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Analysis of new drug reimbursement decision in South Korea: over a decade of experience

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Objective

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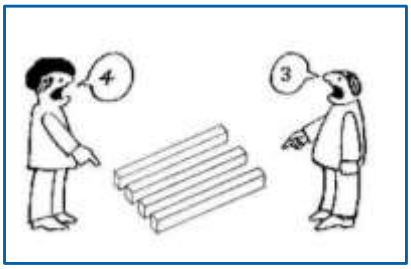
Objective

Conflicting opinions by different stakeholders on listing rate and time to patient access



To analyze the rate of listing and time to patient access based on publicly disclosed reports for reimbursement decisions during the period over a decade in Korea

Ref) http://www.slideshare.net

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Methods

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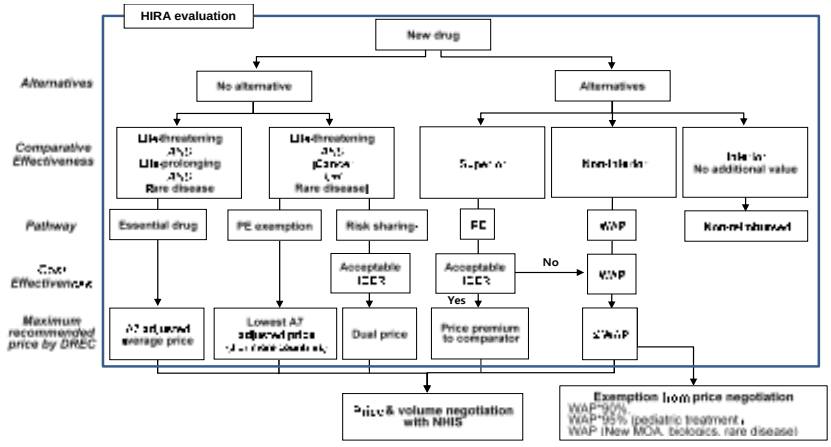
Methods

New drug reimbursement and pricing decision process



HIRA: Health Insurance Review and Assessment Service
ICER: Incremental cost-effectiveness ratio
PE: Pharmacoeconomics evaluation
MOA: Mechanism of action
WAP: Weighted average price
DREC: Drug reimbursement evaluation committee
NHIS: National Health Insurance Service
A7: Seven advanced reference countries (US, UK, Italy, German, Japan, Swiss and France)

[a] Depends on the type of risk sharing, pharmacoeconomics evaluation is needed. Four types of risk sharing are as following; Refund, Conditional treatment continuation, Expenditure cap, Utilization cap

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Methods

Variables and statistical analysis

All new drugs during the period under positive listing system from July 2007 to March 2018

- Using disclosed evaluation results by HIRA

Drug category and HIRA review process

- Three drug types: Oncology, orphan and the others
- HIRA review pathway: Before / after introduction of new pathways

Listing rate and time to patient access

- Time to patient access: Time to event analysis (Kaplan-Meier plot)
  - ✓ Event: National Health Insurance listing
  - ✓ Censored data: Calculated the date from MFDS approval to the last DREC

HIRA: Health Insurance Review and Assessment Service; MFDS: Ministry of Food and Drug Safety
DREC: Drug Reimbursement Evaluation Committee

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Results

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Characteristics of submitted drugs by listing status

		Total (N=360)	Listed drugs (n=298)	Non-listed drugs (n=62)	p-value
Drug category	Oncology drugs	59 (16.4)	49 (16.4)	10 (16.1)	1.000
	Orphan drugs	52 (14.4)	37 (12.4)	15 (24.2)	0.027
	Non-oncology & non-orphan drugs	249 (69.2)	212 (71.1)	37 (59.7)	0.096
HIRA review pathway	Essential drugs	9 (2.5)	9 (3.0)	0	0.368
	Acceptable cost-effectiveness	286 (79.4)	269 (90.3)	17 (27.4)	<0.001
	CEA/CUA	57	56	1	
	CMA or below WAP	229	213	16	
	PE exemption	16 (4.4)	15 (5.0)	1 (1.6)	0.325
	Risk sharing agreement	18 (5.0)	18 (6.0)	0	0.052
Etc	Assessed under changed regulation [a]	111 (30.8)	104 (34.9)	7 (11.3)	<0.001
	Domestic company	147 (40.8)	115 (38.6)	32 (51.6)	0.065
	A7 listing status (≥3 countries)	188 (52.2)	160 (53.7)	28 (45.2)	0.264

