

# Analysis of factors behind differences between official drug pricing and cost-effectiveness evaluation in Japan and policy implications

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## INTRODUCTION

The Japanese system can be described as a “two-step cost-effectiveness evaluation system”. The government sets drug prices based on efficacy and safety achieving board and prompt reimbursement by public insurance followed by cost-effectiveness assessments based on ICER-QALY.

## OBJECTIVE

This study aims to investigate whether there are differences in judgments between official drug pricing and cost-effectiveness evaluation (CEE). Moreover, it categorizes the factors that cause these differences and derives policy implications.

## METHOD

Thirty-two products have been evaluated in Japan between 2019 and May 2025. A descriptive analysis was conducted based on the public reports on drug pricing and cost-effectiveness evaluations. We then focused on the thirty-two products that had completed the cost-effectiveness evaluations.

## RESULTS

- The price of 75% of the 32 products has been adjusted downward. Seventeen products received a premium when their prices were listed; however, their prices have decreased based on the CEE (Table A).
- We categorized the five factors that caused the differences (Table B).
  - I. Evaluation of innovation that is not directly reflected in the cost-effectiveness evaluation
  - II. Evaluation of innovation when effectiveness is observed only in a subset of patient population
  - III. Selected comparators: whether to limit a comparator to an existing drug/device or not
  - IV. Selected comparators and evaluation of innovation: whether to use an older drug/device as a comparator or not
  - V. Selected comparators when no data exists at the time of Evaluation

Table A Differences between official drug pricing and CEE

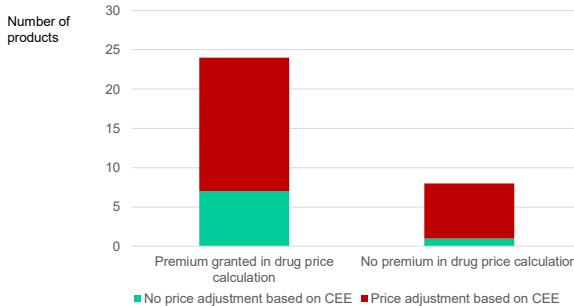
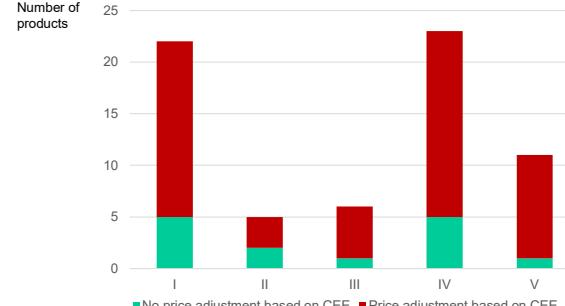


Table B Five factors that caused the differences



- The details for each factor.
  - The comparator for drug prices and cost-effectiveness differed for 30 (93.8%) of the 32 products. Of the 32 products, only four products (12.5%) are compared with new drugs.
  - The price of the 4 products are maintained only for those that obtain a premium for efficacy based on the clinical trial (Table D-1).
  - The efficacy premium tends to have a direct impact on quality of life for CEE, whereas other premiums are less likely to be reflected (Table D-2).

Table C Difference in comparator

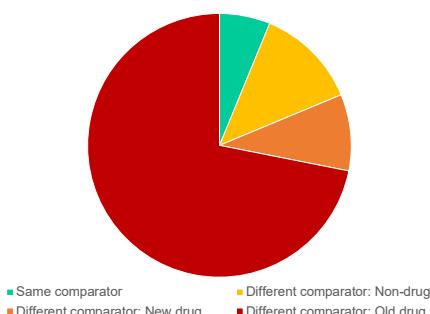


Table D-1 Additional price adjustment based on CEE by type of premium at price listing

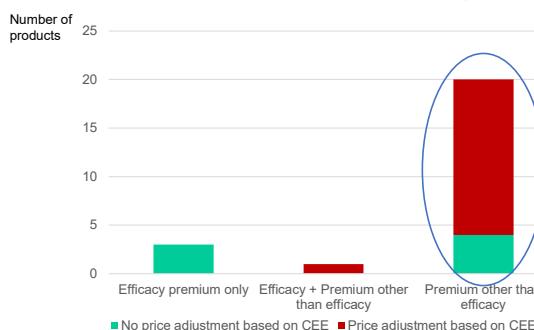


Table D-2 Premium with less likely to be reflected on QOL for CEE

Type of premium	Number of products	
	No price adjustment based on CEE	Price adjustment based on CEE
New MOA	1	7
Efficacy for insufficient efficacy cases	2	8
Standard treatment	1	5
Convenience	1	5
Reduction of invasiveness	0	1

## Major findings

- There were several differences between official drug pricing and cost-effectiveness evaluation/HTA such as selection of comparator.
- Five major impactful factors, which caused the differences are identified and most impactful factors are less value of innovation and selecting older comparator.
- Some innovation are difficult to reflect to the value in cost-effectiveness evaluation framework.

## CONCLUSIONS

Several differences between official drug pricing and cost-effectiveness evaluation have been identified. Therefore, consistent implementation is required between drug pricing and cost-effectiveness evaluation and reducing these differences can improve the predictability of official pricing for companies that are interested in developing or launching their products in Japan and other countries where official prices in Japan are referred.

## REFERENCES

- <https://c2h.niph.go.jp/results/item.html>
- [https://www.mhlw.go.jp/stf/shinki/shinki-chuo\\_128154.html](https://www.mhlw.go.jp/stf/shinki/shinki-chuo_128154.html)

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