

The HTA experience in Korea

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Background

South Korea



- **Republic of Korea**
- **Population:**
 - 48.46 million (2007)
 - Economically active pop. 24.2million (2007)
 - Rate of Increase : 0.33% (2007)
 - Pop 65years : 9.9% (2007)
- **Life Expectancy:**
 - Males 75.7 years, females 82.4 years (2006)
- **National Health Expenditure:**
 - 6.4% of GDP (2006)
 - 1,480 US\$ PPP (per capita)
- **Pharmaceutical Industry:**
 - 1.4% of GDP

Korean Health Security System

- Two components:
 - National Health Insurance (96.4% of pop.)
 - Achieving universal health coverage in 1989, only 12 years after the introduction of NHI in 1977
 - Funded by beneficiaries contribution
 - Medical Assistance (3.6% of pop.)
 - Provides support to lower income groups
 - Funded by the government

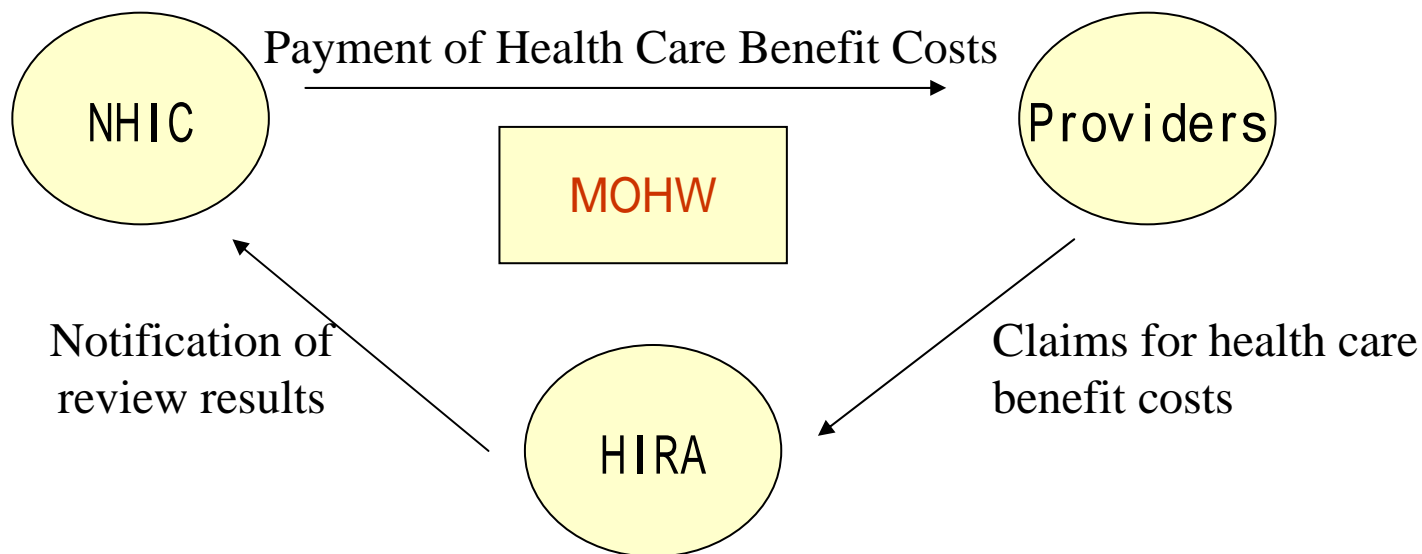
Brief History

- In 1977, all companies with more than 500 employees are required to provide health insurance.
- In 1989, all citizens are covered by universal health insurance.
- In 1997, The National Health Insurance Corporation(NHIC) was created, integrating all insurers.
- In July 2000,
 - All health insurance management systems were integrated.
 - The Health Insurance Review Agency(HIRA) was established as an independent agency.

