# HTA implication in Patient Access & Critical Factors to make a Balance for Innovative Medicines

## (10-year Experiences with HTA system in Korea)

**ISSUE PANEL 6**
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**10:30 ~ 11:30 AM**

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### *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)

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

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

*Mi-Young You, HIRA,*
***Panel Session***

HTAi SEOUL 2013

Reimbursement decisions of the PBCAC (January 2007–December 2014) Unit: number of molecules, %

| Year | Acceptance rate (ICC's [RIC's]) |
|---|---|
| Total | 69.2 (65.5) |
| Oncology drugs[a] | 51.6 (51.5) |
| Others[b] | 71.6 (67.5) |

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

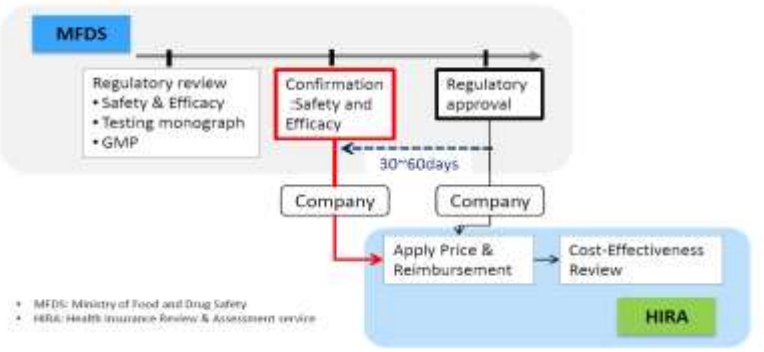
# Evolution of HTA System in Korea

| | |
|---|---|
| Policy Changes | • Higher ICER threshold (Dec, 2013)<br>• Risk Sharing Agreement (Jan, 2014)<br>• Exemption of PE, Price Negotiation (May, 2015) |
| More Engagement | • Wider Participation of various stakeholders (Patients, Industry, HCP, Civil group, National Assembly)<br>• Regulatory-Price approval Linkage System |
| Strengthen Infrastructure | • Better Manpower: various experts (Stat., Epi, Medical)<br>• Data Availability: Public use of HIRA/NHIS data<br>• 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 Pubic Use

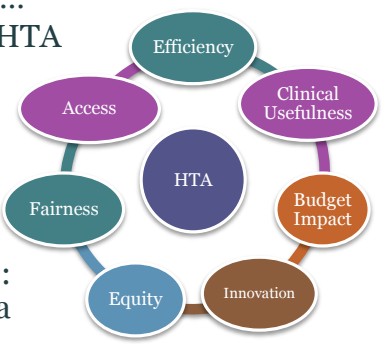
| | Type | Characteristics | Available data |
|---|---|---|---|
| HIRA | NPS | - All patients<br>- 3% of all patients (approx. 1.4 million) | 2010-2015 |
| | NIS<br>Inpatient | - 13% of inpatients (approx. 0.7 million)<br>- 1% of outpatients (approx. 0.4 million) | 2009-2015 |
| | APS<br>Elderly | -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

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.)**