PRICING STRATEGY SIMULATION UNDER JAPAN'S HEALTH TECHNOLOGY ASSESSMENT SYSTEM: TRADE-OFFS BETWEEN USEFULNESS PREMIUM WITH PRICE MAINTENANCE PROGRAM AND PRICE REDUCTION RISK

MSR 29

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Introduction

- Japan continues to review price adjustments under its cost-effectiveness assessment system. A proposal would reduce the full drug price by up to 15% for products that increase costs without added benefit[1]. Products receiving a utility premium (UP) may qualify for the Patent-period Price Maintenance Program for Innovative Drugs (PMP), deferring reductions until generic entry or 15 years after listing. However, proving added benefit can be difficult with non-inferiority or single-arm trials, creating a trade-off between long-term price maintenance and price-adjustment risk.

Objective

- This study examines why additional benefit was not demonstrated and compares the long-term price and profitability of obtaining a UP with PMP eligibility versus avoiding a UP, to identify the strategy that maximizes corporate profit.

Method

- This study was conducted in the following two phases.

Phase 1 — **Current-State Analysis from the public reports[3]**
Identify why additional benefit was not demonstrated among products previously assessed for cost-effectiveness.

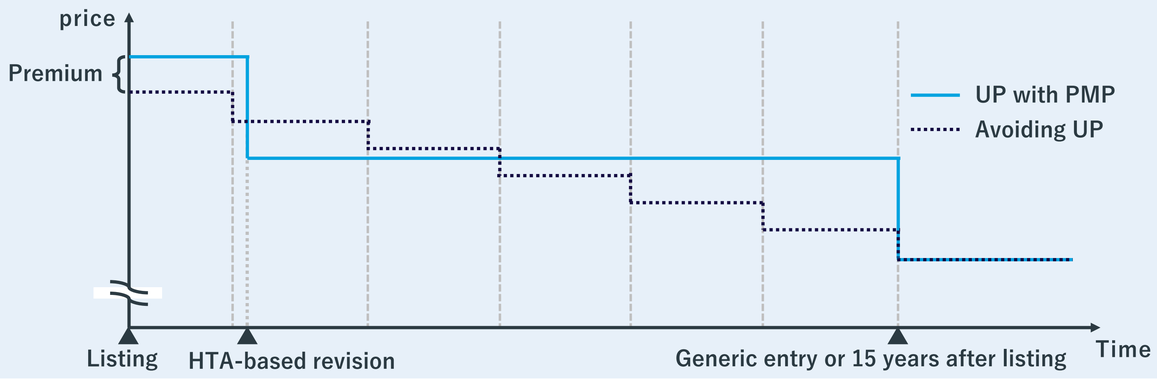
Phase 2 — **Comparison of Long-Term Profitability Between Two Strategies**
1. Obtaining a UP with PMP eligibility (UP with PMP)
2. Not obtaining a UP (Avoiding UP)

Parameters used in the base case

- Pre-premium annual drug cost: JPY 10,000
- Mean time to price adjustment: 687 days after listing
- Mean biennial price revision rate: −1.18%
- Utility premium rate: 5%
- Price reduction rate: 15%
- Not account for patient population size
- Scenario analyses varied the premium from 5%–60% and the price reduction from 0%–15%.

Figure 1: Illustrative Drug Price Changes

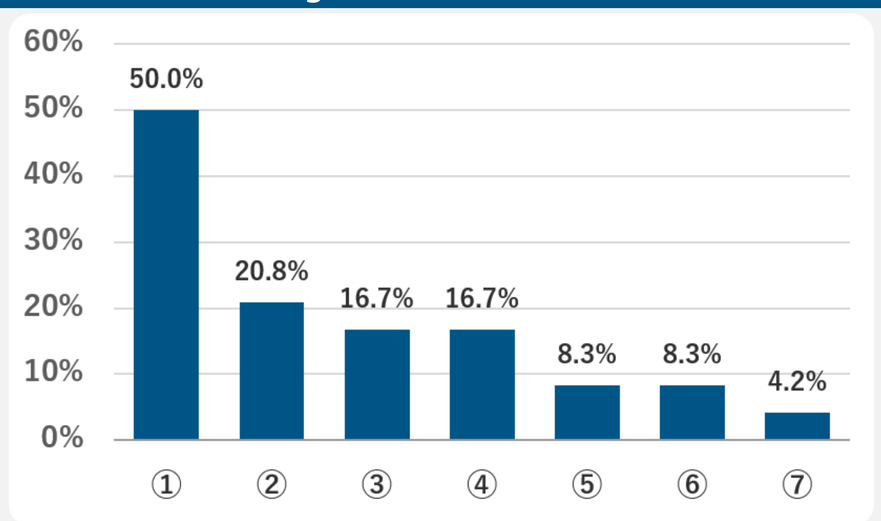
Role of the PMP
- The PMP defers market price–based reductions for new drugs to promote innovative drug development and address drug lag and loss.
- A premium is added at each price revision to offset the reduction.
- After generic entry or 15 years from listing, accumulated premiums are deducted at the next price revision.



