Japan’s FY2026 Drug Pricing Reform: Policy Changes and Pricing Implications

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INTRODUCTION

- In early December, Japan’s Ministry of Health, Labour and Welfare (MHLW) proposed a draft outline for the FY2026 drug pricing reform
- The outline was approved on December 26 by the Central Social Insurance Medical Council (Chuikyo) and will take effect from April
- The drug pricing reforms have stirred debate among industry stakeholders, revealing tensions between cost containment and innovation incentives

OBJECTIVE

- To analyse the proposed FY2026 drug pricing reform in Japan, with a focus on changes to reimbursement mechanisms and the resulting implications for drug pricing

METHODS

- Systematic literature review of publicly available policy documents, official government statements, and stakeholder responses from December 2025 to February 2026

RESULTS

The updates can be divided into 6 categories:

1 NHI drug price spending

- FY2026 revisions continue to correct gaps between average real-world purchase prices and NHI list prices
- The FY2025 price survey shows an average price gap of ~4.8%, down from ~5.2% shown in the previous survey
- NHI will cut drug prices by 0.87%, which is expected to generate ¥106bn in savings (more than two thirds of the total ¥150bn savings estimated from the FY2026 healthcare reforms)

2 Foreign price adjustment

- The reform retains the existing foreign price reference framework, including the current reference markets used for comparison: US, UK, DE and FR
- However, applicants will now be required to state whether the cited German price is post-AMNOG and only negotiated prices will be referenced

3 PMP price premiums

- The price maintenance premium will be renamed the patent-period price maintenance program for innovative drugs, or 革新的新薬薬価維持制度, using the same initialism (PMP)
- The “new mechanism of action drugs” will be removed as a PMP eligibility criterion in order to improve transparency
- Products with NHI–market price divergence exceeding the average divergence rate (~4.8%) remain ineligible for PMP
- Cumulative PMP deductions will be applied before price-floor rules, preventing unintended price erosion

4 Market expansion repricing (MER)

- The “Huge seller” rule, which acts as MER for blockbuster medicines, will be renamed the special price adjustment for sustainable health system and sales scale (SPA-SSS)
- The maximum price-cut threshold has been loosened to ¥300bn and ten times forecast sales (previously ¥150bn), but the actual price reduction has been raised from 50% to 66.7%
- Automatic MER for similar products via the “spillover rule” has been abolished

5 Long-listed products (LLPs)

- Previously the extent of LLP price reduction was divided into three categories depending on the substitution rate (uptake vs. originator):
  1. **G1** applied drastic price cuts where generic uptake was high
  2. **G2** offered a gradual price erosion where generic uptake was limited
  3. **C** offers an exception to price reductions where generic substitution was difficult
- The FY2026 reform stipulates G1 price reductions will apply 5-years after generic launch (or once biosimilars are listed) regardless of substitution rate, with G2/C categories eliminated
- LLP prices will now be progressively reduced to the weighted-average generic price via G1 price cuts, with an additional 2% reduction applied

6 Paediatric premiums

- Although marketability + paediatric premiums can still technically apply in conjunction, products targeting rare, paediatric conditions will only be eligible for the latter
- Furthermore, the paediatric premium is now capped at the comparator’s premium to ensure consistency

Pending items to be included in FY2027

- Decisions on other potential reforms have been deferred pending "objective verification" of the system in 2026, including the scope of cost-effectiveness assessment (CEA), comparator selection rules for innovative medicines, cost disclosure requirements, and application of MER to regenerative medicines
- Chuikyo have agreed to conduct industry consultations focusing on the expansion of CEA as a price cutting tool for drugs deemed to offer no additional benefit

CONCLUSIONS

- The FY2026 reform represents an incremental tightening rather than a structural overhaul, with most changes refining existing mechanisms, while postponing discussions on several contentious issues, including the expansion of cost-effectiveness assessment (CEA)
- Chuikyo’s updates focus on revising price-adjustment rules to balance budgetary sustainability with innovation incentives, recalibrating both innovation-linked premiums and post-launch repricing mechanisms
- Although cost containment remains the primary policy anchor, mechanisms increasingly target the highest-spend products through higher MER reductions and accelerated price erosion for long-listed products, on top of continued NHI price cuts

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