Republic of Korea

Recent and planned developments in pharmaceutical policies 2025/2026

CHANGES IN PRICING

Key Drug Pricing Reforms

The Health Insurance Policy Deliberation Committee adopted key pricing reforms in March 2026 to optimize pharmaceutical expenditures and strengthen generic drug quality.

The reimbursement rate for **generics and off-patent drugs** will be reduced from 53.55% to 45%, reflecting domestic cost structures and international benchmarks.

To mitigate market impact, the adjustment will be implemented gradually, with reductions of approximately 2 percentage points per year through 2029.

Quality requirements for generics will also be reinforced. The pricing adjustment rate applied to products without in-house bioequivalence studies or without the use of MFDS-registered active pharmaceutical ingredients will be lowered from 85% to 80%.

CHANGES IN REIMBURSEMENT

Fast-Track Reimbursement System for Rare Disease Therapies

The Health Insurance Policy Deliberation Committee adopted a set of pharmaceutical pricing reform including a **fast-track reimbursement system** (March 26, 2026) to reduce the listing timeline for rare disease therapies from up to 240 days to within 100 days. The reform focuses on process acceleration and parallelization. The traditional sequential pathway—approval, evaluation, negotiation, and committee review will be compressed, with key steps.

A major change is the shift from a sequential to a parallel review system, enabling concurrent participation of regulatory and payer bodies from the approval stage to reduce overall timelines.

The system supports early access through parallel clinical and pricing assessments, followed by post-listing evaluation using real-world evidence (RWE) to reassess outcomes and adjust pricing. Initial pricing may reference international benchmarks, with subsequent adjustments based on real-world data (RWD).

A pilot program will launch in the second half of 2026, with expert committee oversight to strengthen evaluation processes.

National Initiatives on Antibiotic Use/AMR

Current Status of National Antimicrobial Resistance (AMR) Management in Korea

The Republic of Korea has implemented national strategies to combat antimicrobial resistance (AMR) since the **First National Action Plan (2016–2020),** focusing on reducing antimicrobial use and strengthening infection prevention and control. In 2016, Korea joined the **WHO Global Antimicrobial Resistance Surveillance System (GLASS)** and established **Kor-GLASS**, enabling systematic monitoring of resistance trends using hospital-based data. Quality Assessment Programmes for pharmaceutical benefits led by HIRA were strengthened and expanded as key implementation measures. **The Second National Action Plan (2021–2025)** expands efforts to promote appropriate antimicrobial use, enhance surveillance, and contain AMR spread. Key measures include developing prescribing guidelines, implementing **antimicrobial stewardship programs (ASPs),** monitoring antimicrobial use and resistance, and evaluating prescribing practices. Clinical decision-support tools have also been introduced. Public awareness initiatives, including campaigns during World Antimicrobial Awareness Week, aim to improve understanding and responsible antimicrobial use. To support benchmarking, the Korea Disease Control and Prevention Agency developed the **Korea National Antimicrobial Use Analysis System (KONAS)** in 2020, with participation expanding to 154 healthcare institutions by April 2026. The ASP pilot project (launched in 2024) promotes multidisciplinary stewardship activities such as prescription review, education, and monitoring. Future strategies aim to expand ASP implementation

SPECIAL TOPIC:
Regulation, pricing and reimbursement of pharmaceutical combination products

Overview

Combination drug products in Korea are formulations containing two or more active ingredients in fixed proportions within a single dosage form. Marketing authorization is granted by the Ministry of Food and Drug Safety, and reimbursement status and pricing are determined through evaluation by the Health Insurance Review and Assessment Service. and final price negotiations are conducted by the National Health Insurance Service (New active substances are subject to full price negotiations, whereas calculated (priced) products are subject only to supply-related negotiations).

Definition: Finished pharmaceutical products comprising two or more (≥2) active pharmaceutical ingredients(APIs) in a single dosage form.

Reimbursement: The Drug Reimbursement Evaluation Committee (DREC) assesses the clinical effectiveness and, where applicable, cost-effectiveness of fixed-dose combination products, and determines reimbursement eligibility while providing recommendations on pricing.

Pricing: It is determined in accordance with Appendix 1 of the 'Criteria for Determination and Adjustment of Pharmaceutical Reimbursement Price. Under Korean pharmaceutical pricing regulations, typically the price of combination products is determined by adjusting the reference price of each component according to its dosage strength, followed by the application of a fixed proportion (e.g., 53.55%).; alternative criteria may apply (e.g., incrementally modified drugs by innovative companies, narcotics, biologics).

Non-reimbursed products: Non-reimbursed combination products in Korea are subject to **a free-pricing system**, whereby prices are determined by manufacturers and healthcare providers without direct government price regulation, with patients bearing full cost out-of-pocket.