

# NEWSLETTER

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Healthcare / Life Sciences Group

## CONTACT



**Jin Hwan Chung**

T: +82,2,772,4711  
E: [jinhwan.chung@leeko.com](mailto:jinhwan.chung@leeko.com)



**Keum Nang PARK**

T: +82,2,2191,3036  
E: [keumnang.park@leeko.com](mailto:keumnang.park@leeko.com)



**Hyun Ah SONG**

T: +82,2,772,4903  
E: [hyunah.song@leeko.com](mailto:hyunah.song@leeko.com)



**Eileen Jaiyoung SHIN**

T: +82,2,772,4831  
E: [eileen.shin@leeko.com](mailto:eileen.shin@leeko.com)

## The New Administration's Policy Outlook for Healthcare / Life Sciences

With the inauguration of Yoon Seok-yeol as the 20<sup>th</sup> president of Korea scheduled to take place on May 10, 2022, the Presidential Transition Committee (the **Committee**) announced 110 national initiatives for the new administration (the **Initiatives**) on May 3, 2022. In connection with national healthcare, (1) improvement and sophistication of countermeasure against pandemics, (2) stimulation of digital health and bio industries, (3) expansion of essential medical services and alleviation of medical cost burdens, and (4) strengthening of preventive health management are included in the Initiatives.

### ■ Improvement and Sophistication of Countermeasure against Pandemics

It is understood that the designation of the improvement and sophistication of countermeasure against pandemic as a priority national agenda is to accelerate the nation's safe return to normal life and to prepare for the advent of any new pandemic disease. As the COVID 19 pandemic has highlighted the importance of the development of vaccines and therapeutics for pandemic diseases, the Committee announced that the new administration will establish a comprehensive plan to improve the development track for pandemic disease vaccines and therapeutics through the reform of relevant regulations.

### ■ Digital Health

Special attention should be paid to the Initiative for stimulation of digital health. The digital health sector, characterized as a combination of medical services, drugs, medical devices and ICT (information and communication technology) fields, is one of the fastest growing industries in the world. Korean companies are key players in the global IT industry and the Korean government has accumulated in the past decades a huge mass of comprehensive personal health information through its national health insurance system. These forces working together has the potential to provide industry players (both Korean and foreign) a tremendous growth opportunity for their digital health businesses. It is anticipated under the Initiatives that for the promotion of the digital health sector, the Ministry of Health and Welfare, as well as

the Ministry of Trade, Industry and Energy and the Ministry of Science and ICT will coordinate in introducing new government policies and providing support through necessary regulatory reform. Lee & Ko can provide clients with a true one-stop service based on deep insight and expertise of multidisciplinary team on all legal, regulatory and policy issues in the digital health sector.

#### ■ **Bio**

The continued growth of the bio industry is also included among the Initiatives. The Committee specifically mentioned that the new administration will build a global bio campus in Korea to promote the bio industry, and set up a mega fund to stimulate the development of innovative bio products. Further, the Committee stated that the new administration will redesign the relevant regulatory framework so as to increase the coherence of government regulation as well as foreseeability in the market, and establish a support system that is coherent with the development cycle and approval phases of a product so that companies can more efficiently introduce products to the market.

#### ■ **Expansion of Essential Medical Services and Alleviation of Medical Cost Burdens**

The Initiative for expanding essential medical services and alleviating medical cost burdens is aimed at achieving universal increase of nation's welfare. For this agenda, the Committee stated that the new administration will introduce a fast-track system under which severe or rare disease patients will have an easier and faster access to treatments for their disease with less financial burdens. In this regard, it is expected that rare and severe diseases therapeutics will be subject to a relatively more proactive and quicker review and decision making process by government bodies such as the National Health Insurance Service and the Health Insurance Review & Assessment Service when determining national insurance reimburseability and reimbursement price

#### ■ **Preventive Health Management**

As for the strengthening of preventive health management, the Committee announced that the new administration will enhance ICT-based healthcare services for chronic disease patients by community healthcare providers and expand untact healthcare services. These healthcare services combine traditional medical services with advanced technologies, and require the proactive participation of healthcare providers. Due to the large number of stakeholders involved in these matters, we anticipate that consensus building among stakeholders will take some time for these projects.

Given that the healthcare and life sciences sectors are highly regulated industries exposed to substantial impact from government policy changes, we advise that healthcare and life sciences companies doing business in Korea pay close attention to developments in the Initiatives and any subsequent policy plans announced by the new administration.

Lee & Ko's Healthcare / Life Sciences Group comprising of attorneys specializing in healthcare and life sciences matters, as well as industry and government experts with

experiences working at the Ministry of Health and Welfare, the Ministry of Food and Drug Safety, the Health Insurance Review & Assessment Service and industry leading companies, offers seasoned and insightful professional services to pharmaceutical/bio companies, medical devices companies, food companies, cosmetic companies and medical institutions. If you have any questions on this newsletter or need any assistance on these matters, please contact Lee & Ko's Healthcare / Life Sciences Group.

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Seoul Office : Hanjin Building, 63 Namdaemun-ro, Jung-gu, Seoul 04532, Korea

PanGyo Office : Techone Tower, 131 Bundangnaegok-ro, Bundang-gu, Seongnam-si, Gyeonggi-do 13529, Korea

Tel : +82-2-772-4000 | Fax : +82-2-772-4001/2 | E-mail : mail@leeko.com | www.leeko.com