P-value was calculated by Fisher's exact test
HIRA: Health Insurance Review and Assessment Service
CEA: Cost-effectiveness analysis; CUA: Cost-utility analysis; CMA: Cost-minimization analysis; WAP: Weighted Average Price
PE: Pharmacoeconomics evaluation; A7: Seven advanced reference countries (US, UK, Italy, German, Japan, Swiss and France)

[a] Regulation change in January 2014: risk-sharing agreement, exemption of pharmacoeconomics analysis and price negotiation

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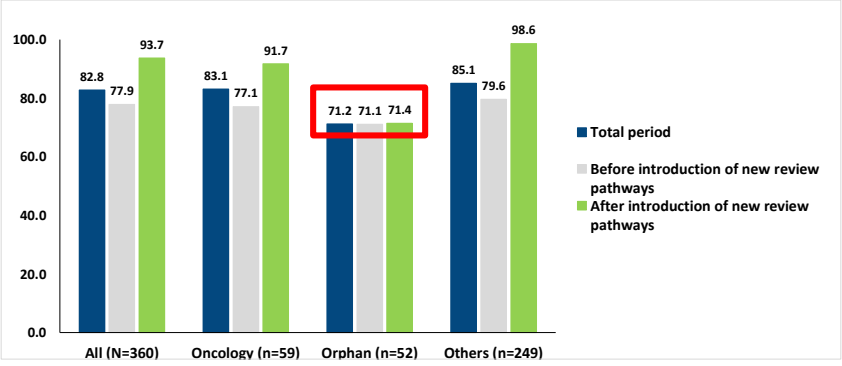
Listing rates by drug types in comparison of before and after the introduction of new review pathways



Time effect is significant...

At 2 years from MFDS, the listing rate of oncology or orphan is around only 50%

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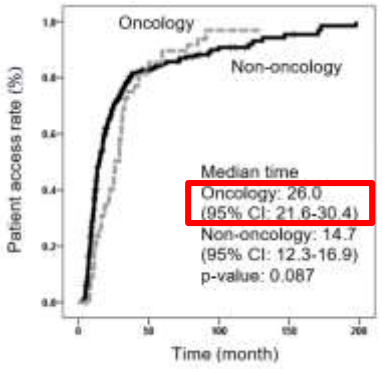
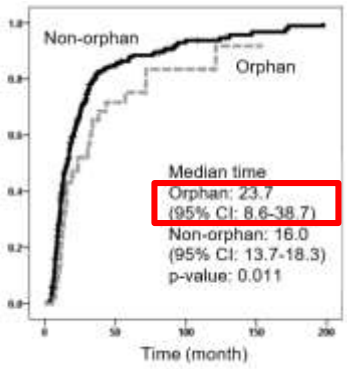
Time to patient access from MFDS approval to listing (1)

❑ **The median time taken for listing for total 360 drugs: 16.2 months (95% CI: 14.1-18.3)**



(a) Oncology drugs (n=59)



(b) Orphan drugs (n=52)

