Opinions on Improving the Drug Price Formation Mechanism

China – Geneal Office of the State Council

Main information

Scope of Application:

Implementation of a "market-led" pricing mechanism, explicitly utilizing the "decisive role of the market" while enhancing government supervision to serve the high-quality development of the pharmaceutical industry and ensure public access to quality and affordable medicines

Effective Date:

March 30th, 2026

Related Provisions:

- Drug Administration Law, art. 85
- Notice on Issuing the Opinions on Promoting Drug Price Reform, State Council, June 1, 2015

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Key Topics

Framework

- The Opinion structures drug prices across the entire lifecycle, implementing mechanisms for **three distinct stages**: launch (new drugs), reimbursement selection (NRDL/insurance), and mature market (off-patent/generic drugs).
- Medical insurance standards as leverage to govern pharmaceutical expenditure.
- Improvement of the management of listed (online) drug prices. The Opinion encourages the construction of a provincial-level pharmaceutical procurement platform integrating bidding, procurement, trading, settlement, and supervision.

What's new

- Differentiated Launch Prices: The Opinion introduces a formal "**enterprise self-assessment**" system for new drugs. For the first time, it explicitly allows high-level innovative drugs to set high launch prices matching R&D risks, while requiring generics to price "reasonably" against competitors.
- Voluntary Price Adjustment Mechanism: Unlike previous static caps, the rules allow manufacturers to adjust prices upward based on **Real-World Evidence** (RWE) if clinical value is proven superior (real-world research results and clinical effectiveness).

Sensitive Factors

- The Opinions formally carve out a space where BMI payment standards do not apply for non-BMI included drugs. While pricing freedom remains, the Opinions introduce "self-assessment + social supervision" as a new constraint mechanism. **Enterprises must justify their prices based on clinical value**, and prices deemed unreasonable can face public scrutiny.
- The Opinion accelerates for the **implementation of a "Class C" drugs**, covered by commercial health insurance.

Drivers

- **Regulated free-price:** Enterprises can still set prices freely for non-BMI drugs, but abnormal pricing triggers government monitoring and potential intervention.
- **Commercial insurance role:** With BMI unable to cover all high-cost innovative drugs, enterprises can actively pursue inclusion in the commercial insurance "Category C" directory. This provides a legitimate, regulated channel for premium pricing without relying on BMI negotiation.
- **RWE:** The Opinion explicitly allows price adjustments based on RWE results and clinical effectiveness data. Companies are encouraged to invest in real-world evidence (RWE) studies to support premium pricing