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KOREA'S DRUG PRICING POLICIES IN 2023

In 2023, major drug pricing policy changes are expected to be made to **reinforce the reimbursement coverage of innovative drugs and the drug prices follow-up management system**. BKL Healthcare Team reviewed the relevant policy trends and changes in laws and regulations and analyzed the considerations for pharmaceutical companies. Below is a summary of the latest major changes and developments in this field.

A. Ministry of Health and Welfare: "We Will Strengthen the Coverage of Innovative Drugs"

1. Expanding the Scope of the Risk Sharing Agreement

Even if it is not a rare disease treatment, any "medicine that results in clinically meaningful improvements in the quality of life" is expected to be covered by the risk-sharing agreement (the "**RSA**") in recognition of its innovativeness. In a recent public hearing held in the National Assembly, the Ministry of Health and Welfare (the "**MoHW**") announced such direction of revising the drug pricing system.

This is the result of efforts made by the ongoing "Paying for Innovation" public-private discussion group (the "**Discussion Group**"), and it is highly likely that the relevant regulations will be amended during the first half of 2023. The Discussion Group is composed of the MoHW, the Health Insurance Review and Assessment Service (the "**HIRA**"), the National Health Insurance Service (the "**NHIS**"), and three pharmaceutical associations: Korean Research-based Pharmaceutical Industry Association, Korea Biomedicine Industry Association, and Korea Pharmaceutical and Bio-Pharma Manufacturers Association. The Discussion Group has met at five (5) bi-weekly meetings since January and discussed ways to better reward innovative new drugs.

The Discussion Group was formed as the MoHW announced that it would strengthen the coverage of drugs if they are deemed sufficiently innovative in the wake of the short supply of acetaminophen in Korea. It is noteworthy that the Korean government is taking the initiative in seeking to improve the regulatory framework related to the drug pricing system.

2. Implementation of Three Linked Steps: License, Evaluation and Negotiation

The NHIS has added an additional step of drug price negotiation to its current linked system of license and evaluation. In this new system, the three processes are being simultaneously carried out, which is expected to reduce the time required for the listing of new drugs.

The license-evaluation-negotiation system is scheduled to start as a pilot project in the first half of 2023, for drugs (i) that are used by patients with a shorter life expectancy of six months to one year, (ii) that have a few patients, and (iii) that have no alternative medications and have sufficient improvement effects. Since details of the pilot project are not yet fixed, one possibility is that a pharmaceutical

company first offers to the HIRA or the MoHW to apply the pilot project to any drugs that meet some (if not all) of the foregoing requirements.

In order for the system to be successfully implemented, it is necessary to share the review results by the HIRA with the NHIS one or two weeks prior to the meeting of the Drug Reimbursement Evaluation Committee. Hence, the review period at the HIRA level is expected to be shorter than before.

B. HIRA's Tightening Management of High-Priced Drugs

1. Tightening the Management of High-Priced Drugs

The HIRA formed the New Drug Performance Management Department in last July and established the High-Priced Drug Management System at the end of last year. Both were designed to provide an efficient follow-up management of drugs to which the performance-based refund RSA type applies.

Starting with Kymriah, drugs to which the performance-based RSA type apply were newly listed in Korea in 2022. In the future, the Korean government is expected to utilize"performance-based refund type" more to manage drug prices in order to reduce the financial impact caused by high-priced drugs.

Performance results produced by the High-Priced Drug Management System will be used to calculate the amount of refunds to be paid by pharmaceutical companies. If the performance of a drug is not satisfactory, the pharmaceutical company will have to refund certain expenses to the NHIS as agreed under a contract. When applying one or more typesof RSA, including performance-based refund, it is important that the agreement be duly executed upon legally reasonable terms and conditions with respect to the contract period, the amount of refund, and the procedure for reporting the performance result.

2. Amending the HIRA Regulations (Effective from January 2023)

The HIRA's internal regulation, the Regulations on Standards and Procedures for Evaluation of Drugs, was amended as of January 1, 2023. The key amendments are as follows:

a. Canada was added to the drug price reference country list, which now has eight countries, the U.S., the U. K., France, Germany, Switzerland, Japan, Italy, and Canada to refer to in evaluating a new drug price. In addition, detailed calculation method, including the calculation of the exchange rate, was revised.