* Mean time is two fold higher than median

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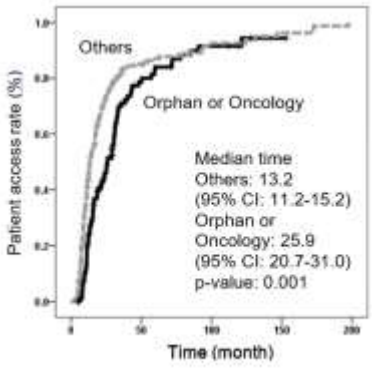
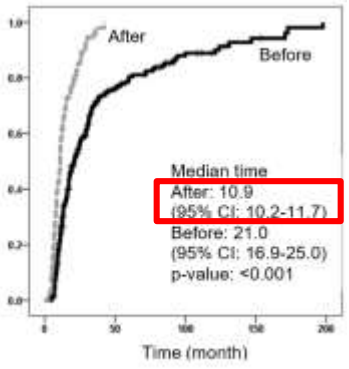
The time to patient access from MFDS approval to listing (2)

❑ **After the introduction of new pathway, the median time is 10.9 months (95% CI: 10.2-11.7)**
- The main driver is an exemption of price negotiation with WAP pathway



(c) Other drugs (n=249)



(d) Regulation changed (n=111)

* Mean time is two fold higher than median

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Limitations

Used the MFDS approval date, not submission to HIRA as the initiation of application

Analyzed only disclosed information by HIRA

- Sensitive information is censored such as submission price, weighted average price of alternatives and price of comparators for cost-effectiveness analysis
- Only final submission data is included in HIRA's reports

MFDS: Ministry of Food and Drug Safety
HIRA: Health Insurance Review and Assessment Service

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Proposals from industry perspective

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Meaningful improvement in patient access by Government's initiative

Substantial improvement on listing rate owing to RSA and PE exemption, especially for oncology drugs

- All drug → Before: 77.9% vs. After: 93.7%
- Oncology drugs → Before: 77.1% vs. After: 91.7%
- Examples
  - ✓ ERBITUX (cetuximab) via RSA and CAPRELSA (vandetanib) via PE exemption

Shortened the time to patient access for WAP pathway through exemption from price negotiation

- WAP with price negotiation exempted: 10.9 months (95% CI: 8.7-13.1)

Even improvement...

Patients who have severe or intractable disease go through a hard time for > 2 years without optimal treatment

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Unmet needs in orphan drugs' coverage

Indistinct impact of new pathways on a coverage for orphan drugs

- Listing rate at status quo in spite of introduction of the new pathways **(71.1% vs. 71.4%)**
- **Not much advantage** in pricing and reimbursement decision for **orphan disease compared to rare disease treatment**

Some orphan drugs were rejected despite of the long review period

- Time to patient access
  - ✓ **Average 44.5 months** (95% CI: 29.8-59.2) vs. Median 23.7 months (95% CI: 8.6-38.7)
- Example
  - ✓ XOLAIR (omalizumab): orphan drug for severe allergic asthma, with the longest period (11 years) remaining non-reimbursement owing to uncertainty in cost-effectiveness

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Limitations of PharmacoEconomics (PE) approach

PE is the only pathway to get a premium to alternatives but...

- Most specialty drugs used new pathway, not conventional PE approach
- **Only 57 (16%) of total drugs** were accepted through CUA or CEA

Longer review period and a rocky road

- Time to patient access with PE: **28.9 months** (95% CI: 22.8-35.1)
- RSA requires cost-effectiveness data to decide the net price
  - ✓ Time to patient access with RSA: 29.1 months (95% CI: 25.5-32.7)
  - ✓ Time to patient access with PE exemption: 18.7 months (95% CI: 11.9-25.4)

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Proposals from industry

Expand NHI coverage to other disease area

- NHI coverage was weighted towards oncology
- Urgency for **non-life threatening but rare or intractable disease**

Give flexibility in PE assessment

- Focus on drugs' value, not only speed
  - ✓ Most drugs listed through CMA or below WAP **(same or less compared with alternatives)**
- Time to consider from various angles: discount rate, selection of comparator, utility, **flexibility of acceptable ICER** and etc.

Broaden adoption of new pathway (RSA and PE exemption)

- Showed clear advantage in pricing and timeline
- Need a **relaxation in the eligibility scope**: only oncology or rare disease treatment, no alternative and life-threatening
- Create additional new pathway (e.g., listing accompanied with post-assessment)

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Thank you

Any questions?

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