HPR100

Analysis of the drug price level of anticancer and rare disease drugs after the implementation of economic evaluation exemption in South Korea

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INTRODUCTION

- In Korea, pharmacoeconomic evaluation (PE) exemption track was introduced in May 2015 to improve patient accessibility for anticancer and rare disease drugs.
- Price criteria of PE exemption was set based on the results of a retrospective analysis that the drug prices of anticancer and rare disease drugs were similar to the lowest price of the adjusted price of advanced 7 foreign countries (A7 countries: France, Germany, Italy, Japan, Switzerland, UK, and USA) at the time of introduction of PE exemption.

Eligible criteria for PE exemption

- Drugs that meet all of the following condition:

1. Anticancer drugs or **rare disease drugs**
2. Clinical need: ① or ②
① **No alternative treatment methods** (incl. drugs)
② **No** products or treatment methods that are in **equivalent therapeutic positions** that are used to treat **serious, life-threatening disease**
3. The difficulty of producing evidence: ① or ② or ③
① **Approved by** MFDS based on the data from a **single-arm clinical trial without a control group**
② **Approved by** MFDS based on the data from **phase 2 clinical trial** with a control group, **without the phase 3 condition**
③ The difficulty of producing evidence is deemed difficult by the Committee due to **the small number of target patients**
4. A drug **listed in 3 or more of** A7 countries

Price criteria of PE exemption

- **The lowest price of the adjusted price** of A7 countries

OBJECTIVE

- This research aims to analyze the level of new drug(anticancer and rare disease drugs) price compared to the adjusted price of A7 countries after the implementation of PE exemption in Korea .

METHODS

Data sources & Method

- We reviewed the new drug price of anticancer and rare disease drugs evaluated as positive reimbursement recommendation by the Pharmaceutical Benefit Coverage Assessment Committee (PBCAC) at Health insurance Review & Assessment Service (HIRA) from May 2015 to June 2022.
- We analyzed the difference of the drug price level according to the cost-effectiveness evaluation method (PE vs. PE exemption) by Mann-Whitney test.
  - Drugs that were not suitable for drug price level analysis were excluded (listed in less than 3 of A7 countries, etc.)

Methods (cont)

Variables & Definition

- Drug price level:

$$\frac{\text{the submission price that evaluated as reimbursement recommendation by PBCAC}}{\text{the lowest A7 adjusted price}} \times 100\ (\%)$$