HIRA

- Established: July 1, 2000
- Headquarters & 7 branch offices nationwide
- Staff (total: 1,749)
 - Management(including the president) 107
 - Administration 418
 - Review staff 1004
 - IT specialist 150
 - Researchers 53
 - Others 17

HIRA in Health Care System



● Major activities

- Conduct medical fee review
- Assess the appropriateness of medical care
- Develop review standards
- Conduct research on review and assessment methodologies
- Health technology assessment

HTA system in Korea

HTA in Korea

- Different HTA process for different technology
- Medical procedures should be reviewed for safety and effectiveness by the HTA committee to be listed on the schedule (Medical Act)
- If medical products are related to a new procedure, they should also be reviewed by the HTA committee
- Expert committee within HIRA reviews the efficiency of medical procedures and medical products
- KFDA reviews the safety and efficacy of pharmaceuticals, and PBEC reviews effectiveness and efficiency

Responsible organization for HTA

	safety	Efficacy (effectiveness)	Efficiency
Medical procedures	HTA committee		HIRA
Medical devices & products	KFDA	KFDA/HTA committee	
Drugs		KFDA/HIRA	

HTA committee

- Created as part of HIRA according to the ‘Medical Act’ and ‘National Health Insurance Rules on Healthcare Benefit Standards’ (2007),
- HTA committee has 20 members
 - Specialized sub-committees (internal medicine, surgery, oriental medicine, dental care) advise the committee.
 - Has a mandate to review the evidence and make a recommendation for Minister
- A new independent HTA agency is scheduled to be established in 2009.

HTA process for new health tech. (excluding drug)

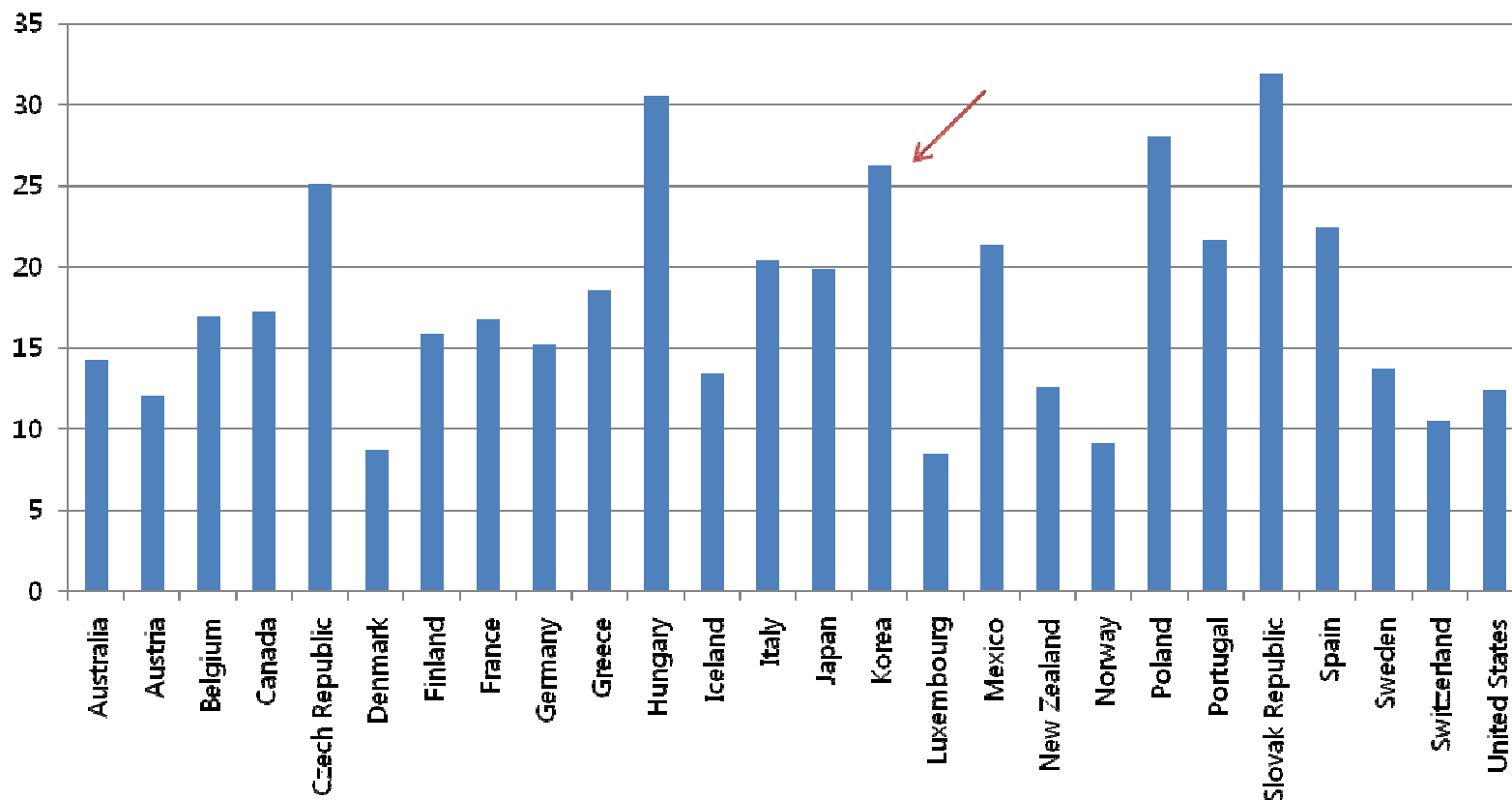
- Submission
- Practical review by HIRA staff
- Evaluation by The HTA committee
- Reporting of evaluation results to MOHW
- Review by The Health Insurance Policy Deliberation Committee
- Notification

