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South Korea's Sweeping Drug Pricing Reform: Risks and Strategic Responses

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I. Background

On March 26, 2026, the Ministry of Health and Welfare (MOHW) convened a meeting of the Health Insurance Policy Deliberation Committee (HIPDC) and approved a comprehensive reform of Korea's drug pricing system. The reform introduces significant structural changes that are expected to have broad and lasting implications for both domestic and multinational pharmaceutical companies. This initiative builds on the policy direction initially announced by MOHW in November 2025 and will be implemented through a series of amendments to applicable notifications and regulations in accordance with the timeline set by MOHW.

Shin & Kim LLC's Healthcare Team outlines the key elements of the reform, highlights the principal risks for industry participants, and identifies strategic considerations for companies navigating the evolving pricing landscape.

II. New Drugs: Expedited Listing and Enhanced Patient Access

A. Expedited Listing for Rare Disease Treatments (Pilot in 2026; Institutionalized in 2027)

Accelerating health insurance coverage for rare disease treatments is among the 123 national policy priorities of the current administration, and was also identified as a key initiative under the Joint Government Plan for Strengthening Support for Rare, Severe, and Intractable Diseases, released on January 5, 2026.

In line with this policy direction, the reform introduces an expedited listing pathway designed to complete the listing process—including reimbursement criteria review by the Health Insurance Review and Assessment Service (HIRA) and price negotiations with the National Health Insurance Service (NHIS)—within 100 days. Under this framework, reimbursement prices are expected to be benchmarked to a specified percentage of the average price in select foreign jurisdictions. The regime also introduces a post-listing management mechanism under which clinical outcomes will be periodically assessed, with potential adjustments to reimbursement levels and coverage scope based on such clinical

outcomes.

B. Expedited Listing with Post-Market Evaluation for Innovative Drugs (From 2028)

The government plans to extend the expedited listing model beyond rare disease treatments to a broader category of innovative drugs, and to establish a framework for post-listing price and reimbursement scope adjustment based on observed clinical outcomes. The government has characterized this framework as an "outcome-based drug evaluation model," potentially integrated with digital health technologies. Notably, however, the reform contemplates a selective application of this pathway to certain qualifying innovative drugs, rather than the broader application initially proposed in November 2025.

C. Increase in ICER Threshold (Policy Research in 2026; Implementation in 2027)

The government has been exploring measures to address longstanding concerns that the cost-effectiveness used in new drug assessments—the Incremental Cost-Effectiveness Ratio (ICER) threshold—is set too low, thereby restricting patient access to innovative medicines. Since 2024, MOHW has been applying the ICER threshold more flexibly. The reform now envisages a more systematic approach by introducing weighted adjustments that reflect disease severity, therapeutic benefit, and budget impact, among other factors, enabling a more structured upward recalibration of the ICER threshold.

Note: The ICER (Incremental Cost-Effectiveness Ratio) represents the additional cost required per unit of incremental health effect gained by a new drug relative to its comparator. A drug is considered cost-effective when its ICER falls below the applicable threshold.

D. Flexible Pricing Contracts (From First Half of 2026)

The reform introduces a "flexible pricing contract" mechanism under which NHIS and pharmaceutical companies may agree on a reimbursement price that is distinct from the listed price. This mechanism is available for not only for new drugs, but also for patent-expired originators, products exiting risk-sharing arrangements, incrementally modified drugs, and biosimilars, among other drugs. The government aims to finalize and implement this mechanism within the first half of 2026.

III. Newly Listing Generics: Reduced Pricing Rates and Constraints on Multi-Product Listing

A. Reduction in Base Reimbursement Rate (From Second Half of 2026)

Under the current system, the reimbursement prices for both generics and patent-expired originators with generics listed are ultimately reduced to 53.55% of the pre-generic-entry originator price (the "base reimbursement rate"), after any applicable temporary price premiums. The November 2025 proposal had announced an intention to revise this base

rate to the “40s” range, and this March 2026 reform finalizes the new base reimbursement rate at 45%.

B. Measures to Discourage Multi-Product Generic Listing (From Second Half of 2026)

(Enhanced Price Reductions for Failure to Meet Qualification Requirements) Where a generic fails to meet the applicable qualification requirements, the applicable reimbursement level will be reduced from 85% to 80%, thereby increasing the pricing disadvantage associated with non-compliance.

