Pricing and Reimbursement of Generic Medicines in Korea

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Eun Joo Hwang

Health Insurance Review & Assessment Service
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- National Health Insurance system

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I. Introduction
Overview of Korea

- Population: 50 million (26th in the world)
- Per capita GDP: $29,836 ppp (25th)
- Pop. Over 65: 11.0%
- Per capita NHE: $2,023
- NHE in GDP: 6.9%

(As of 2010)
Pharmaceuticals Market by sub-sector (US$bn) 2011

- 50% (7,427) Patented drugs
- 32% (4,706) Generic drugs
- 18% (2,616) OTC medicines

Pharmaceuticals Market in Korea (I)

Pharmaceuticals Market Forecast 2007-2021

Source: Korea Pharmaceutical Manufacturers Association (KPMA), BMI
Particular tendency of market

The trend is driven by the government’s desire to develop the country’s biotechnology industry and domestic companies’ strategy of shifting their portfolio away from an over-reliance on generic medicines.
Healthcare Infrastructure

Healthcare Organizations: Total: 82,948
- Clinics: 27,837
- Pharmacy stores: 21,079
- Dental clinics: 15,058
- Clinics of oriental medicine: 12,585
- Small hospital: 9,888
- Long-term care hospitals: 4,444
- General hospital: 1,375
- Dental hospital: 988
- Tertiary hospital: 275

Health manpower:
- Physician: 84,544
- Pharmacist: 16,826
- Dentist: 11,877
- Doctor of oriental medicines: 3,364
- Nurse: 2,141

(As of 2011)
Korean National Health Insurance System: outline

- **Population Coverage**
  - 97% of the total population (48.6 million people)
    - Medical Aid Scheme for the low income (3% of the total population)

- **Benefit Amount**
  - 39.4 trillion won ($32 billion)
    - Medical Aid: 4.8 trillion won ($4 billion)

- **Benefit Coverage**
  - 80% or more covered for inpatients
  - 50~70% covered for outpatients

- **Payment Method**
  - Fee-for-Service / DRG (7 Diseases)

**Achievements**
- Universal coverage within 12 years
- The 5th rank of Healthcare Achievements (OECD)

*note* as of December 2009
National Health Insurance Program

**Structure**

- Hospitals: 2,688
- Clinics: 55,698
- Pharmacies: 21,079
- Others: 3,508

**Health Insurance Expense** ('11. 36.1 trillion won)

**General Supervision, Laws**

**Providers**

- Health Insurance Expense
- Claims review, Quality assessment
- Payment ('11. 34.6 trillion won)

**HIRA**

- Claims ('11. 1.25 billion cases)
- Result of claims review

**NHIC**

**The insured**

- Healthcare services
- Contributions

'11. 49.3 million persons (people) (97% of total population)
HIRA’s Function

Mission: ensuring the **quality** and **cost effectiveness**

### Appropriateness of healthcare benefits
- Evidence-based decision for coverage restriction
- Fee schedule & price setup

### Healthcare fee claim monitoring
- Medical Fee Review
- On-site Investigation

### Healthcare quality improvement
- Quality Assessment (overuse, under use, misuse)

### Patient right to know
- Verification of Healthcare Benefit Coverage
- Healthcare Information to Patients

### Development of HIRA Partnership
- Healthcare Providers
- Consumer Groups
- Industry
- Academia

※ Health Technology Assessment (HTA) : New Drug, Medical procedures and medical materials
Organization of Pharmaceutical Benefit Dept.

Pharmaceutical Listing Div.
- listing new drugs and performing economic evaluation of drugs

Pharmaceutical Benefit guideline Div.
- determining of drug benefit standards and safety

Pharmaceutical Appraisal Div.
- listing generic medicines
- managing the existing listed drugs, drug shortage prevention program
- Drug Utilization Review

Pharmaceutical Benefit planning Div.
- implementing actual transaction price investigations and receiving details of drug purchases by healthcare institutions
II. Current practice on Drugs
<table>
<thead>
<tr>
<th>Year</th>
<th>Event Description</th>
</tr>
</thead>
</table>
| 1977.7 | Setting drug pricing standard  
- listing through price registration by manufacturer  
- pricing: **listed price** in the benefit schedule |
| 1999.11 | Introduction of **actual purchasing price reimbursement system**  
- pricing: reimburse the actual purchasing price under the upper limit of the listed price |
| 2000.7 | Introduction of **“Negative list system”**  
- listing all licensed drugs |
| 2006.12 | Introduction of **“Positive list system”** |
| 2012.1 | Drug-pricing policy reform  
- identical price for equivalent medicines; max. price is reduced to 70% for the first year after the first generic medicine is registered after patent expiry. Further reduced by **53.55%** thereafter. |
Introduction of Positive List System ’06