Economic Evaluation of Pharmaceuticals

Context

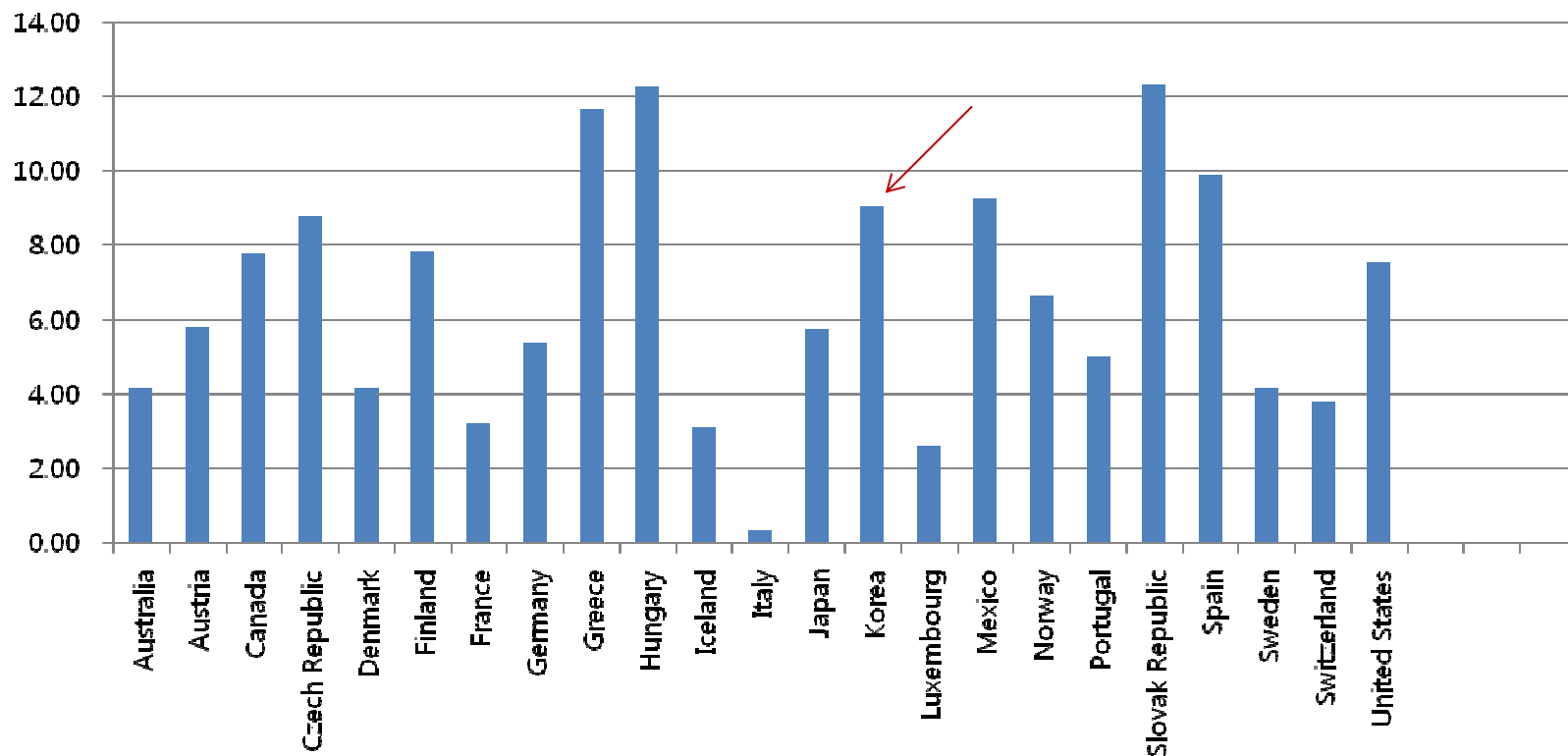
- Rapidly increasing drug exp.
 - Annual growth rate, higher than 9%
 - Among the highest of OECD countries
 - Structural change to high priced drug explains more than 50% of increase
- Inefficient listing system
 - Critique the current negative system, where high priced new drugs with marginal benefits can be listed
- Growing concern about the “value for money”

