



Re-evaluation of existing drugs in South Korea

Eun Young Bae

Department of Health Policy and Management
Sangji University

eybae@sangji.ac.kr, June 2009

Contents

- Background
- Drug expenditure rationalization plan
- Re-evaluation of listed drugs
 - Pilot project
 - Review procedure
 - decision
- Issues
- challenges

Background

- South Korea
 - Located in North-East Asia
 - Population 48.60 million (2008)
 - % of senior pop. 10.3%(2008)
 - Health security system
 - National Health Insurance : 96.3% of p
 - Medical Assistance : 3.7% of pop.
 - National health expenditure
 - 6.4% of GDP in 2006
 - 1,480 US\$ PPP (per capita)
 - Life expectancy
 - Males 76.1 years, females 82.7years (2007)



Drug expenditure in Korea

- High spending on pharmaceutical products
 - 26% of total health expenditure (2006)
 - Growth rate, above 9%/yr
 - Highest among OECD countries
- Factors leading to increasing drug exp.
 - Inefficient listing system
 - Prescribing behavior
- Introduction of cost-containment policies after 2001
- Despite many attempts to curtail it, drug expenditure continue to rise

Drug expenditure rationalization plan

- The government announced the drug expenditure rationalization plan (DERP) in May 2006,
- The key contents of the DERP
 - Improve the quality of pharmaceutical products
 - Improve transparency of the drug distribution system
 - Change the listing system from negative to positive one
 - Introduce the price negotiation procedure in NHI
 - Secure the quality and cost-effectiveness of drug use

Source: Ministry of Health and Welfare, 2006.

The Positive list system (PLS)

- The PLS was introduced in 2007,
 - Under the PLS, only clinically and economically valuable drugs will be listed
 - New drugs to be priced higher than existing drugs are required to submit PE data
 - submission of PE data was voluntary in 2007, but became mandatory from 2008
- The government announced the re-evaluation of existing drugs over a 5 year period (2007-2011)

Source: Ministry of Health and Welfare, 2006.

Re-evaluation of listed drugs

- Drugs that are not considered to be cost-effective will be eliminated from the list
- The Health Insurance Review and Assessment service (HIRA) is tasked with reviewing the existing drugs
 - HIRA is also responsible for reviewing the new drugs
- Rationale for re-evaluation
 - Too many drugs are listed on the national formulary (around 20,000), which negatively influences the efficiency of the system
 - The principle of listing should be impartially applied to both old and new drugs.
 - If the comparator is not cost-effective, the value of new drugs will also not be appropriately evaluated

Grouping the drugs and priority setting

Classification of therapeutic groups

- Substitutable drugs for a certain disease are grouped together
- Referred to WHO ATC code/ LFN(TLV)'s classification
- Consulted external experts

In 2006

Prioritize the therapeutic groups

- Considered the sales amount, and
 - current knowledge of evidence for safety and effectiveness
 - difficulties of implementation
- Consulted the external experts/ stakeholders

In 2006

Announced re-evaluation schedule

- 5 year time schedule for re-evaluation
- Pilot project for 2 groups

Apr
2007

Pilot project

- The aim of the pilot project was to identify, in advance, the issues uncovered during the evaluation
- Two groups among the 49, were chosen as pilot groups
 - Lipid modifying agents (ATC code C10)
 - Antimigraine preparations(ATC code N02C)
- HIRA chose two groups after reviewing current HTA knowledge, and consultation with external experts
 - Two groups were judged to be appropriate in terms of sales size, complexity of evaluation, and acceptability of decision