- The concerns of cost containment and the efficient use of limited resources
  - 2001-2005, 173% increase in pharmaceutical expenditure
    - 14.6% annual growth in pharmaceutical expenditure

<table>
<thead>
<tr>
<th>Year</th>
<th>’06.1.1</th>
<th>’07.1.1</th>
<th>’08.1.1</th>
<th>’09.1.1</th>
<th>’10.1.1</th>
<th>’11.1.1</th>
<th>’12.1.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of listed drug(s)</td>
<td>21,740</td>
<td>20,775</td>
<td>15,223</td>
<td>14,900</td>
<td>14,883</td>
<td>14,410</td>
<td>13,814</td>
</tr>
</tbody>
</table>

Positive List (29.Dec, 2006)

Total pharmaceutical expenditure (Trillion, KRW)

% of total health expenditure (%)

* KRW: South Korean Won
Positive List System (I)

- Selection of drugs effective in both therapeutic and economic aspects for health insurance benefit coverage

- Separation of reimbursement and price decision (new drug)
  - Reimbursement assessment: HIRA
  - Price negotiation: NHIC and the manufacturer

- Volunteer application for new drug listing
  - Able to list “essential drugs” by the authority of Minister of Health & Welfare when needed

- Review of the reimbursement status of listed drugs
  - Exclusion of the drugs not produced nor claimed for 2 years
  - Re-evaluation of listing status and the price
### Positive List System (II)

<table>
<thead>
<tr>
<th>System</th>
<th>Before 2007</th>
<th>After 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reimbursement system</td>
<td>● Negative list</td>
<td>● Positive list</td>
</tr>
<tr>
<td></td>
<td>▪ listing almost all drugs (unless the drug listed as “not to reimburse”)</td>
<td>▪ only listing drugs that are clinically and economically valuable</td>
</tr>
<tr>
<td>Approving reimbursement</td>
<td>● Advisory committee of MOHW</td>
<td>● Advisory committee of HIRA</td>
</tr>
<tr>
<td></td>
<td>▪ Composed of stakeholders</td>
<td>▪ Composed of experts</td>
</tr>
<tr>
<td>Pricing</td>
<td>● Advisory committee of MOHW</td>
<td>● Negotiated between NHIC &amp; manufacturer</td>
</tr>
<tr>
<td></td>
<td>▪ International price ratio comparisons with existing therapeutic alternatives</td>
<td>▪ Amount of total replaceable drugs expenses</td>
</tr>
<tr>
<td></td>
<td>▪ Premiums for innovation</td>
<td>▪ Reimbursement price of OECD member countries, etc.</td>
</tr>
<tr>
<td>Revisions of Reimbursement status and Price</td>
<td>● Review the reimbursement status of listed drugs</td>
<td>● price-volume agreements</td>
</tr>
<tr>
<td></td>
<td>● off-patent drugs</td>
<td>● off-patent drugs</td>
</tr>
</tbody>
</table>
Achievements

- **Re-evaluation of listed drugs**

  ✓ Excluding the drugs not produced nor claimed for 2 years

<table>
<thead>
<tr>
<th>Number of Listed Drugs</th>
<th>Negative list System (Jan. 2007)</th>
<th>Positive list System (Jan, 2012)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>20,775</td>
<td>13,814</td>
</tr>
</tbody>
</table>

✓ Review the reimbursement status of listed drugs.

<table>
<thead>
<tr>
<th>Year</th>
<th>08.7</th>
<th>09.8</th>
<th>11.1</th>
<th>11.7</th>
<th>12.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic groups</td>
<td>Migraine</td>
<td>Hyperlipidemia</td>
<td>High blood pressure</td>
<td>Circulatory and 4 therapy groups</td>
<td>Diabetes and 40 therapy groups</td>
</tr>
<tr>
<td>Subjects (drugs)</td>
<td>57</td>
<td>321</td>
<td>732</td>
<td>2,932</td>
<td>9,765</td>
</tr>
<tr>
<td>Price reduction(drugs)</td>
<td>2</td>
<td>126</td>
<td>264</td>
<td>759</td>
<td>2,661</td>
</tr>
<tr>
<td>Delist</td>
<td>0</td>
<td>7</td>
<td>2</td>
<td>216</td>
<td>334</td>
</tr>
</tbody>
</table>
Drug-Pricing Policy Reform ’11

Government Release

“Reform of drug pricing and advancement of the pharmaceutical industry”
- announced in 12 Aug. 2011

Objective
- Reasonable drug expenditure management
- Encouraging development of the pharmaceutical industry

Expected Outcome
- Drug expenditure of health insurance benefit: 29.3% (’10) → 24% (’13)
- Innovative pharmaceutical companies’ R & D portion upward adjustment: by 2015 to 15%