Pharmaceutical expenditure, % of total expenditure on health (2005)



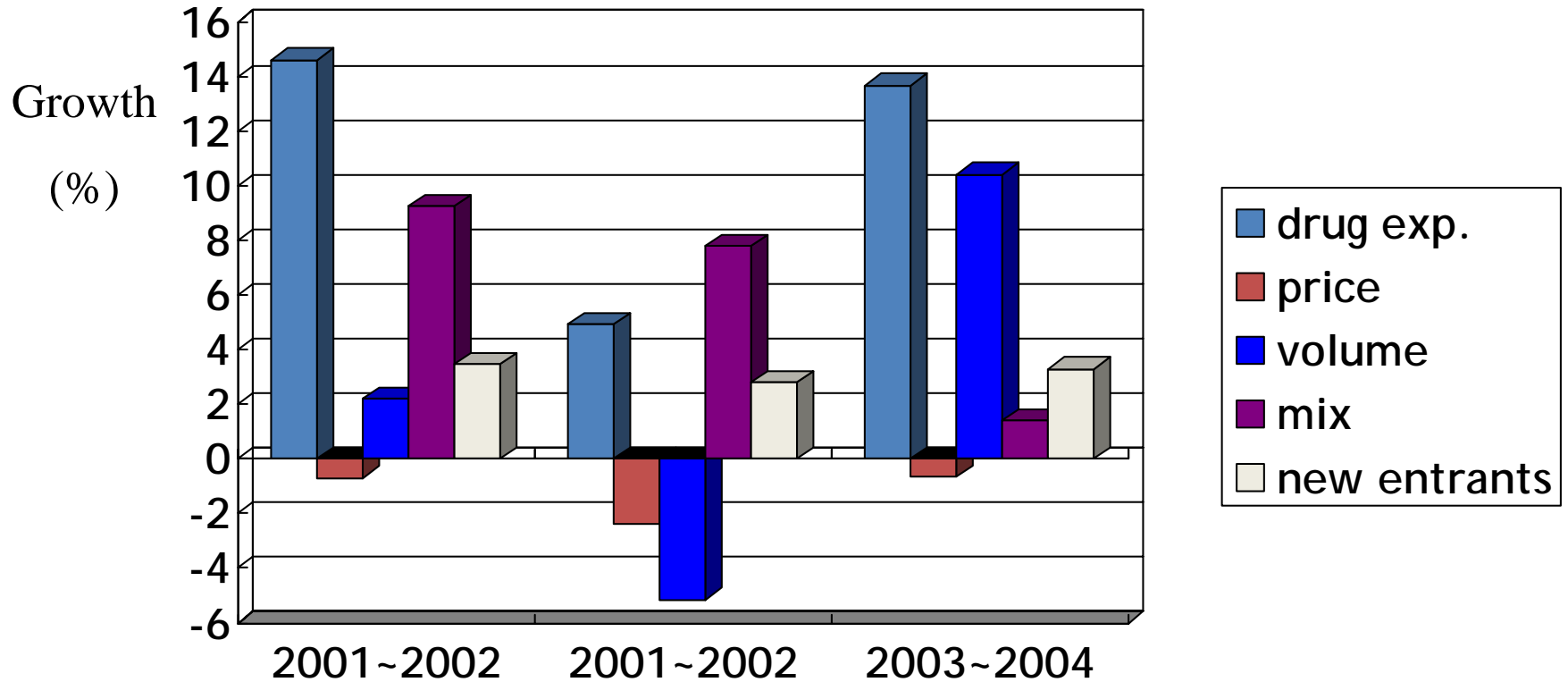
Source: OECD Health Data 2007