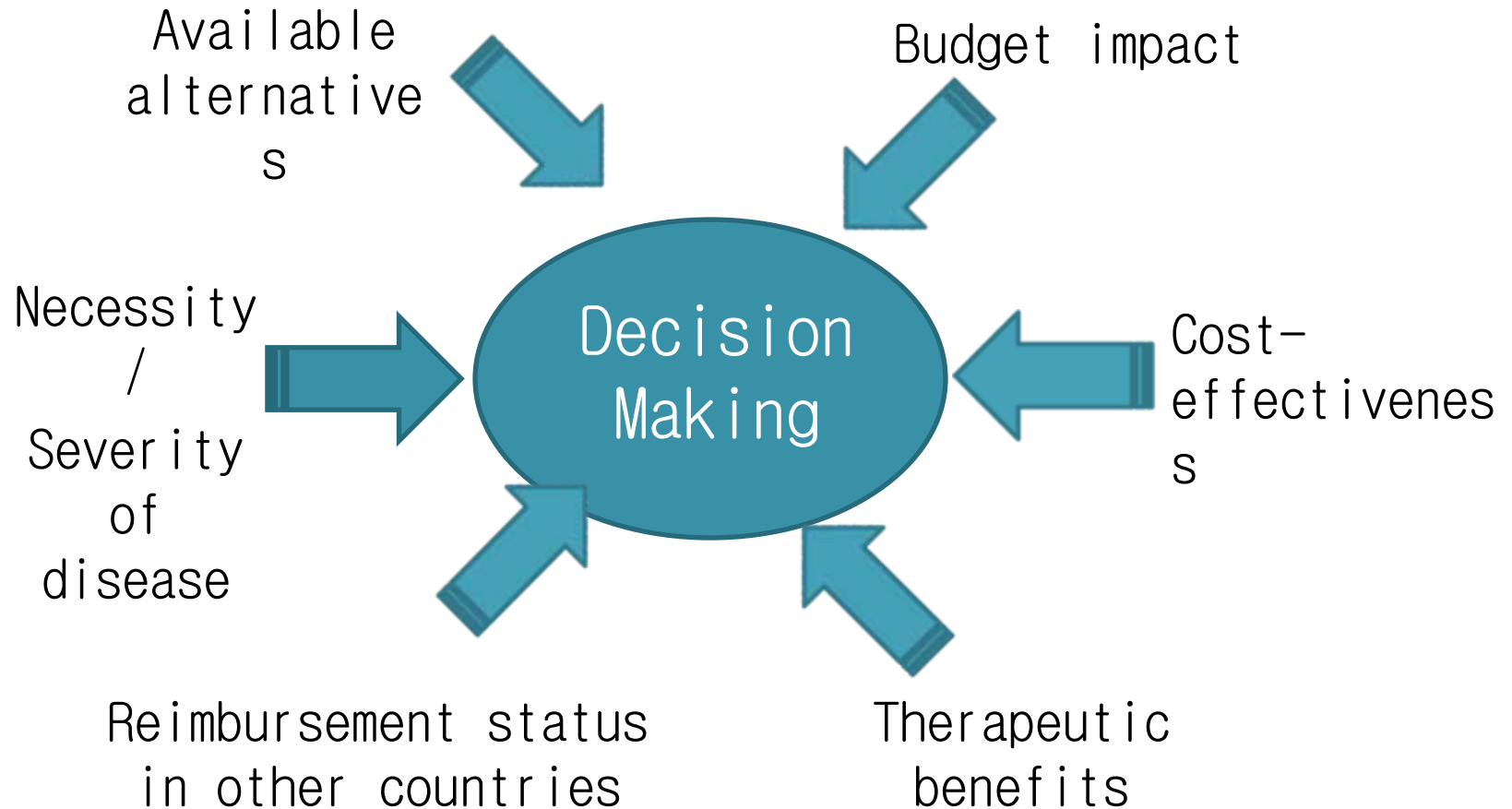
Review procedure

- Announce the products and time schedule for re-evaluation
- Request that companies submit data on effectiveness and cost-effectiveness of their listed drugs
- Screening phase
 - Opinions of medical societies
 - Textbooks/ Guidelines/ existing review literatures
 - Daily cost/ Market share/ Foreign price
 - WHO essential drugs list
 - After the screening phase, a few drugs were de-listed due to uncertain clinical effectiveness

