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Korea's Innovative Pharmaceutical Company Certification System Undergoes Its Most Significant Overhaul Since 2012: Implications and Response Strategies

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I. Background

On March 26, 2026, the Ministry of Health and Welfare pre-announced draft amendments to the Enforcement Decree and Enforcement Rules of the Special Act on Support for the Pharmaceutical Industry (the "Special Act"), together with proposed revisions to the Administrative Notice governing Innovative Pharmaceutical Company ("IPC") Certification.

These proposed amendments represent the most significant overhaul of the IPC certification regime since its introduction in 2012 and are expected to mark a major inflection point for Korea's pharmaceutical and biotechnology industry.

Notably, on the same date, the Health Insurance Policy Deliberation Committee approved the "National Health Insurance Drug Pricing Improvement Plan," which places IPC certification at the center of Korea's drug pricing framework. Against this backdrop, the ability to obtain and maintain IPC certification is likely to become a critical strategic and regulatory priority for pharmaceutical companies.

In this newsletter, Shin & Kim's Healthcare Team analyzes the key aspects of the proposed amendments and outlines practical considerations for companies seeking to navigate the evolving certification landscape.

II. Key Proposed Amendments

A. Strengthened R&D Expenditure Requirements (Enforcement Decree, Art. 2-2(1))

The proposed amendments increase the minimum ratio of pharmaceutical R&D expenditure to pharmaceutical sales required for IPC certification eligibility. The revised thresholds are as follows:

- Companies with a three-year average pharmaceutical sales of less than KRW 100 billion: 9% of pharmaceutical sales (increased from 7%; the alternative threshold of at least KRW 5 billion in annual pharmaceutical R&D expenditure is eliminated).
- Companies with a three-year average pharmaceutical sales of KRW 100 billion or more: 7% of pharmaceutical sales (increased from 5%).
- Companies holding cGMP or EU GMP certification: 5% of pharmaceutical sales (increased from 3%), provided that the fact of holding such certification shall be evidenced by documents produced within the three years preceding the certification review.

[Table 1] Proposed Amendment to Pharmaceutical R&D Expenditure Ratio Requirements by Sales Tier

Category	R&D Expenditure as a Percentage of Pharmaceutical Sales	
	Current Requirement	Proposed Requirement
Three-year average pharmaceutical sales below KRW 100 billion	At least KRW 5 billion in annual pharmaceutical R&D expenditure, OR 7% or more of pharmaceutical sales	9% of pharmaceutical sales
Three-year average pharmaceutical sales of KRW 100 billion or more	5% of pharmaceutical sales	7% of pharmaceutical sales
Holders of cGMP or EU GMP quality certification	3% of pharmaceutical sales	5% of pharmaceutical sales

While the amendments will generally take effect upon promulgation, the increased R&D expenditure thresholds will become effective after a three-year transition period. The revised thresholds will apply to all new certification applications and renewal applications submitted on or after the effective date.

B. Revised Evaluation Criteria for IPC Certification

The proposed amendments introduce a significantly revised evaluation framework for IPC certification, reflecting a shift toward greater transparency, objectivity, and policy alignment. The number of evaluation items has been reduced from 25 to 17, and the maximum total score has been adjusted from 120 to 100 points. At the same time, several key criteria—including R&D investment, clinical trial activity, and pharmaceutical export performance—have been converted from qualitative assessments to quantitative metrics, thereby reducing evaluator discretion and enhancing predictability in the certification process.

In addition, the proposed amendments introduce a new evaluation category for corporate social responsibility, including activities that contribute to the stabilization of the pharmaceutical supply chain. The minimum passing score of 65 points has also been expressly codified, and authorities are now required to provide written notice specifying the

grounds for rejection in cases where certification is denied.