(Strengthening of Tiered Price Reduction Mechanism) Under the current tiered pricing system, a stepped price reduction—whereby the listed generic receives a price equal to 85% of the immediately preceding lowest price—applies beginning from the 20th generic listed for a given formulation, regardless of whether the qualification requirements are satisfied. The reform accelerates the trigger point for this stepped reduction to the 13th generic, significantly tightening the economics of multi-product generic entry.

(Control Measures for Generics Exceeding Thirteen Listings per Formulation) For generics that cause the number of listed products for a given formulation to exceed thirteen, a pricing mechanism equivalent to the stepped reduction will apply, further disincentivizing excessive market entry.

IV. Already-Listed Drugs: Phased Price Reductions and Periodic Reassessment

A. Phased Reduction of Prices for Already-Listed Drugs (2026–2036)

While the newly established 45% base reimbursement rate will apply prospectively to newly listed drugs, the reform also provides for a staged reduction of prices for already-listed drugs, with the objective of reaching 45% over an eleven-year period from 2026 through 2036. This measure applies to both generics and patent-expired originators with generics listed, except for drugs for which price maintenance is deemed necessary to ensure supply stability.

The reduction schedule is structured as follows: (i) Phase 1 applies to drugs listed prior to 2012, beginning in the second half of 2026 with an initial reduction to 51%, followed by annual reductions of 2%, reaching 45% by 2029; and (ii) Phase 2 applies to drugs listed in or after 2013, beginning in 2030 and reaching 45% by 2033. Notably, classification into Phase 1 or Phase 2 is determined based on the timing of the first generic entry for the same active ingredient, rather than the listing date of each individual product.

In addition, special provisions will apply to Innovative Pharmaceutical Companies and Quasi-Innovative Pharmaceutical Companies, allowing them to maintain pricing at 49% for an additional four years and at 47% for an additional three years, respectively. As a result, the timing at which such products ultimately reach the 45% level is expected to be 2032 and 2036, respectively.

TABLE 1: Expected Schedule for Price Reductions for Already-Listed Drugs (%)

Phase	Company Type	'26	'27	'28	'29	'30	'31	'32	'33	'34	'35	'36
Phase 1 (Pre-2012 Listing)	Innovative	51	49	49	49	49	49	45				
	Quasi-Innovative	51	49	47	47	47	47	45				
	General	51	49	47	45							
Phase 2 (Post-2013 Listing)	Innovative					51	49	49	49	49	49	45
	Quasi-Innovative					51	49	47	47	47	47	45
	General					51	49	47	45			

Note: Shaded cells (blue) indicate the special grace periods applicable to Innovative and Quasi-Innovative Pharmaceutical Companies.

B. Re-evaluation of Reimbursement Appropriateness (From 2026)

Currently, the reimbursement appropriateness re-evaluation framework selects target drugs based on factors such as whether the product has been listed prior to the introduction of the positive listing system, claims volume, and overseas listing status, and allows for the possibility of maintaining coverage through price reductions, taking into account the availability of alternative therapies and treatment costs. Under the reform, however, re-evaluation will instead focus on drugs for which a reassessment of clinical usefulness is clearly warranted. The available outcomes are expected to be limited to: (i) maintenance of coverage; (ii) delisting; or (iii) conversion to selective benefit (with 50% or 80% co-payment).

C. Periodic Price Adjustment (Model Finalized 2027–2029; Adjustments from 2030)

The government plans to introduce, beginning in 2030, a new pricing mechanism under which drug prices will be reduced on a periodic basis every three to five years, based on a comprehensive assessment framework that takes into account factors such as the number of products per active ingredient, market structure (including sales, generic penetration, and competitive dynamics), and cross-country price comparisons. This new mechanism will take effect in the year following the completion of Phase 1 price reductions for already-listed drugs applicable to general companies, i.e., beginning in 2030.

V. Supply-Critical Drugs: Enhancement of Regulatory Framework and Incentives

A. Expanded Designation and Enhanced Compensation for Drugs Designated under the

Drug Shortage Prevention Program (From Second Half of 2026)

The government will facilitate the inclusion of medically necessary drugs into the Drug Shortage Prevention Program by relaxing designation criteria. In addition, compensation will be strengthened through the introduction of a policy premium (up to 10%) and improvements to cost calculation methodologies, among other mechanisms. Pharmaceutical companies with a high level of contribution to the supply of such drugs will be designated as Supply Stability Leaders and will receive preferential treatment.

