc/controller?p_service=Content.show&p_applic=CCC&pContentID=26&p_service=Content.show



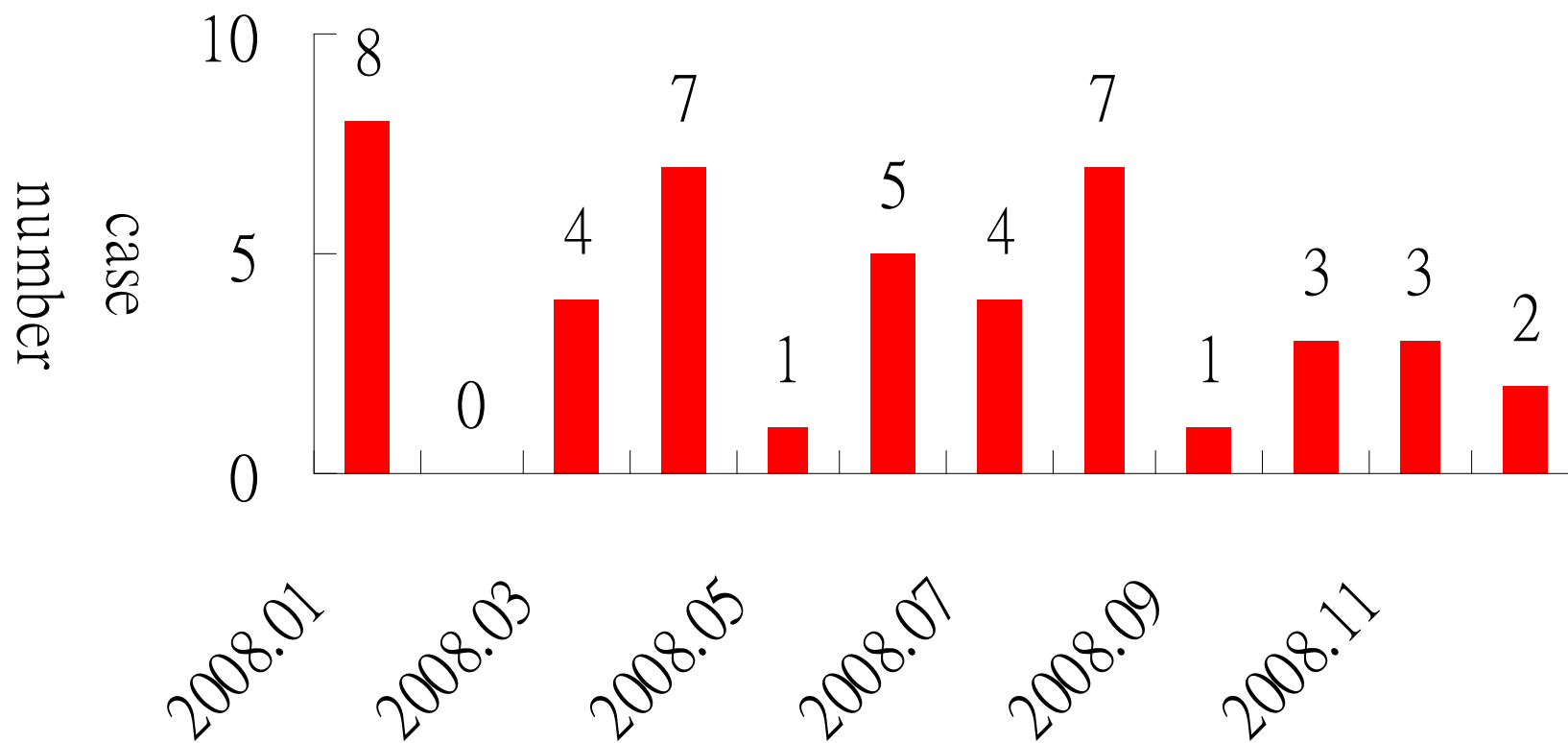
Challenges faced in 2008

- **Industry did not support**
 - Prolong the reimb. decision?
 - Lower price determined?
 - Lack of transparency in the process
 - If reimb. price is still low, why invest more money to conduct local PE study?
- **Lack of experts on SR, PE, BIA**
- **Academia wish to conduct HTA research, not assessment of new drugs for reimb. purpose**



Number of cases evaluated by HTA/CDE (Jan ~ Dec, 2008) (N=47)

Cases discussed at DBC meeting/BNHI
(N=45)





Indicators - new drugs

Cases discussed at 1st DBC meeting		2008.Q1		2008.Q2		2008.Q3		2008.Q4	
		Cases	%	Cases	%	Cases	%	Cases	%
Reach Conclusion DBC / BNHI	Per.Q	11/12	91.6	11/12	91.6	10/12	83.3	7/8	87.5
	accumulated	11/12	91.6	22/24	91.6	32/36	88.8	39/44	88.6
Comparator Agreement CDE / DBC	Per.Q	3/7	42.8	11/11	100	8/10	80.0	6/6	100
	accumulated	3/7	42.8	14/18	77.7	22/28	78.5	28/34	82.3
Assessment Time (32 day) HTA/CDE	Per.Q	12/12	100	8/13	61.5	11/12	91.6	8/8	100
	accumulated	12/12	100	20/25	80	31/37	83.7	39/45	86.6
Assessment Process (42day) HTA/CDE	Per.Q	12/12	100	8/13	61.5	12/12	100	6/8	75
	accumulated	12/12	100	20/25	80	32/37	86.4	38/45	84.4



Research projects (01~12, 2008)

1. The preview of the changes on current reimbursement of cholesterol-lowering therapy **(Completed)**
2. Clinical outcomes evaluation of Guaifenesin **(C)**
3. Effectiveness and economic evaluation of Visudyne **(C)**
4. The review and compilation of the guidelines for the use of factor VIII products **(C)**
5. Comparison of the current Bureau of National Health Insurance (BNHI) reimbursement guidance for anti-osteoporotic drugs with those of other countries **(C)**
6. Recombinant human activated protein C (Xigris)- effectiveness **(C)**
7. The impact of changing proton pump inhibitors reimbursement guideline
8. Whether patients without cardiovascular disease, LDL-C between 130 and 160 mg/dL should receive reimbursement of cholesterol-lowering drug therapy
9. Evaluation of the reimbursement guideline revisions for the treatment of chronic hepatitis B patients covered by National Health Insurance and clinical effectiveness of the chronic hepatitis B drug treatments
10. The cost-effectiveness analysis of three anti-tumor drugs
11. DM drug-glitazone, its cost benefit
12. Herbal extract- its effectiveness and economic evaluation



Future Developments in Taiwan

- **Define breakthrough, innovative, substantial improvement product, and in dossier**
 - May have median price of the ten reference countries, as an incentive for local PE study
 - Ask for supporting comparative effectiveness summarized information
 - Detailed budget impact analysis
- **More transparency**
 - Comments from manuf. before DBC meeting
 - Process timeline and reasons of decision on web.
- **Discuss ICER thresholds _decision making rules**



Thank you for your attention!