Results in phase 1

- Public assessments found no evidence of additional benefit for 39.5% of the evaluated products (17/43). When the assessed population was used as the denominator, the corresponding proportion was 24.5% (24/98).
- Of the populations in which no additional benefit was demonstrated, 50.0% (12/24) involved a mismatch between the comparator used in the clinical trial and that used in the cost-effectiveness assessment, resulting in reliance on an indirect comparison.
- The next most frequent factor, accounting for 20.8% (5/24), was evaluation using a non-final, surrogate outcome on which regulatory approval had been based.

Figure 2: Factors contributing to the failure to demonstrate additional benefit



① Different comparators between the clinical trial and the cost-effectiveness assessment, requiring an indirect comparison (n=12), ② Regulatory approval based on surrogate outcomes rather than final patient-relevant outcomes (n=5), ③ Regulatory approval based on non-inferiority trials (n=4), ④ Clinical trial population not aligned with the target population and/or inability to demonstrate additional benefit based on other available evidence (n=4), ⑤ Availability of more recent data (n=2), ⑥ Clinical trial limitations (e.g., subgroup analyses, small sample size) (n=2), ⑦ Demonstration of additional benefit not supported by a systematic review (SR) (n=1)

Results in phase 2

- UP with PMP generated higher cumulative sales than Avoiding UP during the first three years following launch. However, from Year 4 onward, Avoiding UP yielded higher cumulative sales. Over the 15-year time horizon, cumulative sales were greater under the Avoiding UP scenario (1 USD =159 JPY).

Figure 3: Cumulative sales comparing UP with PMP with Avoiding UP

*Calculations are based on a start date of May 29, 2026.

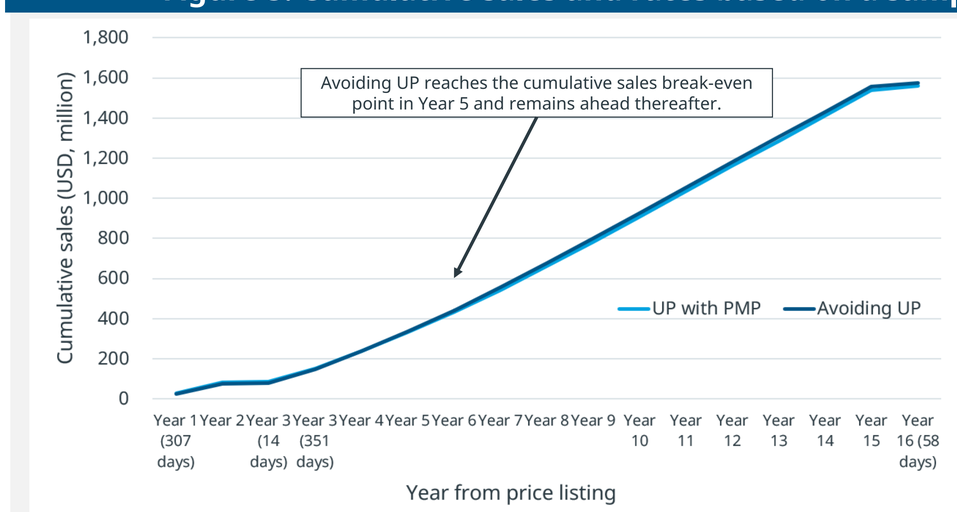
- With a 5% UP rate, the UP with PMP scenario generated higher cumulative sales over a 15-year period when the price reduction rate was 9% or less (**>1**). In contrast, when the price reduction rate was 10% or greater, the Avoiding UP scenario generated higher cumulative sales (**<1**).

