I. General status

- Pharmaceutical industry
- Drug status
- Pharmaceutical expenditure
- NHI listing system
Pharmaceutical industry

### Domestic/Multi-national (2015)

<table>
<thead>
<tr>
<th>Total</th>
<th>Domestic</th>
<th>Multi-national</th>
</tr>
</thead>
<tbody>
<tr>
<td>454 (338)</td>
<td>386 (305)</td>
<td>68 (33)</td>
</tr>
</tbody>
</table>

* ( ) is the ones that submitted NHI benefit claim in 2015

### Manufacturer/Importer (2015)

<table>
<thead>
<tr>
<th>Total</th>
<th>Manufacturer</th>
<th>Importer</th>
</tr>
</thead>
<tbody>
<tr>
<td>454</td>
<td>261</td>
<td>193</td>
</tr>
</tbody>
</table>

* Companies that do both were categorized as manufacturer

**Associations**

- Korea Pharmaceutical Manufacturers Association
- Korean Research-based Pharmaceutical Industry Association
- Korea Biomedicine Industry Association
- Korea Drug Research Association
## Drug status

### Distribution/listing, prescription drug/OTC

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Prescription drug</th>
<th>OTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of distributed</td>
<td>24,624</td>
<td>16,238</td>
<td>8,386</td>
</tr>
<tr>
<td>(supplied) drugs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2014)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of listed drugs</td>
<td>20,401</td>
<td>18,458</td>
<td>1,943</td>
</tr>
<tr>
<td>ini NHI (2015)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### No. of listed drugs by year

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>15,223</td>
<td>14,900</td>
<td>14,883</td>
<td>14,410</td>
<td>13,814</td>
<td>14,576</td>
<td>15,734</td>
<td>17,115</td>
<td>20,401</td>
</tr>
</tbody>
</table>

(Unit : number)

(Unit : 1st of each month, no. of items)
### Pharmaceutical expenditure

**Drug expenditure as a % of total health expenditure (2015)**

<table>
<thead>
<tr>
<th>Total health expenditure</th>
<th>Pharmaceutical expenditure</th>
</tr>
</thead>
<tbody>
<tr>
<td>KRW 53.9 trillion</td>
<td>KRW 14.1 trillion (26.15%)</td>
</tr>
</tbody>
</table>

**Prescription of in–house/outpatient (2015)**

<table>
<thead>
<tr>
<th>Total</th>
<th>In-house</th>
<th>Outpatient</th>
</tr>
</thead>
<tbody>
<tr>
<td>KRW 14.05 trillion</td>
<td>KRW 4.3 trillion (30.8%)</td>
<td>KRW 9.7 trillion (69.2%)</td>
</tr>
</tbody>
</table>

### Drug benefit claim by type of institution (2015)

[unit : KRW 100 mil]

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Tertiary</th>
<th>General</th>
<th>Hospital</th>
<th>Long-term care</th>
<th>Clinic</th>
<th>Dental hospital</th>
<th>Dental clinic</th>
<th>pharmacies</th>
<th>Oriental hospital</th>
<th>Oriental clinic</th>
<th>Else</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amount</strong></td>
<td>140,986</td>
<td>18,866</td>
<td>12,885</td>
<td>4,645</td>
<td>817</td>
<td>5,051</td>
<td>17</td>
<td>86</td>
<td>97,319</td>
<td>24</td>
<td>263</td>
<td>1,013</td>
</tr>
<tr>
<td><strong>%</strong></td>
<td>100%</td>
<td>13.4%</td>
<td>9.1%</td>
<td>3.3%</td>
<td>0.6%</td>
<td>3.6%</td>
<td>0.0%</td>
<td>0.1%</td>
<td>69.0%</td>
<td>0.0%</td>
<td>0.2%</td>
<td>0.7%</td>
</tr>
</tbody>
</table>
*Until 2013, the figures of 4 classification were adjusted with FFS and fixed price system. From 2014, the figures were produced based on FFS, and DRG and per-diem rate were excluded.
Ⅱ. Coverage decision and ceiling price
NHI listing system

Negative list system (Past)

- Introduction: July 2000
- Definition
  - Drugs that failed to obtain permission were excluded from coverage
  - Mandatory application of safety permission for the Ministry of Food and Drug Safety

Positive list system (Present)

- Introduction: December 2006
- Definition
  - Pharmaceutical companies apply for coverage, essential drugs are listed by authority
  - Coverage decision (HIRA) → Price negotiation (NHIS)
### Introduction