Annual growth in pharmaceutical expenditure per capita, 2001-2005



Source: OECD Health Data 2007

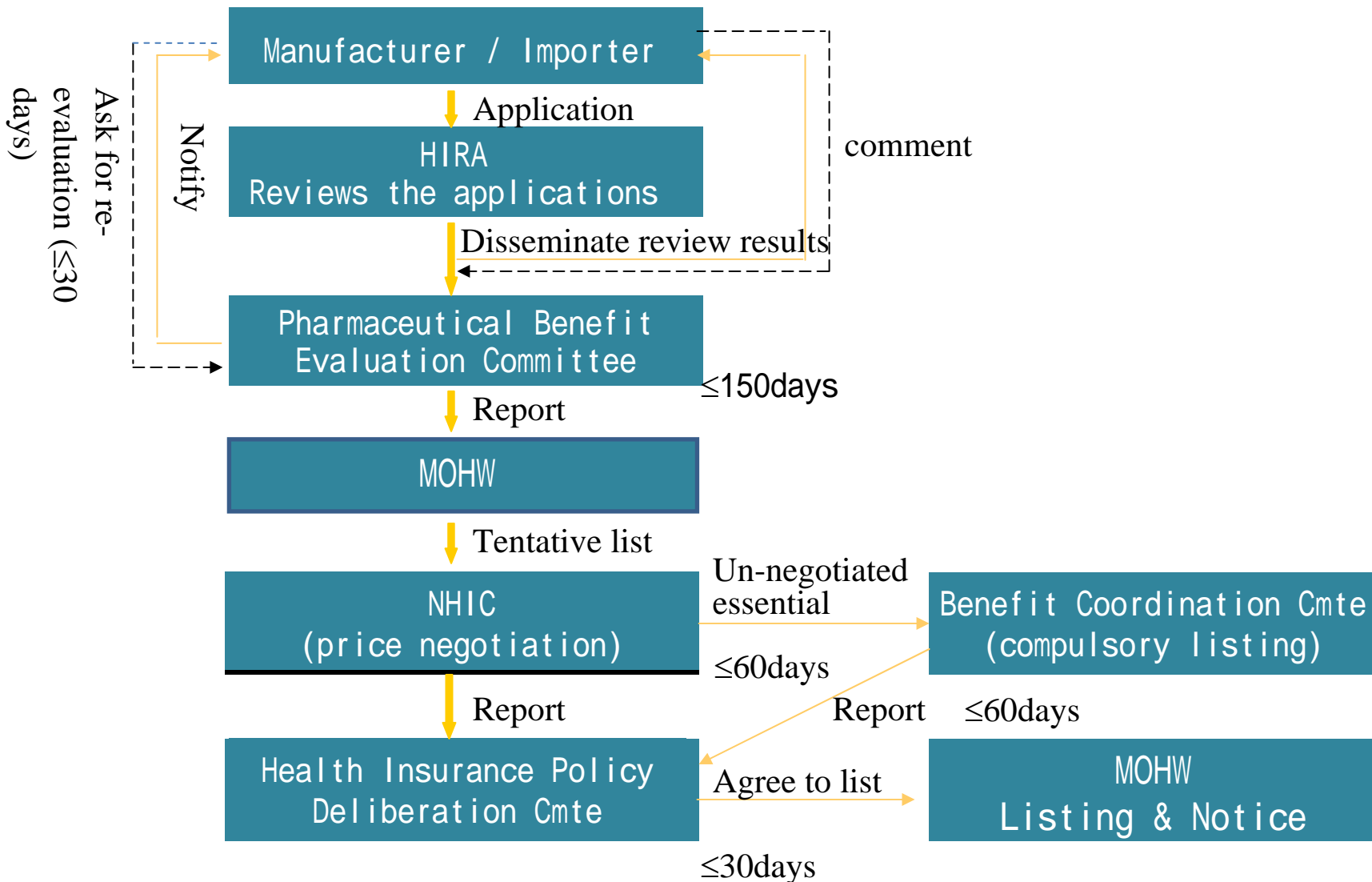
Contributing factors for drug exp. growth