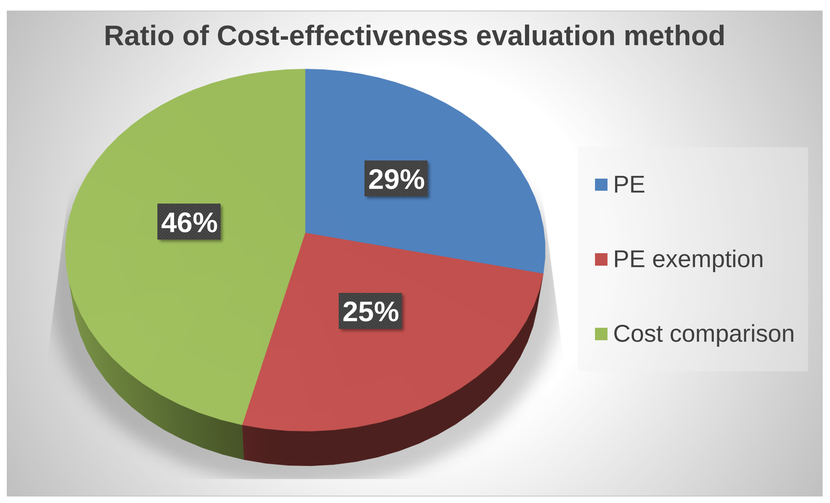
RESULTS

The Price Level of New Drug For Anticancer and Rare Disease

Cost-effectiveness evaluation method of anticancer and rare disease drugs

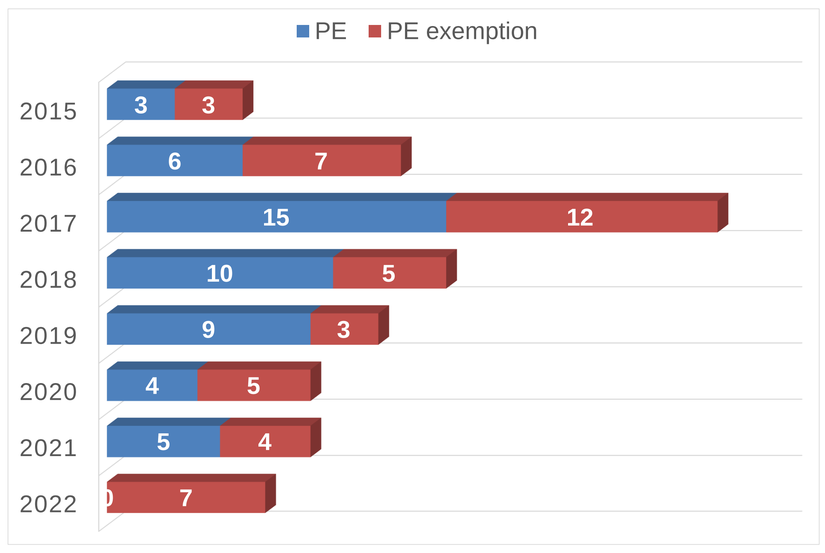
- There were total 182 drugs for anticancer and rare disease treatment recommended for the reimbursement by PBCAC from May 2015 to June 2022.
  - 52 and 46 drugs were evaluated through PE and PE exemption, respectively.
  - In particular, the number of PE drugs has declined sharply since 2017, and all 7 drugs in 2022 were evaluated through PE exemption. .

Figure 1. Percentage of Cost-effectiveness evaluation method of anticancer and rare disease drugs



* PE: Pharmacoeconomic Evaluation (Cost-Effectiveness/Utility Analysis)
** Cost comparison: Drug Cost Comparison with Alternatives (incl. CMA)

Figure 2. Number of anticancer and rare disease drugs by the year of evaluation

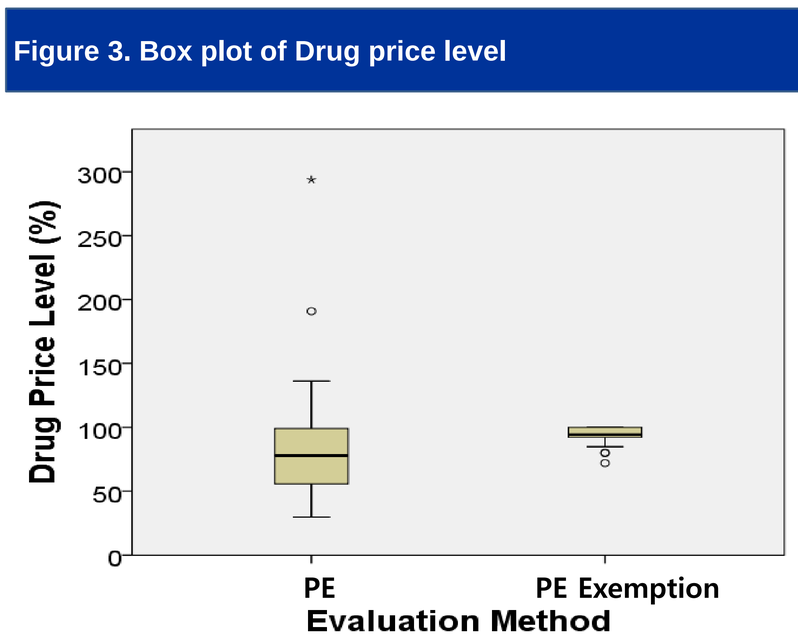


RESULTS (cont)

Drug price level of anticancer and rare disease drugs

- A total of 78 drugs were used in the drug price level analysis.
  - For the 37 drugs evaluated through PE, the median drug price level was 77.9 % compared to the lowest A7 adjusted price.
  - For the 41 drugs evaluated through PE exemption, the median drug price level was 94.2 % compared to the lowest A7 adjusted price.
- As a result of the distribution through Box plot, outliers were identified.
  - All points that lie outside the range defined by quartiles +/- 1.5 * IQR

Figure 3. Box plot of Drug price level



- After removing outliers, the level of drug price compared to the lowest A7 adjusted price of the drugs exempted PE was significantly higher than that of the drugs with PE by about 18% (77.4% vs. 95.8%, p = 0.001).

Table 1. Drug price level compared to the lowest A7 adjusted price

	PE	PE exemption
Number	35	38
Mean Drug Price Level	**77.4 %**	**95.8 %**
	p = 0.001	

* P value was calculated using Mann-Whitney U test

CONCLUSIONS

- The transparency of foreign drug prices is gradually falling owing to the application of Risk Sharing Agreement(RSA). Moreover, the number of drugs exempted from PE is recently increasing in South Korea.
- We found that the PE exemption drug prices were higher than the drug prices with PE, even though they were exempted from submitting economic evaluation data.
- Therefore, it is necessary to reexamine the price criteria for PE exemption.