Figure 4: Rates of UP with PMP with Avoiding UP

Price reduction by HTA \ UP ranges	5%	10%	15%	20%	25%	30%	35%	40%	45%	50%	55%	60%
0%	1.0952	1.1474	1.1995	1.2517	1.3038	1.3560	1.4081	1.4603	1.5124	1.5646	1.6167	1.6689
1%	1.0856	1.1373	1.1890	1.2407	1.2924	1.3441	1.3958	1.4475	1.4992	1.5509	1.6026	1.6543
2%	1.0761	1.1273	1.1785	1.2298	1.2810	1.3323	1.3835	1.4347	1.4860	1.5372	1.5885	1.6397
3%	1.0665	1.1173	1.1680	1.2188	1.2696	1.3204	1.3712	1.4220	1.4728	1.5235	1.5743	1.6251
4%	1.0569	1.1072	1.1576	1.2079	1.2582	1.3085	1.3589	1.4092	1.4595	1.5099	1.5602	1.6105
5%	1.0473	1.0972	1.1471	1.1969	1.2468	1.2967	1.3466	1.3964	1.4463	1.4962	1.5460	1.5959
6%	1.0377	1.0872	1.1366	1.1860	1.2354	1.2848	1.3342	1.3837	1.4331	1.4825	1.5319	1.5813
7%	1.0282	1.0771	1.1261	1.1750	1.2240	1.2730	1.3219	1.3709	1.4198	1.4688	1.5178	1.5667
8%	1.0186	1.0671	1.1156	1.1641	1.2126	1.2611	1.3096	1.3581	1.4066	1.4551	1.5036	1.5521
9%	1.0090	1.0571	1.1051	1.1532	1.2012	1.2492	1.2973	1.3453	1.3934	1.4414	1.4895	1.5375
10%	0.9994	1.0470	1.0946	1.1422	1.1898	1.2374	1.2850	1.3326	1.3802	1.4278	1.4754	1.5229
11%	0.9899	1.0370	1.0841	1.1313	1.1784	1.2255	1.2727	1.3198	1.3669	1.4141	1.4612	1.5083
12%	0.9803	1.0270	1.0736	1.1203	1.1670	1.2137	1.2604	1.3070	1.3537	1.4004	1.4471	1.4938
13%	0.9707	1.0169	1.0631	1.1094	1.1556	1.2018	1.2480	1.2943	1.3405	1.3867	1.4329	1.4792
14%	0.9611	1.0069	1.0527	1.0984	1.1442	1.1900	1.2357	1.2815	1.3273	1.3730	1.4188	1.4646
15%	0.9515	0.9969	1.0422	1.0875	1.1328	1.1781	1.2234	1.2687	1.3140	1.3593	1.4047	1.4500

- Although the cumulative sales of the Avoiding UP scenario surpassed those of the UP with PMP scenario from Year 5 onward, the UP with PMP scenario still generated higher cumulative sales over the 15-year period when the price reduction rate was up to 14% (**>1**).

Figure 5: Cumulative sales and rates based on a sample drug



Price reduction by HTA \ UP ranges	10%
0%	1.1550
1%	1.1440
2%	1.1330
3%	1.1220
4%	1.1110
5%	1.1000
6%	1.0890
7%	1.0780
8%	1.0670
9%	1.0560
10%	1.0450
11%	1.0340
12%	1.0230
13%	1.0120
14%	1.0010
15%	0.9900

*Calculations are based on a start date of May 29, 2026.

**Product X drug price: approximately JPY 9,000. Patient numbers based on the company analysis report[4], with the patient population from Year 11 onward assumed to be equal to that in Year 10.

Discussion

✓ **Findings of phase 1**
- The primary factor contributing to the failure to demonstrate additional benefit was the use of indirect comparisons. The next most frequent factor was evaluation using a non-final, surrogate outcome on which regulatory approval had been based.

✓ **Limitations in generalizing the phase 2 results**
- The simulation results are strongly influenced by drug price and expected market size (patient population), making it difficult to derive generalizable conclusions. In addition, the simulation does not account for products whose raw material costs are added after the premium is applied.

✓ **Limitations of the cumulative sales forecast assumptions in phase 2**
- For future cumulative sales, the simulation assumes that drug prices remain unchanged for 15 years under UP with PMP. For Avoiding UP, it considers only the average biennial price revision rate. It does not account for cases in which prices are not maintained despite PMP eligibility because the average discrepancy rate is exceeded, or products are subject to market-expansion repricing.

Conclusion

Considering the factors that led to the absence of demonstrated additional benefit, a strategic assessment should be conducted to determine which of the two strategies is expected to deliver superior long-term revenue outcomes.

Conflict of interest

- No conflict of interest

Reference & Supplementary Information

1. MHLW: https://www.mhlw.go.jp/stf/newpage_68051.html
2. MHLW: https://www.mhlw.go.jp/content/12400000/001696834.pdf
3. C2H: https://c2h.niph.go.jp/en/results/item.html
4. C2H: https://c2h.niph.go.jp/en/results/C2H1901.html