<table>
<thead>
<tr>
<th></th>
<th>Coverage decision</th>
<th>Ceiling price</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>New drugs</strong></td>
<td>HIRA (Pharmaceutical Benefits Committee)</td>
<td>NHIS (Price negotiation)</td>
</tr>
<tr>
<td><strong>Generics</strong></td>
<td>HIRA (according to the pricing formula)</td>
<td></td>
</tr>
</tbody>
</table>

**HIRA (Pharmaceutical Benefits Committee)**
Coverage decision for new drugs

1. Benefit assessment
   - Pharmaceutical Benefits Committee
   Coverage decision

2. Economic evaluation
   - Economic evaluation Sub-committee
   Economic evaluation, validity of submitted materials
   - Effectiveness and cost, appropriateness of model, etc.

3. Benefit standard review
   - Drugs
   - Anti cancer drugs
   - Benefit standard advisory committee
   - Cancer deliberation committee
   - Benefit standard setting considering clinical utility

4. Risk Sharing Review
   - Subcommittee of risk sharing system
   - Application of Risk Sharing Agreement, review validity of the proposed type

New drugs

Pharmaceutical company

Generics

Within 120(150) days

Within 45~75 days

Within 60 days

Within 30 days

HIRA (Pharmaceutical Benefits Committee)

NHIS

⑤ Price negotiation

⑥ NHIPDC review

⑦ Notification of the price

• Cost increase against effectiveness improvement
• ICER value, quality of materials

• Replaceability, curative benefit, benefit standard
• Whether it is essential drug

Within 120(150) days

Pharmaceutical company

Coverage application

New drugs
Coverage decision for new drugs

Pharmaceutical Benefits Committee

- Composition: 70 persons or under (there is also a pool), 22 persons or under (meeting composition)
- Legal characteristics: advisory committee of HIRA to efficiently evaluate drug related benefit appropriateness
- Target of evaluation: coverage for new drugs, benefit standards for new drugs, calculation standard, (generics) ceiling price of drugs, etc.
- Sub-committee: economic evaluation, risk sharing agreement, drug benefit standard, oriental medicine, budget impact analysis

NHIS drug price negotiation

- Consider evaluation results of the Pharmaceutical Benefits Committee, and expected consumption volume
- If the negotiation fails, ‘essential drugs’ will be adjusted by the “Pharmaceutical Benefits Mediation Committee” (MoHW)
QA of new drugs

Select replaceable drug (treatment)

- Improvement of clinical utility:
  - Effectiveness, safety, easiness, etc.

If the drug is not essential drug, economic evaluation and cost-effectiveness materials should be proved.

- Economic evaluation result not proved
  - Review drug administration cost (weighted average price of replaceable drug)
  - Economic evaluation result proved
  - Economic evaluation Sub-committee
    - Alternative assessment method (Lowest price among A7 nations)
    - Target decision, validity of type
    - Other factors to consider:
      - Whether it is listed in other countries
      - Budget impact
      - Severity of disease
      - Acceptability of cost-effectiveness

Pharmaceutical Benefits Committee

Review decision

Cost-effectiveness materials can be waived

Replaceable drug not available

No

Review drug administration cost (weighted average price of replaceable drug)

Weighted average price of replaceable drug X 90%, etc.

Economic evaluation result not proved

- Review drug administration cost (Drop drug price negotiation)
- When there is a clinical need, and evidence production is difficult

Economic evaluation result proved

Orphan drug, etc.

Alternative assessment method (Lowest price among A7 nations)

Other factors to consider:
- Whether it is listed in other countries
- Budget impact
- Severity of disease
- Acceptability of cost-effectiveness

Working level review

- Benefit standard review and setting
  - (Drugs) Benefit standard sub-committee
  - (Anticancer drug) Cancer review committee
- Yes
- No
- Review coverage decision

No

Yes
Price negotiation can be waived

When the benefit appropriateness is recognized with “average price of replaceable drug”

- If the pharmaceutical company accepts 90% - 100% of “weighted average price of replaceable drug” (considering the characteristics of new drugs such as the level of difficulty in development), the NHIS can waive price negotiation (60 days)
- Yet, negotiation for estimated reimbursement will occur after listing, so the same post-management is applied

<table>
<thead>
<tr>
<th>Type</th>
<th>Threshold price for negotiation exemption</th>
</tr>
</thead>
<tbody>
<tr>
<td>① New ingredient, ② Biologics, ③ Orphan drug</td>
<td>Weighted average price of replaceable drug</td>
</tr>
<tr>
<td>④ Existing ingredient drug</td>
<td>Weighted average price * 0.9</td>
</tr>
<tr>
<td>⑤ pediatric drug</td>
<td>Weighted average price * 0.95</td>
</tr>
</tbody>
</table>
Coverage decision for new drugs

Economic evaluation

- Compared to existing drugs, drugs with higher clinical and economic value are selected to be listed to protect finite insurance fund.
  - Economic evaluation by comparing cost and outcome.

