Two Decades of the Positive List System in South Korea: Balancing Access and Sustainability Through Evidence-Based HTA

HPR103

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Background

- Dec 2006: South Korea shifted from a Negative List System (NLS) to a Positive List System (PLS) to improve the efficiency of pharmaceutical spending and reimburse medicines with therapeutic and economic value.
- The reform responded to rapidly rising pharmaceutical expenditure. (29.2% of total healthcare spending in 2005)
- Policy refinements since then have aimed to improve patient access.

Negative List System (NLS) → **Positive List System (PLS)**

Objectives

- Review the 20-year achievement of South Korea's PLS and evaluate its impact on reimbursement decision-making, patient access and pharmaceutical benefit management

Methods

- Descriptive retrospective review of reimbursement policies and outcomes
- Data source: HIRA, 2007–2025
- Key indicators: reimbursement rates, assessment timelines, and major policy reforms

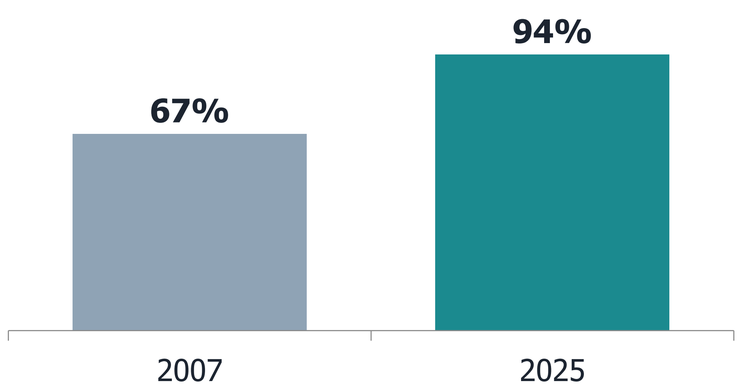
Results: Access, Timeliness & Sustainability

742
pharmaceutical reimbursement assessments, 2007–2025

78%
positive PBCAC recommendation (576 of 742)

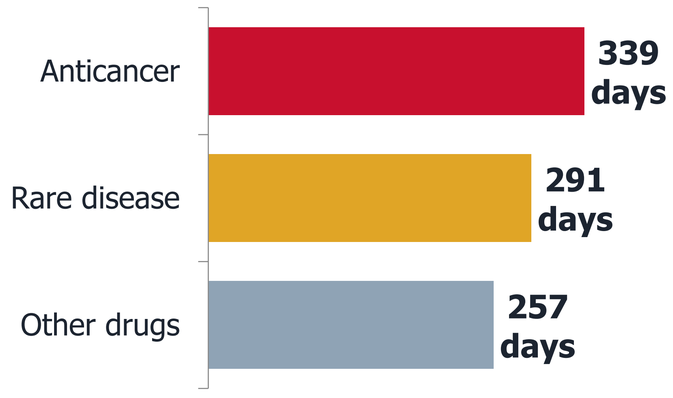
109 days
mean assessment time* from submission
**Excluding Time spent on supplementation*

Positive recommendation rate



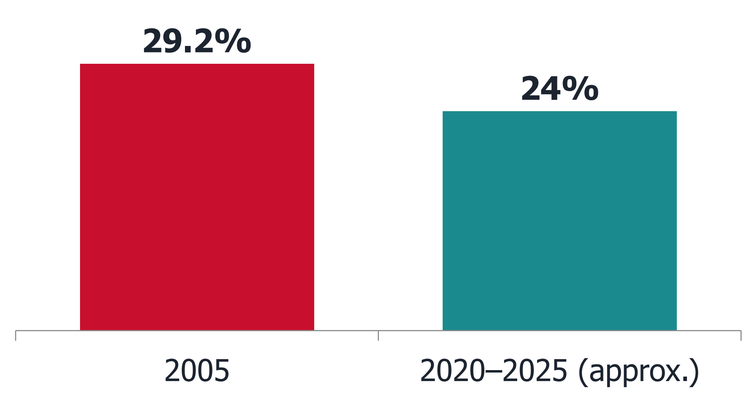
Generally increased since PLS introduction: 67% (2007) to 94% (2025)

Mean time to listing (days)



Assessment duration was similar across drug categories; time to listing was longer for anticancer and rare disease drugs.

Pharmaceutical share of total healthcare spending

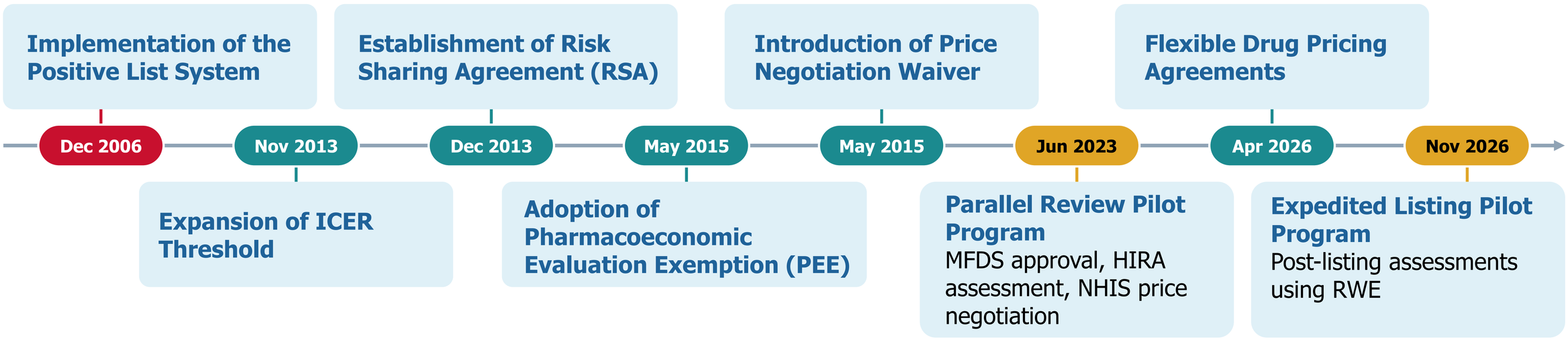


Stable at approximately 24% of total healthcare expenditure in 2020–2025

Policy Milestones of PLS in South Korea

PLS launch · Policy · Pilot program

RSA, PEE and flexible ICER thresholds particularly benefited oncology and rare disease treatments.



Conclusions

Over time, PLS in South Korea has developed into a mature HTA-based reimbursement framework that balances patient access with financial sustainability. Recent policy reforms are expected to introduce an expedited reimbursement pathway incorporating real-world evidence (RWE) and flexible pricing scheme.

Abbreviations

- PBCAC: Pharmaceutical Benefit Coverage Assessment Committee
- ICER: Incremental Cost-Effectiveness Ratio

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