Current HTA Process in Taiwan

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Introducing a new drug to the health care system in Taiwan

- **Step 1: Marketing approval**
  - *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)
  - *Appraisal:* Stakeholders Meeting (2013)
  - *Decision:* National Health Insurance Administration, MHW
Structure of CDE (1998~2012)

Center for Drug Evaluation (CDE)

- Project Management
- Preclinical Sciences
- Clinical Sciences
- Medical Devices
- Resource Development

Division of Health Technology Assessment (2007)

Future

- COMPUS, SCKE
- Research HTA

Short term

Value Assessment of New Drugs for reimb.

Provide evidences to Drug Benefit Committee/NHIA on comparative effectiveness, cost-effectiveness and budget impact analysis
Difference between NDA & HTA Review

**NDA**
- Efficacy, Safety, Product Quality
- RCT, placebo trial
- Short-term, surrogate outcomes
- Broad indication
- Less local issue except ethnic factors

**HTA**
- Comparative effectiveness
- Indirect comparison
- Cost-effectiveness analysis
- Real world trial, active comparator, modeling
- Local epidemiology for budget impact analysis
- Narrow down indication
- Ethical/ social/ political issues
New Process under 2nd-NHI (starting 2013)

Ministry of Health and Welfare

NHIA

Drug assessment report in 42 days

National Institute of HTA (NIHTA)

☑ New drugs
☑ Medical devices
☑ Diagnostics
☑ Procedures
Adding more research-oriented HTA

Drug Benefit Expert Group Meeting

Recommendation for listing & pricing

Stakeholders Meeting

Make coverage decision:
Covered / Not covered /
Conditionally covered
Set the price

Recommendation for listing & pricing
Starting 2008, the new drug HTA process

Manufacturers make dossier submissions → NHIA

HTA in CDE

Review

Therapeutic Evaluation
Pharmacoeconomic Evaluation

Provide assessment report in 42 days

Two major reviewers

Drug Benefit Expert Group Meeting in NHIA

Cases for discussion

Stakeholders Meeting to decide benefit status: full, restricted, no, and price

Some cases to report to stakeholders meeting

Final decision: NHIA

New chemical entity
New indication
New route of Adm.
New combination
## Reporting Cases and Discussions in Stakeholders Meeting (Drugs)

<table>
<thead>
<tr>
<th>Reporting Cases</th>
<th>Discussions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Changes of reimbursement regulations of drugs whose ingredients are already listed.</td>
<td>1. Listing of 1st drug in ATC (a new category).</td>
</tr>
<tr>
<td>2. Proposals of listing new drug items (including new items meeting the quality criteria for incentive pricing, TPN).</td>
<td>2. Increase of payment prices of essential drugs and drugs for rare diseases.</td>
</tr>
<tr>
<td>3. Price-Volume adjustment (including grouping mechanism change, PV agreement review, international reference pricing review)</td>
<td></td>
</tr>
<tr>
<td>4. Proposals of delisting drug items.</td>
<td></td>
</tr>
</tbody>
</table>
Pricing and Reimbursement Guideline (1)

- **Category 1 new drug**: (Breakthrough innovative product)
  - Via head-to-head comparison or indirect comparison indicates substantial improvement of the therapeutic value

- **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%.
  - If less than 5 countries have the price info, after the effective date, at 4th quarter every year, price will be reevaluate against the ten reference countries until more than 5 countries have the price.

*UK, Germany, Japan, Swiss, US, Belgian, Australia, France, Sweden and Canada*
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
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
# Example of International Price Ratio

<table>
<thead>
<tr>
<th>Country</th>
<th>New drug A</th>
<th>Comparator B</th>
<th>Ratio (A/B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>NT$ 639.50</td>
<td>480.33</td>
<td>1.33</td>
</tr>
<tr>
<td>Japan</td>
<td>No</td>
<td>252.20</td>
<td>--</td>
</tr>
<tr>
<td>UK</td>
<td>NT$ 390.91</td>
<td>230.42</td>
<td>1.69</td>
</tr>
<tr>
<td>Canada</td>
<td>No</td>
<td>198.50</td>
<td>--</td>
</tr>
<tr>
<td>Germany</td>
<td>NT$ 455.00</td>
<td>256.32</td>
<td>1.77</td>
</tr>
<tr>
<td>France</td>
<td>NT$ 458.72</td>
<td>240.92</td>
<td>1.90</td>
</tr>
<tr>
<td>Belgian</td>
<td>NT$ 403.05</td>
<td>No</td>
<td>--</td>
</tr>
<tr>
<td>Sweden</td>
<td>No</td>
<td>200.78</td>
<td>--</td>
</tr>
<tr>
<td>Swiss</td>
<td>NT$ 420.60</td>
<td>262.95</td>
<td>1.59</td>
</tr>
<tr>
<td>Australia</td>
<td>NT$ 365.21</td>
<td>188.89</td>
<td>1.93</td>
</tr>
<tr>
<td>BNHI price</td>
<td></td>
<td>NT$ 185</td>
<td></td>
</tr>
</tbody>
</table>

(1) Determine the median: 
(UK 1.69 + Ger 1.77) ÷ 2 = 1.73

(2) Price of ND = Comparator × Median Price Ratio

= NT$ 185 × 1.73 = NT$ 320
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%.
For Category 2B drug

**Example of Dosage Regimen Ratio**

<table>
<thead>
<tr>
<th>New Drug A</th>
<th>Comparator B</th>
</tr>
</thead>
<tbody>
<tr>
<td># 1, BID, 2 Tab/day</td>
<td>#2, TID, 6 Tab/day</td>
</tr>
<tr>
<td>(1 x 2 = 2)</td>
<td>(2 x 3 = 6)</td>
</tr>
</tbody>
</table>

