



GR Korea healthcare newsletter

# The 22<sup>nd</sup> General Election:

## Results & impacts for biopharma

April 2024

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### The 22<sup>nd</sup> General Election pledges on healthcare and the projections

On April 10, the 22<sup>nd</sup> General Election was held, with many pledges related to the biopharma industry from both the ruling and opposition parties. This testifies to the fact that there is now a bipartisan consensus on the importance of the domestic biopharma industry in the wake of COVID-19. Industry stakeholder have responded favorably to this consensus, believing such policy support will go a long way in helping the domestic industry leapfrog into overseas markets.

While pledge wording and focus varied slightly between the ruling and opposition parties, both ultimately agreed that the overall direction for improving treatment for chronic, rare and intractable diseases should focus on reducing patient burden, e.g., by expanding health insurance coverage and enhancing access to treatments.

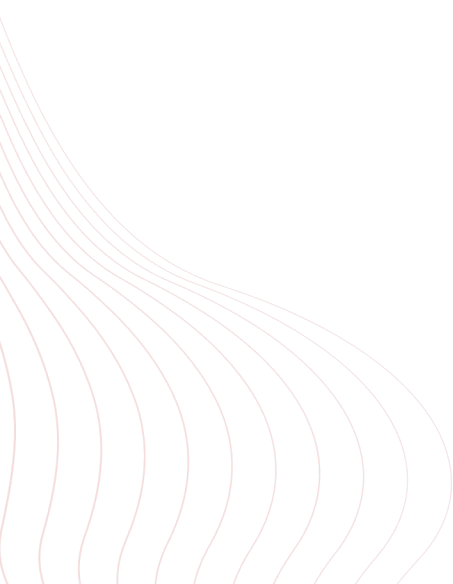
In particular, attention is focused on the realization of the promises made by the main opposition Democratic Party of Korea (DP), which will hold an absolute majority of over 170 seats in the National Assembly (NA) for the next four years. With the ultimate goal of transforming Korea into a global biopharmaceutical powerhouse, the DP promised to increase R&D investment and introduce a customized pricing system suitable for facilitating global market entry, signaling its

willingness to promote domestic industries. The DP also mentioned establishing a public big-data platform and applying AI to new drug development. In particular, as improvement of the drug pricing system has been a long-standing issue in the industry, expectations among industry stakeholders are now growing on the implementation of this promise.

Additionally, the DP, along with its satellite party, the Democratic Party Alliance, have publicly promised reimbursement for 'advanced robotic surgery' that has been proven to be effective in treating diseases such as prostate cancer. Moreover, the DP also pledged to strengthen management of diseases that have not been addressed often in policy, such as improving the national health checkup program to eradicate Hepatitis C, increasing support for people with Type I diabetes, and enhancing public awareness of pediatric obesity and diabetes. These commitments, which are expected to benefit some pharmaceutical companies, necessitate close monitoring to see how they will be implemented into specific policies.

Finally, **the future composition of the NA Health and Welfare Committee (HWC) in the 22<sup>nd</sup> National Assembly could also be a factor in healthcare policy.** Among incumbent members of the HWC, while 6 DP NA members (Kang Sun-woo, Kim Min-seok, Kim Won-soon, Nam In-soon, Seo Young-seok, and Han Jeong-ae) who ran for their seats have managed to win and return to the NA for another 4-year term, only 2 NA members (Kim Mi-ae and Baek Jong-heon) from the ruling People Power Party (PPP) have managed to retain their seats.

There are some NA member-elects with medical backgrounds with a high possibility of being appointed to the HWC, such as DP NA members-elect Kim Yoon and Jeon Jong-deok, Reform Party NA member-elect Lee Ju-young, PPP NA members-elect In Yo-han and Han Ji-ah, and Rebuilding Korea Party NA member-elect Kim Sun-min. However, they are all proportional representatives and **many of the NA members-elect from opposition parties are expected to focus on public healthcare, meaning their views on the aforementioned issues may vary,** making this another important element for close monitoring.