[Table 2] General Innovative Pharmaceutical Company Evaluation Criteria

Category	Assessment Item	Sub-Item	Points	
			General IPC	Sub-total
Input Resources Excellence (30 pts)	R&D Investment	① Total scale of pharmaceutical R&D investment	6	20
		② R&D investment as a percentage of total pharmaceutical sales	4	
		③ Attraction of external pharmaceutical R&D investment and related performance	10	
	Research Personnel	① Excellence of research personnel organization and composition	5	5
	Research & Production Facilities	① Investment in and construction of research and production facilities (equipment)	5	5
R&D Activity Innovation (30 pts)	R&D Strategy	① R&D vision and medium-to-long-term strategic plan	5	10
		② Appropriateness of medium-to-long-term plans	5	
	Alliance & Collaboration	① Domestic and international university, research institute, and corporate alliances; open innovation in R&D	8	8
	Pre-clinical Candidates & Clinical Trials	① Number of clinical trials by development stage	5	12
		② Innovation of the R&D project portfolio	7	
Technology & Economic Performance Excellence (25 pts)	Pharmaceutical Patents & Technology Transfer	① Excellence of proprietary technologies and patent strategy	3	8
		② Excellence of pharmaceutical and platform technology transfer results	5	
	Overseas Pharmaceutical Expansion	① Scale of pharmaceutical exports	5	12
		② Excellence of overseas expansion capabilities and performance	7	
	Domestic Distribution of Innovative	① Excellence of innovative pharmaceutical development and distribution results	5	5

	Pharmaceuticals			
Social Contribution & Responsibility (15 pts)	Social Responsibility	① Excellence of CSR activities contributing to pharmaceutical supply chain stabilization	10	10
	Corporate Transparency & Ethics	① ESG management, efforts to secure managerial ethics and transparency	5	5
TOTAL			**100**	**100**

C. New Certification Category for Foreign-Invested IPC

The proposed amendments introduce a new certification category specifically for foreign-invested pharmaceutical companies, accompanied by tailored evaluation criteria that reflect the operational characteristics of such entities. Under this framework, greater weight is assigned to factors such as the ownership of research and production facilities and open innovation activities, including the attraction of foreign capital, joint research, and cross-border R&D collaboration. Foreign-invested pharmaceutical companies may elect to apply under either the general IPC certification criteria or the criteria for foreign-invested IPC, depending on which framework is more advantageous in light of their operational profile.

[Table 3] Comparative Evaluation Criteria: General vs. Foreign-Invested Applicants

Category	Assessment Item	Sub-Item	Points	
			General	Foreign-Invested
Input Resources Excellence (General: 30 pts / Foreign-Invested: 33 pts)	R&D Investment	① Total scale of pharmaceutical R&D investment	6	6
		② R&D investment as a percentage of total pharmaceutical sales	4	4
		③ Attraction of external pharmaceutical R&D investment and related performance	10	10
	Research Personnel	① Excellence of research personnel organization and composition	5	5
	Research & Production Facilities	① Investment in and construction of research and production facilities (equipment)	5	-
		① Ownership of research and production facilities (equipment)	-	**8**
R&D Activity Innovation	R&D Strategy	① R&D vision and medium-to-long-term strategic plan	5	5

(General: 30 pts / Foreign-Invested: 32 pts)		② Appropriateness of medium-to-long-term plans	5	5
	Alliance & Collaboration	① Domestic and international university, research institute, and corporate alliances; open innovation in R&D	8	-
		① Attraction of foreign capital, joint research, and open innovation for R&D	-	12
	Pre-clinical Candidates & Clinical Trials	① Number of clinical trials by development stage	5	5
		② Innovation of the R&D project portfolio	7	5
Technology & Economic Performance Excellence (General: 25 pts / Foreign-Invested: 20 pts)	Pharmaceutical Patents & Technology Transfer	① Excellence of proprietary technologies and patent strategy	3	-
		① Excellence of technologies and patents	-	2
		② Excellence of pharmaceutical and platform technology transfer results	5	3
	Overseas Pharmaceutical Expansion	① Scale of pharmaceutical exports	5	5
		② Excellence of overseas expansion capabilities and performance	7	5
	Domestic Distribution of Innovative Pharmaceuticals	① Excellence of innovative pharmaceutical development and distribution results	5	5
Social Contribution & Responsibility (15 pts)	Social Responsibility	① Excellence of CSR activities contributing to pharmaceutical supply chain stabilization	10	10
	Corporate Transparency & Ethics	① ESG management, efforts to secure managerial ethics and transparency	5	5
합계			100	100

D. Rebate Compliance and Certification Strategy

The proposed amendments introduce significant revisions to the rebate-related certification criteria, warranting close attention from industry participants. Under the current framework, administrative dispositions imposed more than five years prior to a certification renewal review are excluded from consideration. The proposed amendments modify this approach by shifting the reference point from the date of the administrative disposition to the date on which the underlying rebate violation concluded. As a result, violations that concluded more than five years prior to the relevant certification review—whether initial or renewal—will no longer be taken into account. This approach appears to align

with the broader legislative framework under Article 23 of the Framework Act on Administration, which provides that administrative sanctions may not be imposed once five years have elapsed from the date a violation has ceased.