Change to Positive list

- Before 2006, all drugs that received market approval were automatically listed with some exceptions
- After 2007, Only clinically and economically valuable drugs can be listed (following “Drug Expenditure Rationalization Plan” announced in May 2006)
 - PE data is necessary for listing (mandatory requirement from 2008)
- Re-evaluate “listed” drugs(2007-2012)
 - 5 year plan(2007-2012)
 - HIRA is currently doing pilot project(2007~)

Process of new drug listing



Submissions that require PE data

- New drugs (New active substances)
- Drugs with new route of administration
- Drugs with new indication
- Exempted from submission of PE data
 - Similar but not inferior, and less expensive than existing drugs
 - Orphan drugs used for rare disease

PE guidelines

- All submissions with PE data have to abide by PE guidelines published in 2006.
- Current guidelines were developed by HIRA to reflect local conditions for PE
 - Data availability
 - Knowledge and experience in the area
 - Nation-specific conditions
- Published guidelines will be revised periodically

Contents of Guidelines

- Societal perspective
- CEA/CUA are preferred
- Report the results as ICER
- Describe the evaluation process in enough detail to be replicated
- Comparator: most prevalent one
- Use less biased data sources/ head-to-head trials are preferred
- All the details of data search and selection process should be presented

Contents of Guidelines (cont)

- Identify all the relevant cost items (productivity cost: present separately)
- Final intended outcome is recommended
- Use QALYs for CUA
- 5% discount rate (Do SA for 0, 3, 7.5%)
- For all the assumptions and other sources of uncertainty underlying PE analysis, Do SA
- Use domestic data at least for price and utilization
- Address equity related implications
- Do the budget impact analysis

Review

- For transparent, fair, and quality review
 - HIRA formulated the whole process of consideration and published it on their website
 - Developed templates: submission format, template for reviewers
 - Permit manufacturers to appeal their position
 - Hearing from manufacturers
 - Re-evaluation
 - Implemented conflict of interest guidelines