On 4 April, the second meeting of the Bio-health Innovation Committee since its founding was held to review implementation progress on bio-health policies, and to discuss further how to further promote bio-health innovation via regulatory easing.

In particular, while evaluating plans to ease regulations, the committee first discussed how to improve 8 out of the 20 policy areas identified at the first meeting in December 2023, and decided to open a 'Regulatory Reform Platform' at the Korea Health Industry Development Institute (KHIDI) to proactively listen to voices in the field and work to remove unnecessary regulatory hurdles. KHIDI will establish both online and offline feedback channels and will discuss possible solutions jointly among biopharma firms, relevant ministries, and industry associations as a 'One-stop Regulatory Solution.'

The government has announced that it will actively address the backlog of challenges through this committee, and that it will serve as a control tower for public-private and cross-ministrial partnership. It will be necessary to monitor how the committee's remit to regulatory reform will play out in the future.

## **Public-private partnerships for bio-health as a future growth engine**

### **MFDS's Regulatory Innovation Task 3.0 to be released in May**

The Ministry of Food and Drug Safety (MFDS) has announced that it will soon unveil its Regulatory Innovation Task 3.0, following both its '100 tasks' with the inauguration of President Yoon Seok-yeol in 2022, and the Regulatory Innovation Task 2.0 launched in 2023.

To date, regulatory innovation tasks in general have mainly focused on supporting new technologies, improving public welfare, implementing international standards harmonization, and revamping procedural regulations. In 2022, practical challenges within the pharmaceutical industry took center stage, while in 2023, the focus was on improving regulations for emerging industries such as AI-based medical devices and digital healthcare, in addition to proposals for improving regulations to reflect evolving industry conditions.

For the upcoming announcement, MFDS has been extraordinarily cautious, only stating that relevant departments are reviewing proposed items. Therefore, industry stakeholders are paying close attention to which tasks might be included in the next agenda for deregulation. The announcement is expected to be made by late May at the latest.

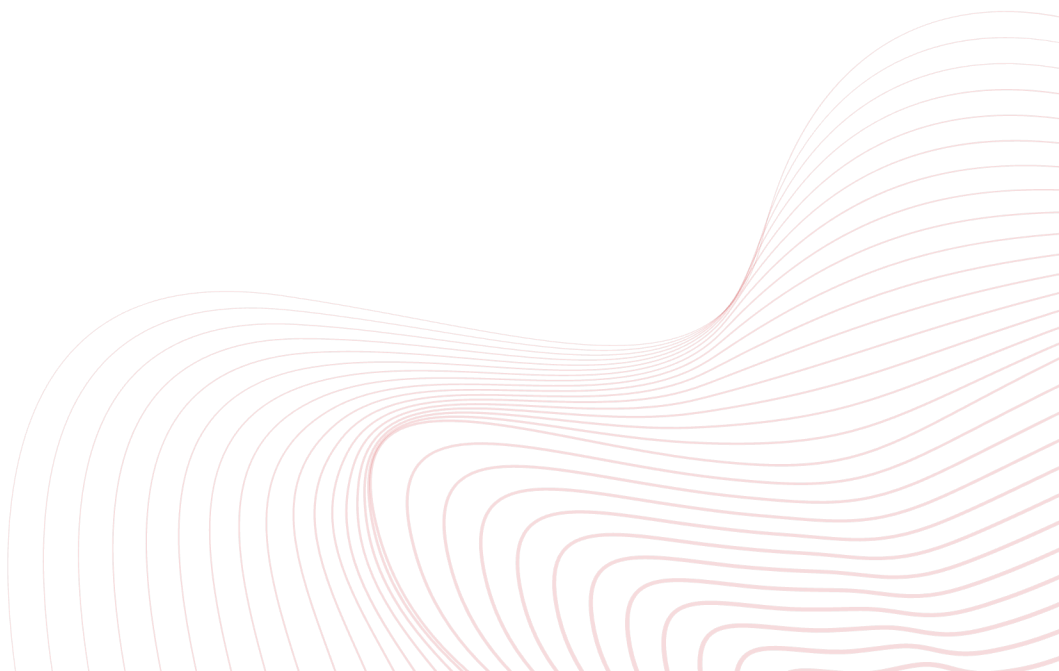


## President Yoon's Advanced Bio Initiative

At the 24<sup>th</sup> Civil Debate held on 26 March, President Yoon Seok-yeol emphasized 'advanced bio' as one of the key game-changer technologies expected to change the future and indicated intent to gather opinions from experts in industry, academia, and research institutes with the goal of announcing an 'Advanced Bio Initiative' to build Korea into a global biopharma powerhouse this July.