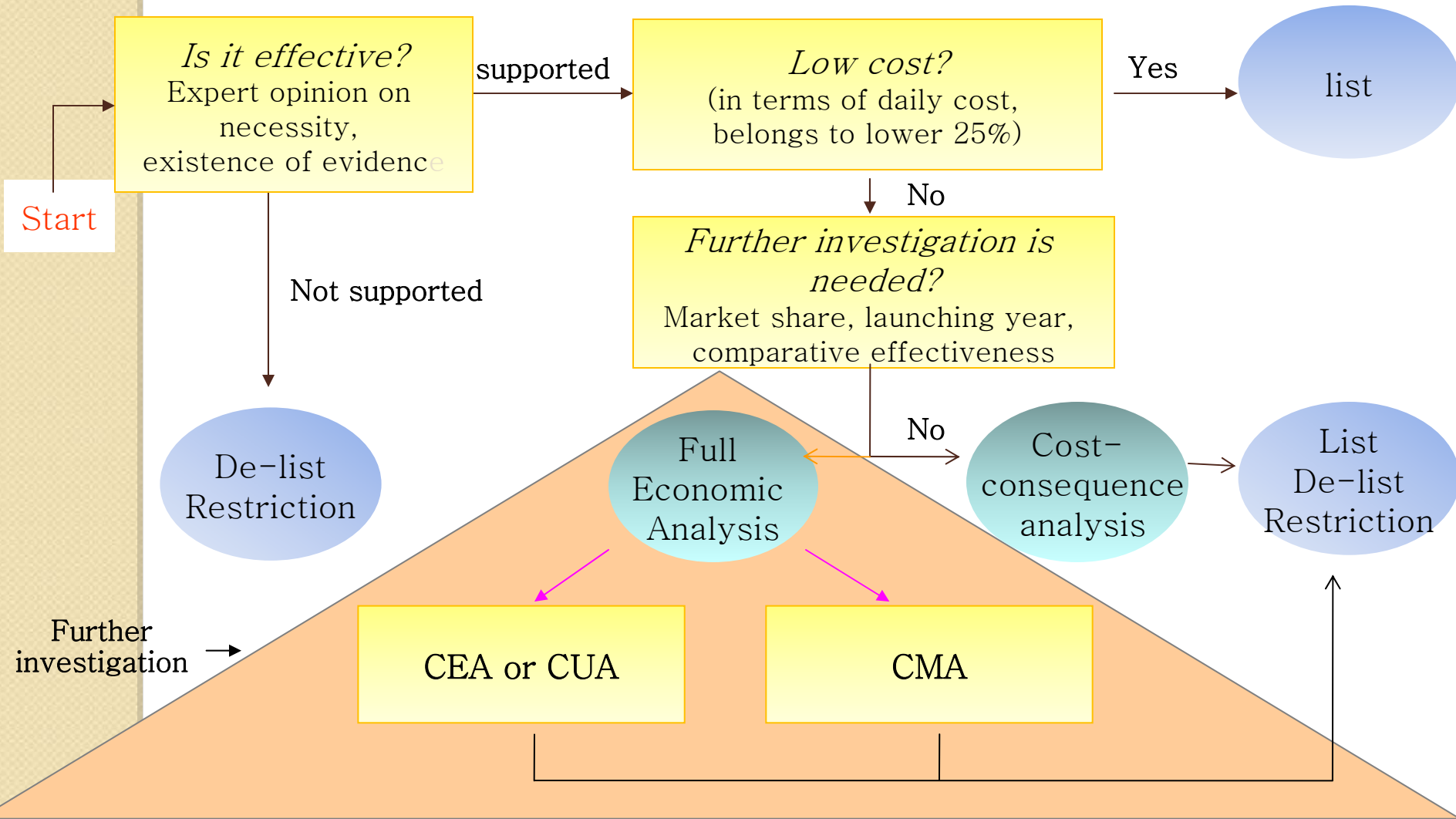
Review procedure

- Full assessment phase
 - More comprehensive investigation of the effectiveness and cost-effectiveness of drugs that passed screening phase
 - For pilot groups, following drugs were chosen for full economic analysis:
 - Statins (hyperlipidaemia)
 - Triptans (migraine)
- Comprehensive appraisal phase
 - Decision making by drug reimbursement evaluation committee (DREC)
 - Dominated drugs were identified and recommended for de-listing or price decrease

Factors considered in deliberation



Decision scheme



Source: Health Assessment and Review Service, 2008.

Appeal

- within 30 days of the official notification of the evaluation result
 - In case of lipid modifying agents, companies had 60days
- Companies have opportunities to submit their opinions on the review result before the final decision

Advisory group

- HIRA created an advisory group for the pilot project('07.8)
 - Members of medical societies for neurology, cardiology, pharmacology, health economist, statistician, etc. (20 experts)
- All methodological issues were discussed in the advisory group meeting
- HIRA held several open workshop
 - To explain the evaluation method, procedure and outcome indicator
 - To explain the evaluation result, and get comments from stakeholders
 - Until the final decision is made, 5 workshops have been held

Decision

- Lipid lowering agent
 - 21 ingredients(321 products) were reviewed
 - 8 remained on the list
 - 3 were de-listed because of insufficient evidence
 - One was listed with restrictions
 - 9 lowered their prices
- Antimigraine preparations
 - 11 ingredients were reviewed
 - 8 remained on the list
 - One was listed with restrictions
 - 2 lowered their prices

Source: Health Assessment and Review Service, 2009.

Issues (1)

- **Comprehensiveness of evaluation**
 - Each drug has a different safety profile, so it is too restrictive to only compare the main outcome indicators
- **Surrogate vs. final intended outcome**
 - If some drugs have not verified their value in terms of mortality and morbidity, should those drugs be de-listed?
 - If the regulatory agency did not require final outcome for approval, should HIRA not decide the relative effectiveness based on final outcome indicator?

Issues (2)

- How to consider uncertainty in the decision
 - Uncertainty of clinical effectiveness and cost-effectiveness
 - Insufficient evidence
- How to consider the population's need
- Price adjustment vs. reimbursement decision
 - If a certain drug are evaluated to be “not cost-effective”, that drug should be de-listed, but by suggesting an acceptable price range, HIRA overstepped its boundaries



Issues (3)

- Separation of assessment and appraisal process
 - Assessment and appraisal process are not clearly separated, which provided room for endless disputes on assessment results.
- Lack of manpower
- Impractical time schedule

Challenges

- Political challenges to de-listing of existing drugs
 - *Among currently listed drugs, which is not valuable?* -Same question with regards to new drugs, but much more vulnerable one!
 - It is critical to procure procedural legitimacy and to get medical societies' support
- How to incorporate social values in decision making
- Balance between treatment choice and efficiency
 - How many drugs are enough to meet the population's need without loss of efficiency

Risk of wrong decision

		Truth	
		A is dominated	A is not dominated
Decision	De-list A		Wrong decision
	Continue to list A	Wrong decision	

Who should bear the risk of a wrong decision?



Thank you for your attention!!