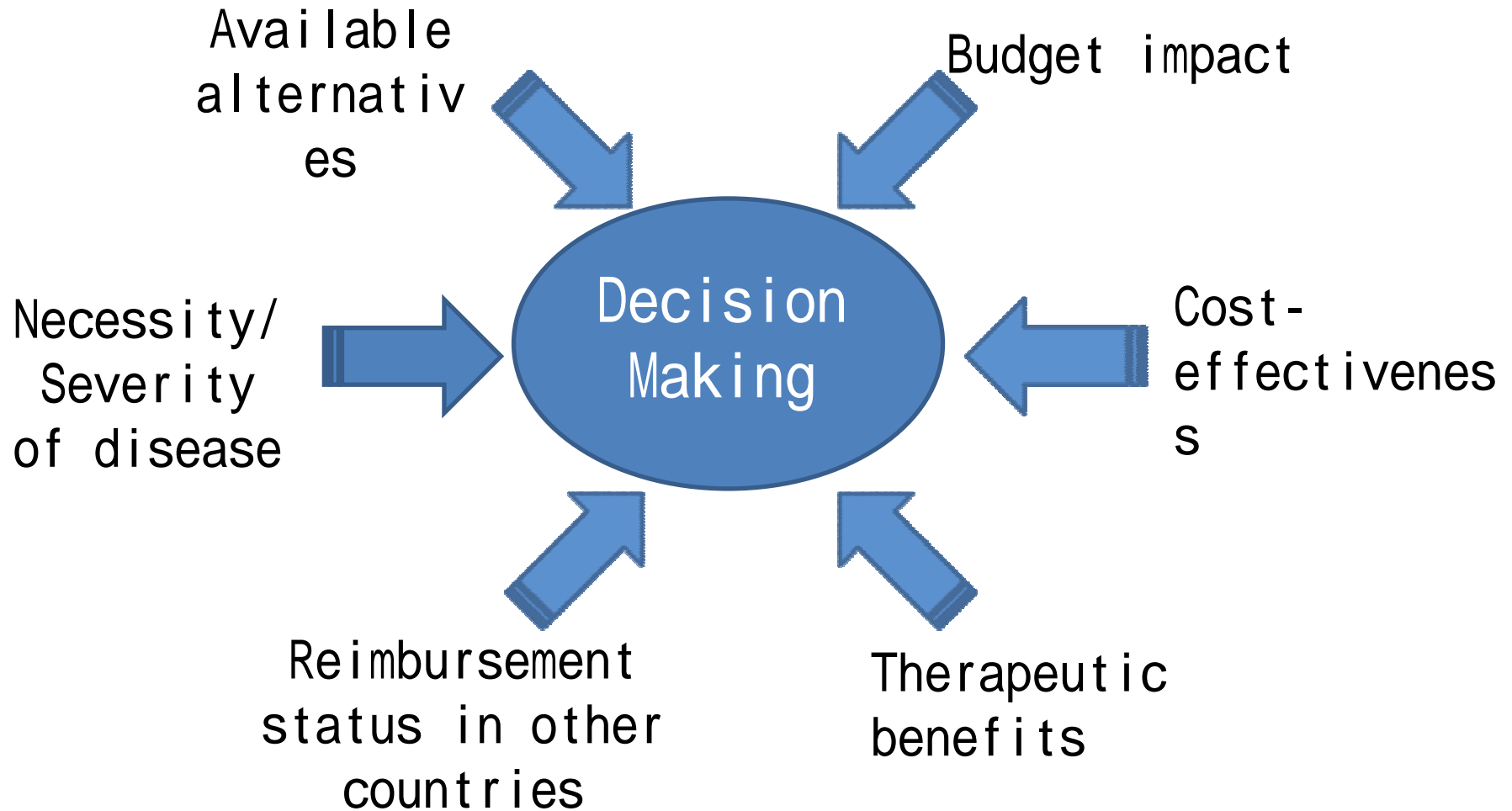
Reviewer

- HIRA reviews submissions in-house
- The qualification of reviewers
 - Most (internal) reviewers are pharmacists
- Health economists in the research dept. consult internal reviewers
- In addition to PE guidelines, HIRA prepares checklists for reviewers
 - To minimize variations between reviewers
 - To enhance the transparency of the system.