In this regard, the Presidential Advisory Council on Science and Technology (hereinafter referred to as the Council) recently announced that on 25 April, it had deliberated and approved an initiative containing the vision and strategy for the development of three game-changing technologies (AI-based semiconductors, advanced bio, and quantum). The Council emphasized that competition for market leadership in these core strategic technologies is intensifying, and therefore initiatives with specific directions are essential to enter the top three global (G3) countries by 2030 in these sectors.

In particular, the Advanced Bio Initiative aims to make Korea a global market leader by 2035 through specific plans such as investing in new platforms, strengthening the bio value chain, and combining innovation-based technologies with data. Specifically, the government plans to foster digital bio as the key industry driver, convert the petrochemical-based material industry to one based on biochemicals, e.g., via building a biofoundry (an advanced biotechnology based on synthetic biology), secure innovative medical technology, and address global crises such as climate change and infectious diseases. To this end, the government will first focus on incubating human resources, creating an ecosystem and infrastructure, and amending relevant regulations.





## The 3<sup>rd</sup> and 4<sup>th</sup> DTx devices getting product approval

The third and fourth digital therapeutic (DTx) devices in Korea were recently approved by the Ministry of Food and Drug Safety (MFDS). The third DTx device, called Vivid Brain (NewNapse), provides visual perception learning training for patients with vision disorders caused by brain diseases, and the fourth DTx device, EasyBreath (Share&Service), provides customized breathing rehabilitation training for patients with chronic obstructive pulmonary disease, asthma, lung cancer, etc. As the indications covered by DTx devices have thus been expanded beyond simply insomnia, the industry is anticipating faster DTx market expansion moving forward.

Both approved products are software-based medical devices that provide tailored interventions based on proven practices. Market entry and integration into clinical practice was achieved quickly due to close support from MFDS from development to clinical trial design stages, in line with the ministry's 'Integrated Review and Evaluation System for Innovative Medical Devices' implemented in October 2022.

"This approval is an example of how DTx can be utilized not only to treat diseases but also disabilities," said Oh Yoo-kyung, Minister of MFDS. "We expect that DTx can help improve the quality of life of patients suffering from diseases or disabilities." She emphasized that MFDS will continue to lay a solid regulatory support groundwork, by setting preemptive standards and working to accelerate launch and commercialization of DTx products.

Data has been cited as a key growth driver for the digital bio industry, as evidenced by the recent approval of the data-based DTx device WELT-I (a device for relieving insomnia symptoms). In response to the demands for high-quality bio data, the Ministry of Science and ICT (MSIT) established the 'Bio-Health Data Platform Council' on 16 April to begin building a data platform customized for researchers to create data-driven value on this front.

MSIT plans to actively utilize this council as a channel for public-private partnerships and collaboration in the future. The government also shared its plans to first aggregate the scattered data and improve its quality, ultimately operating a comprehensive bio-health data platform with greater security and convenience for data sharing, analysis, and utilization.

**Data platform  
co-developed  
with the public  
& private sector**



## Gridlock on negotiation for medical school enrollment quota

Following up our fourth issue, the below is the current situation on the government's announcement to expand medical school quota.

On 19 April, the government took a step back by announcing that the medical school quota for next year could be reduced from 2,000 to up to 1,000 through "autonomous adjustment of quota by schools". However, the medical community, including medical school deans, professors, and medical associations, rejected the proposal, bringing the conversation back to square one. Add to that the resignations of medical school professors starting 25 April, and the impact on patients from the gaps in care will be even greater. We sincerely hope that the parties can find a dramatic resolution soon.

Contact us to know more of Korea's latest healthcare policies

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