   It is meaningful that the calculation method was eventually revised in 20 years, but the MoHW announced a plan to use foreign countries drug prices as a criterion for the re-evaluation of drug prices, which is causing concern among pharmaceutical companies. As the MoHW is scheduled to announce the scope and standard of drug price reduction this year, we should continue to pay attention to their announcement.

b. The economic evaluation may now be omitted for any "drug used for children and proven clinically to meaningfully improve the quality of life."However, since it is now the prerequisite that the number of patients be small, there is concern that the scope is reduced anyway. The HIRA's position is that it would utilize the deliberation of the Drug Reimbursement Evaluation Committee to flexibly apply the standard for the number of patients.

3. Actual Transaction Price System

Biannually, the HIRA has implemented the actual transaction price (the "**ATP**") system, in which if the actual price of the drug distributed is lower than the listed price, the drug price is reduced to the actual price level. The biannual implementation of the ATP system has resulted in repeated reduction of the drug price, and the industry has continuously demanded improvement.

As a result, the HIRA had a research conducted last year in an effort to improve the ATP system and the research results were announced this month. As a short-term improvement to the current system, it is proposed to remove the upper limit of the discount rate of 10%, while setting a buffer zone of 1-2%, and to reflect the low purchase price of national or public hospitals in the calculation of a drug price reduction. However, applying the low purchase price of national or public hospitals is unlikely to be acceptable in policy, and it is suggested that reducing the incentive payment to national or public hospitals could be considered as an alternative.

The biannual ATP system is scheduled to be implemented in 2024. It is expected to be difficult to apply the new standards from next year to reflect the results of the research. As Korea currently operates several drug price follow-up management systems, it will be necessary to discuss on whether to further strengthen the ATP systems with various stakeholders.

C. National Health Insurance Service on Revision of the PVA System

1. Revising the PVA System

The NHIS will revise the price-volume agreement ("**PVA**") system, one of the follow-up drug price management systems, in the second half of 2023. The main point of the revision is to categorize claimed amounts into three sections and apply a higher rate of reduction to a larger amount of claim and a lower rate of reduction to a smaller amount of claim. Therefore, the maximum reduction rate that applies to the formula will be higher than the current 10%.

Currently, if the claim amount increase by 30% or more than the expected amount as agreed with the NHIS, the drug price is reduced through negotiation. Under the revised system, if the amount of claim increases by more than 10% and is KRW 5 billion or more, the drug price will be negotiated.

The system will be revised in the second half of this year, and the revised system will be implemented next year. Any products with a claim amount of KRW 50 billion or more are expected to be directly affected by the revision of the system. However, as the system will be revised based on the results of the research conducted in 2022 by NHIS, when the results of the research are disclosed, the validity and timing of the new formula should be actively discussed by the working group to be formed in May.

2. Shortening the Negotiation Period (Effective January 23)

For the drugs which omit the economic evaluation, the period of drug price negotiation will be shortened from 60 days to 30 days. This expedited listing process is designed to increase access to treatment for patients with severe or rare diseases and will enable the expected claim amount and the

drug price to be discussed in advance of the main negotiation.

However, pharmaceutical companies should not overlook that they have to apply for an expedited registration process when they submit documents to the HIRA. If an expedited registration process fails to be applied upon submission of documents to the HIRA, the negotiation period will not be shortened. Another important point is that any matters agreed during the prior discussion cannot be changed in the main negotiation.

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For any inquiry or questions regarding the content of this newsletter, please contact us. We will update you on changes and developments in the drug pricing system on a quarterly basis.

BKL Healthcare Team

Related Professionals

Won Kyu (John) Choi
Senior Foreign Attorney
T 82.2.3404.0251
E wonkyu.choi@bkl.co.kr

Soo Jin Huh
Partner
T 82.2.3404.6436
E soojin.huh@bkl.co.kr

Hyo Jun An
Partner
T 82.2.3404.6409
E hyojun.an@bkl.co.kr

Yoon Hee Choi
Expert Advisor (Former head of team at HIRA)
T 82.2.3404.1074
E yoonhee.choi@bkl.co.kr