Price of A = Comparator price × (B)/(A)  
NT$ 18.4 × [ (2×3)/(1×2) ]  
= NT$ 55.2

BNHI price: NT$ 18.4
Bonus for price determined by Dosage Regimen Ratio method

- Efficacy better than comparator with evidence support: **add up to 15%**.
- Safety better than comparator with evidence support: **add up to 15%**.
- More convenient to use than comparator, such as longer dosing interval, better route of administration, easier to monitor treatment outcomes, better stability, longer shelf life, easier to carry, easier for compounding, more convenient to use and safety package: **add up to 15%**.
- Clinical meaningful children product: **add up to 15%**.
Needed information in the submission dossier

1. Drug approval information
2. Product detailed information
3. Comparator(s) information
4. Drug prices in international ten ref. countries (including prices of comparators)
5. Reimburse guidelines in other countries
6. Results of clinical trials in Taiwan
7. Summary of PE study (int. or local)
8. HTA reports from UK, Canada, Australia
9. Budget impact analysis
12. Appendixes
10. Evidences that indicate substantial improvement
11. Detailed attributes of the PE study (summarized)

Category 2 new drugs

After Dec. 1, 2010

If category 1 new drug
Format of the HTA Assessment Report

1. Product information, suggest comparators
2. Current status of disease management
3. Availability of assessment report from international society?
   - ✓ NICE/UK ✓ CADTH/Canada ✓ PBAC/Australia
   - □ SMC □ Cochrane, □ INAHTA, □ CRD (York),
   - □ PubMed, □ EMBASE, □ Micromedex, □ MD consult
   - □ others __________
4. Summary of the comparative effectiveness:
5. Summary of the economic evaluation:
6. Taiwan situation: target population, epi. data, budget impact
7. Conclusion (not recommendation of listing)
### Examples in Different Countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Long-HTA (research)</th>
<th>Short-HTA (Reimbursement)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NICE/UK</td>
<td>Multiple TA</td>
<td>Single TA</td>
</tr>
<tr>
<td>CADTH/Canada</td>
<td>Drug Class</td>
<td>CDR (9 weeks)</td>
</tr>
<tr>
<td>PBAC/AU</td>
<td></td>
<td>PBAC (9 weeks)</td>
</tr>
<tr>
<td>South Korea</td>
<td>NECA</td>
<td>HIRA</td>
</tr>
<tr>
<td>Taiwan</td>
<td>HTA/CDE (42 days)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Country</th>
<th>Assessment Agency</th>
<th>Appraisal Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>NICE/UK</td>
<td>Universities</td>
<td>In NICE</td>
</tr>
<tr>
<td>CADTH/Canada</td>
<td>Internal/ Universities</td>
<td>CEDAC</td>
</tr>
<tr>
<td>PBAC/AU</td>
<td>Universities</td>
<td>PBAC</td>
</tr>
<tr>
<td>South Korea</td>
<td>HIRA</td>
<td>HIRA</td>
</tr>
<tr>
<td>Taiwan</td>
<td>HTA/CDE</td>
<td>Stakeholders/NHIA</td>
</tr>
</tbody>
</table>
HTA Involved Several Agencies
(all topics related to resources use decision making)

I. Ministry of Health

- Research topics for decision making (topic selection and scoping)
- Cases submitted for Reimbursement from technology producer

II. Assessment Agency to collect all evidences and produce an Assessment Report

III. Appraisal Committee to make recommendations

IV. Health Insurance Agency: listing, pricing, implementation, tracking, follow-up evaluation
New Process under 2nd-NHI (starting 2013)

Ministry of Health and Welfare

Drug Benefit Expert Group Meeting

NHIA

Drug assessment report in 42 days

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✓ New drugs
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✓ Diagnostics
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Stakeholders Meeting

Make coverage decision:
Covered / Not covered / Conditionally covered
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Recommendation for listing & pricing
26 Members in Stakeholders Meeting
(starting 2013)

1. Insurer and the relevant agencies, one of each. (2)
2. Experts (5)
3. Beneficiary representatives (3)
4. Employer representatives (3)
5. Representatives from contracted medical care institutions, including: (13)
   (1) Taiwan Medical Association, Taiwan Dentist Association, Taiwan Tradition Medicine Asso., Taiwan Pharmacist Asso.
   (2) Taiwan Hospital Association (one of each)
   (3) Medical Center, Regional Hospital, Community Hospital, Primary Care. (two of each)
Major Challenges

- **Capacity Building** lack of Modeler
  - Incentive provided, not many PE study yet.

- **Government topic selection for research**
  - Lack of mechanism and stable funding

- **Public or patient involvement in the decision making process**
  - Mechanism is going to be established but lack of experience

- **Did not decide the decision making rule:**
  - ICER threshold
Threshold of ICER

- USA: US $25,000 ~ US $50,000/QALY
- Canada: US $17,600 ~ US $87,800/QALY
- Australia: US $28,200 ~ US $51,000/LYG
- NICE: £20,000–30,000 ($37,104–55,655) /QALY
- WHO, 2002: <3 GDP/capita/DALY averted
- Australia PBAC: 1.26 ~ 2.29 GDP/capita/life-year gained
- England NICE: 1.4~2.1 GDP/capita/QALY

Value in Health 2004;7:518. Use of Cost-Effectiveness Analysis in Health-Care Resource Allocation Decision-Making: How are cost-effectiveness thresholds expected to emerge?