Deliberation by committee

- Pharmaceutical Benefit Evaluation Committee was newly established in 2007
- PBEC is an independent committee, and has a mandate to review the submission and make recommendations on listing
- PBEC is composed of 18 members who have specialties in the following areas, and staff from the KFDA and HIRA
 - Internal medicine / Surgery / Pediatrics / Pharmacology / Epidemiology / PE / clinical pharmacy

Factors considered in deliberation



Rule of rescue

- The following drugs are considered “necessary drugs for treatment”
 - When there are no alternative treatment
 - When there are no alternative drugs, and indication is for severe life-threatening diseases
 - Used for rare diseases, and is considered necessary to treat those patients
 - Drugs recognized by the committee as drugs necessary to patient treatments
- If price negotiation fails for the above drugs, the benefit coordination committee can determine the price (compulsory listing)

Hearing from manufacturers

- The chair can permit manufacturers to explain their products in front of committee members if it helps committee members consider the value of the submitted drug
 - A measure taken to enhance transparency
- Other experts who are not committee members can also be invited to the meeting at the discretion of the chair

Conflict of Interest

- Committee members should disclose any conflicts of interest to the committee chair and HIRA in advance.
- Committee members are not expected to attend meetings where submissions in which they have a conflict of interest are considered.

Request for re-evaluation

- When their drugs are rejected, manufacturers can request “re-evaluation” based on new evidence which supports the clinical or economical value of their submitted drugs
- After reviewing the newly submitted evidence (including price change), the committee decides whether to uphold its original recommendation

Challenges

Policy/Implementation Gap

- Policy making lead the change and facilitated the development of this area
- There is still a gap between “should do” and “can do”
- Effort to close the gap

Challenges

- Human resource
- Lack of local data
- Decision making related issues
- Threshold
- Controversy between HIRA and sponsors over the selection of comparator, or other methodological issues

Human resource

- The most important barrier
- Experts who can do PE analysis: only a few experts have an experience in PE analysis.
- Reviewers: lack of experience, Limited time line, and shortage of reviewers
- Decision makers: 3 of 18 committee members have expertise in PE. To make a decision in balanced way, other members also need to be well acquainted with PE, its meaning, scope, limit...

Lack of local data

- Guidelines permit the use of international data to acquire the clinical efficacy and disease progression related estimates
- Require local data only on: price, medical utilization
- There are cases where the incidence, or prevalence of disease is different from other countries (especially western countries), and it influences the absolute benefit of the drug
- Genetic differences, and differences in medical practice also influence the clinical benefit
- Lack of quality local clinical data, and quality local epidemiological data

Decision making related issues

- How to consider different aspects of benefit, and relate it to the cost
 - Consistency of decision making is critical because there is no fixed decision rule
- How to reflect the concerns of stakeholders
- How to reflect social values

CE Threshold

- There is no explicit CE threshold
 - Because CE is only one of several factors that is considered in reimbursement decision
 - Other factors: availability of therapeutic alternatives, disease severity, budget impact, price and reimbursement status in other countries, etc
- Companies complaint that there is a lack of transparency in decision making
- GDP per capita is being considered
 - CE threshold should consider overall budget constraints

Choice of Comparator

- There is a conflict over the selection of comparable drugs
 - One main complaint from companies
 - Related to the transparency issue.
- No clear-cut criteria in selection
 - Drugs with same mechanism?
 - Old drug vs. new drug
 - Active comparator vs. placebo
- HIRA is considering the introduction of a ‘prior consultation’ program not linked to the committee’s decision

Future

Future

- Guidelines need to be revised
 - To reflect the issues related to methodology
 - To reflect expansion of research experience and development of methodology in the area
 - More prescriptive guidelines are needed
- Invest in education
 - For Industry: how to support capacity increase in local companies
 - For reviewers
 - For decision makers

Future (cont'd)

- Invest in the increase of local evidence
 - Epidemiological data
 - Clinical research
- Networking?
 - Sharing of information between relevant agency
- More effort to produce evidence in the public domain

Thank you!!