The amendments also eliminate the existing rule under which, where litigation is initiated in connection with a rebate-related administrative disposition, the date on which the court judgment becomes final and conclusive is deemed to be the date of the disposition. In addition, a new provision permits certification (or renewal) to be granted on a conditional basis where an administrative appeal or administrative litigation is pending, subject to revocation within one year following any adverse final determination.

[Table 4] Revisions to Rebate-Related Certification Criteria

Issue	Current Rule	Proposed Amendment
Exclusion threshold	Administrative dispositions imposed more than five years prior to a certification renewal review are excluded from consideration.	Rebate violations that concluded more than five years prior to an initial or renewal certification review are excluded from consideration.
Treatment of judgment date as disposition date	Where litigation is filed in connection with a rebate-related administrative disposition, the date on which the court judgment becomes final and conclusive is deemed to be the date of the disposition.	This provision is deleted.
Conditional certification pending administrative litigation	No applicable provision.	Where an administrative appeal or administrative litigation is pending in connection with a rebate-related administrative disposition, certification (or renewal) may be granted on a conditional basis, subject to revocation within one year following any adverse final determination.

III. Key Takeaways and Recommended Action Items

- **Response to Enhanced R&D Investment Requirements.** In light of the increased R&D expenditure thresholds, companies should promptly reassess their R&D strategies to ensure compliance within the three-year transition period following promulgation of the amended regulations. This may require not only increasing overall investment levels but also reallocating resources to enhance efficiency and strategic impact. In particular, companies should consider leveraging open innovation models—such as collaborations with domestic and international biotech ventures—to improve both the quality and productivity of their R&D investments.

- **Response to Changes in Evaluation Criteria.** As the importance of IPC certification continues to grow, competition among applicants is expected to intensify. Companies that proactively align their operations with the revised evaluation criteria—through systematic performance tracking and robust documentation—will be better positioned, while those that do not may face increasing competitive disadvantage. The introduction of a distinct evaluation category for social responsibility, including contributions to pharmaceutical supply chain stability, also reflects an expanded regulatory focus beyond traditional R&D capabilities. Companies should therefore consider adopting a more integrated approach that addresses both innovation capacity and broader public interest contributions.
- **Implications for Foreign-Invested Pharmaceutical Companies**. The proposed amendments reflect a bifurcated policy approach. Domestic companies are expected to demonstrate independent innovation capabilities, while foreign-invested pharmaceutical companies are evaluated based on their tangible contributions to the Korean pharmaceutical ecosystem. Historically, the certification regime has been viewed as presenting relatively high entry barriers for multinational companies. The introduction of a dedicated certification track for foreign-invested entities is therefore expected to lower these barriers and facilitate broader participation. Eligible foreign-invested companies should actively consider whether certification under the revised framework aligns with their strategic objectives.
- **Response to Revised Rebate-Related Eligibility Criteria.** The revisions to the rebate-related certification criteria are intended to enhance predictability and legal certainty and may mitigate the impact of long-standing compliance issues on certification eligibility. While the existing requirements remain unchanged—namely, that, during the three years preceding the certification or renewal review, there must not be more than one rebate-related administrative sanction and the aggregate value of any economic benefits provided must be below KRW 5 million—the amendments introduce several important changes. In particular, the rule treating the date of final court judgment as the date of administrative disposition has been removed, and violations that concluded more than five years prior to the certification review will no longer be considered. Companies should therefore consider undertaking a comprehensive review of historical compliance matters and reassessing their certification strategies accordingly.

IV. How Shin & Kim Can Help

Of the 48 companies currently maintaining IPC certification, five are scheduled to reach the end of their certification period on November 29, 2026. Together with starting the renewal reviews for these companies, the government may create an opening for additional applicants to enter the certification regime. Given the time required for application preparation and regulatory review, the process of securing certification under the revised framework is already underway, and companies should begin preparing accordingly.

Shin & Kim's Healthcare Team brings together professionals with experience at key regulatory authorities, including the Ministry of Health and Welfare, the Korea Health Industry Development Institute, the Ministry of Food and Drug Safety, and the Health Insurance Review and Assessment Service, as well as industry compliance specialists and practitioners experienced in handling rebate-related investigations and enforcement actions in both criminal and administrative contexts. The firm is well positioned to provide comprehensive legal support in connection with both the acquisition and maintenance of IPC certification. We would be pleased to discuss these developments and their implications for

companies navigating the IPC certification framework.

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