HTA implication in Patient Access & Critical Factors to make a Balance for Innovative Medicines
(10-year Experiences with HTA system in Korea)

Moderator
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Panelists
• Sae-Rak Jang, Yoon-Hee Choi, Health Insurance Review & Assessment Service (HIRA), Korea
• Sungju Kim, Head of Patient Access, Novartis, Korea
• Cammy Yuen, Asia Pacific Area Market Access and Policy Director, Abbvie, Japan
Overview of HTA

- HTA can play a key role in supporting rational decision-making about health technologies based on appropriate evidence.
- HTA has been performed in advanced health systems: Europe, Australia and North America.
- Among Asian countries HTA is already introduced in Korea, Thailand, Taiwan, and is planned in Japan, China, and Hongkong etc.

KOREA: HTA for Better Decision-Making

- In Dec. 2006, new pharmaceutical reimbursement system from Negative listing to Positive listing
  - Cost-effectiveness became a 4th hurdle besides safety, efficacy and quality
  - Submission of PE study became mandatory from 2008 to get premium price for clinically superior drug
- HTA has contributed to Shift from Opinion-based to Evidence-based Decision-Making in Korea
Drug coverage assessment on new drug (2007-2012)

<table>
<thead>
<tr>
<th>Results</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reimbursed</td>
<td>24(61.5)</td>
<td>67(74.7)</td>
<td>62(77.5)</td>
<td>46(69.7)</td>
<td>42(66.7)</td>
<td>53(76.8)</td>
<td>294(72.4)</td>
</tr>
<tr>
<td>Non-reimbursed</td>
<td>15(38.5)</td>
<td>22(25.3)</td>
<td>18(22.5)</td>
<td>20(30.3)</td>
<td>21(33.3)</td>
<td>16(23.2)</td>
<td>112(27.6)</td>
</tr>
<tr>
<td>Total</td>
<td>39(100.0)</td>
<td>89(100.0)</td>
<td>80(100.0)</td>
<td>66(100.0)</td>
<td>63(100.0)</td>
<td>69(100.0)</td>
<td>406(100.0)</td>
</tr>
</tbody>
</table>

- Anticancer: 54.2% were recommended (’07~’12)
- Reasons of rejection: total 112 cases
  - Obscure/unacceptable cost-effectiveness 57%
  - Obscure clinical usefulness 30.4%

Reimbursement decision of the PBAC (January 2007-December 2014) Unit: number of molecules, %.

<table>
<thead>
<tr>
<th>Year</th>
<th>Non-reimbursed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>60(34.3)</td>
</tr>
<tr>
<td>Other drugs</td>
<td>51.6(11.3)</td>
</tr>
<tr>
<td>Ovarial</td>
<td>7(1.02.3)</td>
</tr>
</tbody>
</table>

Source: Bae E-Y et al., Health Policy (2016)

Issues on the HTA of New Drugs

- **Evidence gap** to show clinical usefulness
  - Concerns on how to handle uncertainty of clinical usefulness
    - small population/ immature outcomes (OS)
    - patient heterogeneity between comparators
  - Increased burden of justifying value-for-money with limited data

- **Value**: mainly limited to value for money
  - Cost-effectiveness, comparative effectiveness
  - Limited to consider other values (equity, fairness etc.) explicitly

- **Decision making**: Limited Access to the new drug
  - Strong influence of the ICER (Incremental Cost-Effectiveness Ratio) on Decision
  - Controversy on the fixed threshold value for different drugs & disease
Evolution of HTA System in Korea

Policy Changes
- Higher ICER threshold (Dec, 2013)
- Risk Sharing Agreement (Jan, 2014)
- Exemption of PE, Price Negotiation (May, 2015)

More Engagement
- Wider Participation of various stakeholders (Patients, Industry, HCP, Civil group, National Assembly)
- Regulatory-Price approval Linkage System

Strengthen Infrastructure
- Better Manpower: various experts (Stat., Epi, Medical)
- Data Availability: Public use of HIRA/NHIS data
- Development of Appropriate HTA Methods

Regulatory-Price approval Linkage System
- To reduce time spent for drug access to patients
- allowed to apply pricing dossier for reimbursement (HIRA) after completing review of safety and efficacy (MFDS).
  - 2 month earlier before regulatory approval
NHIS/HIRA Claims Data for Public Use

<table>
<thead>
<tr>
<th>Type</th>
<th>Characteristics</th>
<th>Available data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HIRA</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NPS</td>
<td>All patients - 3% of all patients (approx. 1.4 million)</td>
<td>2010-2015</td>
</tr>
<tr>
<td>NIS Inpatient</td>
<td>13% of inpatients (approx. 0.7 million) - 1% of outpatients (approx. 0.4 million)</td>
<td>2009-2015</td>
</tr>
<tr>
<td>APS Elderly</td>
<td>20% of elderly patients: ≥ 65 years old (approx. 1.0 million)</td>
<td>2010-2015</td>
</tr>
<tr>
<td>PPS Paediatric</td>
<td>10% of paediatric patients &lt; 20 years old - (approx. 1.1 million)</td>
<td>2010-2015</td>
</tr>
<tr>
<td><strong>NHIS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NSC</td>
<td>population-based sample cohort - approximately 1 million</td>
<td>2002-2015</td>
</tr>
<tr>
<td>HealS</td>
<td>regular health examinees (age 40~79) - approximately 510 thousand</td>
<td>2002-2015</td>
</tr>
<tr>
<td>Senior</td>
<td>over 60 years with eligibility in 2002 - approx. 550 thousand</td>
<td>2002-2015</td>
</tr>
<tr>
<td>Working Women</td>
<td>Working women (age 15-64) - approx. 180 thousand</td>
<td>2007-2015</td>
</tr>
<tr>
<td>Infant HealS</td>
<td>5% sample of each birth year (medical check-up)</td>
<td>2008-2015</td>
</tr>
</tbody>
</table>

NHIS: Including eligibility, medical examination data

But, we are still Hungry... for **Better Balance**

- **Better Access**
  - From industry, patients, doctors...
  - Wider exceptions, flexibility for HTA
  - Value for innovation

- **Better balance for other values**
  - From government, academia
  - Financial Sustainability
  - More evidence for effectiveness: post evaluation of immature data
  - Transparency
  - Less Administrative burden
• HTA is a complex field
  ◦ that should reflect social, economic, political and cultural circumstances
  ◦ based on local evidence, values and priorities.

• We would like to share the experience of HTA in Korea and learn lessons from other countries
  ◦ Challenges and lessons in setting up and operating an HTA system
  ◦ Evidence, Value, Decision-making process

Overview of Panel Presentation

• Sae-Rak Jang, Yoonhee Choi (15 mins.)
  ◦ Introduction to Drug Listing System in Korea
  ◦ PLS, RSA, Exemption of PE and negotiation

• Sungju Kim (15 mins.)
  ◦ Analysis of new drug reimbursement decision in South Korea: over a decade of experience
  ◦ Proposals to improve HTA from Industry Perspective

• Cammy Yuen (15 mins.)
  ◦ HTA and access from the regional perspective
  ◦ Policy evolution in other countries for better patient access

• Discussion & ‘Q&A’ session with floor (5 mins.)