B. National Essential Medicines Using Domestically Sourced Raw Materials (From Second Half of 2026)

Under the current system, national essential medicines manufactured using domestic raw materials are eligible for a preferential reimbursement rate of 68% for a period of 5+5 years, applicable only to newly listed drugs. Under the reform, where qualification requirements continue to be satisfied and the number of suppliers remains three or fewer, such preferential pricing will continue beyond the 5+5-year period. In addition, the preferential treatment will apply not only to newly listed drugs but also retroactively to already-listed drugs.

C. Drugs Using Directly Manufactured Raw Materials (From Second Half of 2026)

Under the current system, drugs using directly manufactured raw materials are eligible for a preferential reimbursement rate of 68% for a base period of one year, applicable only to newly listed drugs. Under the reform, such drugs will receive the same level of preferential pricing as national essential medicines using domestically sourced raw materials, and the benefit will be extended to already-listed drugs.

D. Directly Manufactured Antibiotic Injectables and Pediatric Drugs (From Second Half of 2026)

Antibiotic injectables and pediatric drugs that are directly manufactured and supplied by three or fewer companies were not previously eligible for preferential treatment. Under the reform, such products will receive the same level of preferential pricing as national essential medicines using domestically sourced raw materials, including for already-listed drugs. The introduction of this preferential pricing for directly manufactured antibiotic injectables and pediatric drugs was not included in the November 2025 proposal and has been newly added under this March 2026 reform.

E. Exemptions from the Volume-Price Linkage System (From Second Half of 2026)

Drugs for which prices have been increased to enhance production and supply stability will be exempt from price reductions under the volume-price linkage system for a certain period. The government is considering setting the exemption period at three years. In addition, drugs requiring national-level supply management (such as national stockpile medicines) will not be subject to price reductions under the volume-price linkage system.

VI. Company-Type Differentiated Pricing Incentives

A. Innovative Pharmaceutical Companies (From Second Half of 2026)

Innovative Pharmaceutical Companies will receive a preferential reimbursement rate of 60% for a period of 1+3 years upon the listing of new generics. In addition, under the volume-price linkage system, the applicable price reduction will be subject to a mitigation mechanism, with the mitigation ratio increased from the current 30% to 50%. As noted above, Innovative Pharmaceutical Companies will also be granted temporary allowances in connection with the phased price reductions applicable to already-listed drugs.

B. Quasi-Innovative Pharmaceutical Companies (From Second Half of 2026)

Quasi-Innovative Pharmaceutical Companies will receive a preferential reimbursement rate of 50% for a period of 1+3 years upon the listing of new generics and will be eligible for the temporary allowances applicable to already-listed drugs described above. To qualify, a company must meet specified thresholds for pharmaceutical R&D investment relative to pharmaceutical sales—5% for companies with annual revenues of KRW 100 billion or more and 7% for companies with annual revenues below KRW 100 billion. Companies that have been subject to administrative sanctions under the Pharmaceutical Affairs Act, Fair Trade Act, or Pharmaceutical Industry Promotion Act due to rebate-related violations within the past five years are excluded. This category did not exist under the November 2025 proposal and is newly introduced by the March 2026 reform.

C. Supply Stability Leader Companies (From Second Half of 2026)

Pharmaceutical companies for which either (i) the proportion of drugs designated under the Drug Shortage Prevention Program in their production portfolio or (ii) the proportion of such drugs in their total claims amount is 20% or more will be designated as Supply Stability Leader companies. Such companies will receive a preferential reimbursement rate of 50% for a period of 1+3 years upon the listing of new generics. This designation is also newly introduced by the March 2026 reform.