- Incremental cost-effectiveness ratio (ICER)
  - the ratio of the change in costs to incremental benefits of a therapeutic efficacy of the comparison drug.

<table>
<thead>
<tr>
<th>Evaluation type</th>
<th>Type of achievement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost-minimization analysis</td>
<td>The same result</td>
</tr>
<tr>
<td>Cost-effectiveness analysis</td>
<td>The same type of achievement, Different level of achievement</td>
</tr>
<tr>
<td>Cost-utility analysis</td>
<td>Single or multiple achievement, Alternatives do not have to be identical</td>
</tr>
<tr>
<td>Cost-benefit analysis</td>
<td>Single or multiple achievement, alternatives do not have to be identical</td>
</tr>
</tbody>
</table>
## Coverage decision for new drugs

### Special economic evaluation system for orphan drug

#### Detailed condition

<table>
<thead>
<tr>
<th>Type</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>① Orphan drug or anticancer drug</td>
<td>Refer the standards of orphan drugs</td>
</tr>
<tr>
<td>② Clinical needs (one of the two)</td>
<td>When there is no other treatment (including drugs)</td>
</tr>
<tr>
<td></td>
<td>When there is no product or treatment that has the same curative value. When the drug is used for life threatening condition</td>
</tr>
<tr>
<td>③ Difficult to produce evidence (one of the two)</td>
<td>When it received permission from the MFDS as single-arm drugs</td>
</tr>
<tr>
<td></td>
<td>When it received permission from MFDS with phase 2 clinical trial with control group (without phase 3 condition)</td>
</tr>
<tr>
<td></td>
<td>When the committee agrees that the number of patients is too small to produce evidence</td>
</tr>
<tr>
<td>④ Drug listed in 3 or more countries (among A7 nations)</td>
<td></td>
</tr>
</tbody>
</table>

---

A7 nations typically refer to countries such as Canada, France, Germany, Japan, Korea, the United Kingdom, and the United States.
### Special economic evaluation system for orphan drug

#### Post-management after listing

<table>
<thead>
<tr>
<th>Type</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>① A7 nation price monitoring</strong></td>
<td>When the price in A7 nations is lower, the price is adjusted</td>
</tr>
</tbody>
</table>
| **② Benefit standard expansion**    | For 4 years after listing, benefit standard expansion is limited  
                                          * To the request to expand benefit for risk sharing agreement drugs, review the validity of each type (plan to link in the future)  |
| **③ Application of risk sharing agreement (RSA)** | If economic evaluation was waived because “the committee agreed that the number of patients is too small to produce evidence”, the type of RSA is cap on total amount. |
Risk Sharing Agreement

Definition: A contract between the insurer and pharmaceutical companies to share the risk of efficacy/effectiveness of a new drug and budget impact with pharmaceutical companies.

Intent: To secure the availability of irreplaceable and expensive drugs (such as anti-cancer medicine) while keeping the principle of selecting cost-effective drugs.

Target: Anti-cancer medicines that has no alternative or bioequivalence drug or treatment, orphan drugs that are used for life threatening condition.
Types of Risk Sharing Agreement

① **Continued treatment on condition + refund**
   (Continued administration depending on response and refund)
   After certain period of administration, evaluate each patient’s response. Patients with positive response higher than the expectation will keep receiving the NHI benefit, and the reimbursement for the rest will be refunded to NHI by the applicant.

② **Cap on total amount** (Portion of benefit claim above certain amount is refunded)
   When annual drug benefit claim exceeds pre-set annual expenditure, portion of the excess is refunded by the applicant to the NHIS

③ **Refund** (Portion of claimed benefit is refunded)
   Portion of total drug benefit claim is refunded by the applicant to the NHIS

④ **Cap on each patient** (Portion of excess of each patient is refunded)
   Cap for each patient is pre-determined. When exceeded, portion of the excess is refunded by the applicant to the NHIS
## Coverage decision for new drugs

### New drug assessment

<table>
<thead>
<tr>
<th>Year</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>80</td>
<td>66</td>
<td>63</td>
<td>69</td>
<td>60</td>
<td>48</td>
<td>76</td>
</tr>
</tbody>
</table>
THANK YOU