GR Korea healthcare newsletter

# The NA audit for biopharma:

## Key issues & what to expect

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### Summary of the 2023 Health and Welfare Committee's Parliamentary Audit

The 2023 National Assembly Health and Welfare Committee's Parliamentary Audit (hereinafter referred to as the 'Parliamentary Audit') ran from 11 to 25 October. Key issues highlighted included management plans for formalizing telehealth oversight, as well as challenges related to essential medical care, regional medical crises, and a widespread shortage of pediatricians that the incumbent Yoon Suk-yeol administration had promised to resolve.

In addition, the status quo and solutions for other policy issues such as the expansion of medical school enrollment quota, establishment of public medical schools, and introduction of a regional doctor system were also discussed.

Additionally, criticisms of the government's inadequate response to the recently emerging issues with mental health and drug addiction, as well as advisories for monitoring new infectious diseases threats, improving the monitoring systems of healthcare facilities, and providing support for mandatory vaccinations were raised.

**As such, it will be important to closely monitor how various issues brought up during the 2023 Parliamentary Audit are reflected in the regulatory framework moving forward.**

## Bio-health Innovation Commission

**Furthermore, noteworthy government policies for the pharmaceutical and biotech industries have recently begun to take shape.**

**Below is a brief summary :**

A new inter-agency body - called the “Bio-health Innovation Commission” - was formed recently. This committee functions as a body responsible for overseeing and streamlining biopharma sector promotion policies scattered across various ministries. The formation of this committee was proposed and announced during a strategy meeting chaired by President Yoon Suk-yeol in February 2023, as part of his administration’s aim of Korea becoming a global centre for bio-health.

Following the committee’s official launch on 17 October 2023, the committee held its first meeting on 22 December, chaired by Prime Minister Han Duck-soo. During this meeting, various discussions took place regarding fundamental changes to be made by 2024 in areas such as biopharma innovation R&D and the easing of regulatory barriers to healthcare industry innovation. Specifically, the meeting discussed concrete measures to resolve key regulatory hurdles, such as ensuring the rapid on-site use of innovative medical devices and guaranteeing the innovative value of new drugs.

## The 2nd Comprehensive National Health Insurance Plan

Research findings regarding the “2nd Comprehensive National Health Insurance Plan” (hereinafter referred to as the Comprehensive Plan), which outlines the direction of health insurance policy for the next five years starting from 2024, were published on 19 October 2023.

During a policy symposium held on the same day, particular attention was paid to the direction of drug pricing policies as part of the management of health insurance expenditure. Concerns were raised about the Comprehensive Plan’s drug pricing policies’ emphasis on unilateral price reduction measures, as this could pose a threat to the growth of the pharmaceutical industry. Experts also recommended that the government devise drug pricing policies that would facilitate a transition in the local pharmaceutical industry from the existing generics production-focused model, to one that encourages greater investment in the creation of novel drugs.

**Therefore, it will be necessary to continue to keep an eye on how these concerns are addressed and incorporated in the forthcoming final Comprehensive Plan.**

## Proposal for Improving the Drug Pricing System to Ensure Fair Compensation for Innovative Value

In another notable development, a policy proposal to improve the drug pricing system to reflect the innovative value of new drugs, which is being pursued under the Yoon administration, was introduced.

This “Proposal for Improving the Drug Pricing System to Ensure Fair Compensation for Innovative Value” was developed as a consensus of a public-private advisory group, over the period from January to June 2023. It was first discussed by the Health Insurance Policy Deliberation Committee under the Ministry of Health and Welfare in November 2023, before being published at the meeting of the Prime Minister’s Bio-health Innovation Commission on 22 December 2023.

The proposal is primarily intended to incentivize innovative drug development by domestic companies. Accordingly, key points of this proposal include: ▲flexible application of the ICER (Incremental Cost-Effectiveness Ratio) threshold for innovative new drugs ▲favorable pricing for new drugs from innovative pharmaceutical companies ▲application of a risk-sharing mechanism for the treatment of chronic diseases ▲allowing for dual pricing of domestically developed new drugs.

**In the future, this is expected to have a particularly positive impact on domestic pharmaceutical companies that invest substantial R&D costs in the development of novel drugs. On top of this, there would also be flexibility in the evaluation of innovative drugs from abroad, which would in turn lead to their rapid introduction on the domestic market.**

**After reviewing this summary of the key policies set to be finalized and implemented from 2024 and onwards, we encourage you to closely monitor these developments and consider taking appropriate measures where necessary.**

## Second phase drug candidates for the accelerated new drug access pilot project

The process of adding a new drug to Korea's national insurance system reimbursement list is known to be complex and time-consuming. To address this issue, several measures have already been implemented. One such measure, a pilot program starting from the second half of 2023 was launched to shorten the inclusion period for high-cost treatments that target chronic diseases, such as cancer and rare diseases. This program integrates reimbursement evaluation and pricing negotiations starting from product approval application stage with the Ministry of Food and Drug Safety.

The approach could significantly reduce the delay between product approval and when a drug can be prescribed in clinical practice. Health authorities are expediting their efforts to implement this program, as rapid listing and expansion of reimbursement are key elements of the Yoon administration's policy platform.

On 26 June 2023, the Ministry of Health and Welfare selected Qarziba (dinutuximab beta) and Bylvay (odevixibat), two rare pediatric disease treatments, as the first target drugs for the pilot project. Additional secondary drugs will be selected soon based on a demand survey from the second half of 2023. Currently, Novartis' Pluvicto (lutetium Lu-177 vipivotide tetraxetan) and Sanofi's Cablivi (caplacizumab-yhdp) are mentioned as key candidates for inclusion.

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