TABLE 2: Preferential Pricing for Newly Listed Generics by Company Type

Company Type		Current	Nov. 2025 Proposal	Mar. 2026 Reform
Innovative	Pricing	**68%**	68% (top 30%) 70% (bottom 70%)	60%
	Period	1+2+2 yrs – 1 year: base premium – 2 years: ≤3 suppliers – 2 years: subject to DREC* review	3+α yrs	1+3 yrs – 3 years: where domestically manufactured
Quasi-	Pricing			50%

Innovative	Period			1+3 yrs – 3 years: where domestically manufactured
Supply Stability Leader	Pricing			50%
	Period			1+3 yrs – 3 years: where domestically manufactured

(*DREC: Drug Reimbursement and Evaluation Committee)

TABLE 3: (Comparison) Preferential Pricing for Patent-Expired Originators

		Current	Nov. 2025 Proposal	Mar. 2026 Reform
Patent-Expired Originators	Pricing	70%	70%	70% (1 yr) → 60% (3 yrs)
	Period	1+2+2 yrs – 1 year: base premium – 2 years: ≤3 suppliers – 2 years: subject to committee review	3 yrs	1+3 yrs – 3 years: ≤3 suppliers or domestically manufactured

VII. Key Implications and Strategic Considerations

Portfolio Restructuring

In light of the policy direction toward lowering the base reimbursement rate, introducing measures to curb multi-product generic entry, and applying price reductions to already-listed drugs, the revenue base of generic-focused business models is expected to weaken. As a result, pharmaceutical companies are likely to accelerate portfolio restructuring efforts to secure sustainable growth drivers.

Increased Importance of Innovative Pharmaceutical Company Designation

In this environment, designation as an Innovative or Quasi-Innovative Pharmaceutical Company is emerging as both an opportunity to benefit from company-level incentives and an effective means of mitigating the impact of price reductions for already-listed drugs. Given the significant changes to the Innovative Pharmaceutical Company certification system, companies should promptly develop and implement strategies for obtaining or maintaining such designation.

Need for New Strategies to Address Price Reductions

With phased price reductions for already-listed drugs beginning in the second half of 2026, companies will need to assess whether certain products may be excluded from such reductions and consider alternative measures to mitigate the resulting impact. In addition, changes to the reimbursement appropriateness re-evaluation framework—particularly the reduced predictability and the removal of the option to maintain coverage through price reductions—will require a proactive response. Long-term preparation for the periodic price adjustment mechanism, including cross-country price comparisons, will also be necessary.

Opportunities to Enhance Access for Innovative Drugs

The government's policy direction toward expedited listing of innovative drugs, coupled with greater emphasis on post-listing management, presents opportunities to leverage early market access while preparing for subsequent evaluation. In particular, rare disease treatments may benefit significantly if selected for the 2026 pilot program. In addition, the upward adjustment of the ICER threshold is expected to expand access to reimbursement for high-cost innovative drugs, and the use of flexible pricing contracts is likely to increase.

Opportunities for Supply Stability-Related Incentives

Companies with products that may benefit from inclusion in the Drug Shortage Prevention Program should proactively consider such designation in light of the reform. In addition, companies should take advantage of available incentives relating to supply stability, including preferential pricing for national essential medicines using domestically sourced raw materials, directly manufactured drugs, and directly manufactured antibiotic injectables and pediatric drugs, as well as price increases to support supply stability and temporary exemptions from the volume-price linkage system.

VIII. Conclusion

The reform of Korea's drug pricing system is advancing under an accelerated timeline, with key measures—such as price reductions for already-listed drugs—set to take effect beginning in the second half of this year. The industry is therefore entering a period of significant and immediate change. Against this backdrop, companies will need to conduct a careful assessment of the regulatory landscape, identify opportunities amid the challenges, and respond strategically to the direction of reform.

How Shin & Kim Can Help

Shin & Kim's Healthcare Team comprises professionals with extensive experience across relevant government agencies—including the Ministry of Health and Welfare, Korea Health Industry Development Institute, Ministry of Food and Drug Safety, and Health Insurance Review and Assessment Service—as well as the pharmaceutical industry. The team provides comprehensive legal services across key areas of the pharmaceutical sector, including pricing, compliance, and Innovative Pharmaceutical Company certification.

In particular, Shin & Kim's Healthcare Team has been actively engaged in policy developments relating to the current reform and has conducted in-depth analysis and advisory work in this area. The team is well positioned to assist clients in managing risks and developing effective response strategies in connection with the evolving pricing framework.

If you have any questions regarding the reform or would like assistance in developing your response strategy, please contact Shin & Kim's Healthcare Team at any time.

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