Contents
- Same price for equivalent drug
- Re-assessment of medicines already listed (according to the revised pricing policy)
- Setting of excluded drug (to ensure stable supply of medicines)
- R&D promotion: price advantage on drugs manufactured by innovative pharmaceutical firms
Drug-Pricing Policy Reform: effect in ’12

New drug (Original) whose patent has expired & all generic medicines regardless of the order of entry: same price.
### Drug-Pricing Policy Reform: Price advantage

<table>
<thead>
<tr>
<th>Classification</th>
<th>Level</th>
<th>Reason for</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incrementally Modified Drug</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before the development target drug’s</td>
<td>90% or 100% 1)</td>
<td>R&amp;D promotion</td>
</tr>
<tr>
<td>drug’s patent has expired</td>
<td></td>
<td></td>
</tr>
<tr>
<td>After the development target drug’s</td>
<td>100% or 110%</td>
<td></td>
</tr>
<tr>
<td>drug’s patent has expired</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic infusion solution, Orphan drugs</td>
<td>100%</td>
<td>Stable supply</td>
</tr>
<tr>
<td>Narcotics</td>
<td>70%</td>
<td>Management of government</td>
</tr>
<tr>
<td>Biologicals</td>
<td>70%</td>
<td>R&amp;D promotion</td>
</tr>
</tbody>
</table>

1) If the development target product’s patent has expired, the price shall be get adjusted to 100%~110% of the price adjusted.
Drug-Pricing Policy Reform: Price advantage

Duration: “first one year” → 1 year from the date of the first notice for any pharmaceutical products with the identical substance, dosage form, or route of administration.

Amount of price advantage (standards for increases):
- Patent – expired drug: \( \frac{70}{53.55-1} \times 100\% \)
- Generic: \( \frac{59.5}{53.55-1} \times 100\% \)
- Newly developed drugs and generic drugs manufactured by innovative pharmaceutical firms & produced by chemical synthesis: \( \frac{68}{53.55-1} \times 100\% \)

※ If the number of stores selling products with the identical substance, dosage form or route of administration is less than 4, the “first year” will be considered not to have passed.
In the past, drug prices were adjusted in Korea by periodically surveying drug price fluctuations in foreign countries. In April 2012, however, new drug price re-assessment criteria were introduced to help improve the National Health Insurance finances. The prices of original drugs whose patents had expired one year previously or those of generic drugs which were listed one year previously were to be further lowered to 53.55% of the original price before patent expiry.

Result of price reduction (of already-listed drugs)

<table>
<thead>
<tr>
<th>Classification</th>
<th>Figures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Price cut products</td>
<td>about 7,500 (53%)</td>
</tr>
<tr>
<td>Average reduction(%)</td>
<td>about 14%</td>
</tr>
<tr>
<td>Financial savings</td>
<td>about 1.7 trillion won</td>
</tr>
</tbody>
</table>
Listing Procedure

KFDA (Korea Food & Drug Administration): Evaluation on the safety and efficacy (approval of marketing)

New drug

Submission of application
- manufacturer / importer

HIRA (150 days)
Drug Benefit Coverage Assessment Committee (DBCAC)

reimbursement

MOHW (60 days)
- Drug Reimbursement Coordination Committee

Non-reimbursement

Negotiation fail / Non-essential drug

NHIC (60 days)
- Price negotiation

MOHW (60 days)
- Drug Reimbursement Coordination Committee

Negotiation fail / Essential drug

MOHW (30 days)
- Health insurance policy review Committee

MOHW

Generic

Submission of application
- manufacturer / importer

HIRA
Drug Benefit Coverage Assessment Committee (DBCAC)

- Generic (60~90 days)
- IMDs, Biosimilar (30~60 days)

Negotiation success
Required Price Application Documents

- A copy of a manufacture (import) product approval (notification)
- Information on grounds and details of calculation of expected selling price
- Drug information
- Therapy overview
- Textbook articles, drug formulary entries
- Science journal articles
- Comparison with alternative or substitute drugs
- Data for economic assessment
- Financial implications review
- Status of listing in other countries
- Other comments by applicant
Criteria for Decision Making

- Clinical usefulness
  - substitutability, severity of disease, therapeutic benefits
- Cost-effectiveness
  - administering cost & level of improvement in clinical results
  - results of economic evaluations
- Financial impacts
- Reimbursement status and price in foreign countries
- Potential impacts on other aspects of public health, etc

Exceptions for applying criteria – “rule of rescue”

- No alternative treatments and drugs
- & Use for severe, life-threatening diseases
- & Use for a minority of patients who have rare diseases , and etc.
- & Proven to have clinically meaningful improvement
Thank you for your attention!

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