NEWSLETTER

August 2022

Digital Health Team

CONTACT

Kwang Bae PARK

T: +82.2.772.4343
E: kwangbae.park@leeko.com

Jong Soo (Jay) Yoon

T: +82.2.6386.6601
E: jay.yoon@leeko.com

Jin Hwan CHUNG

T: +82.2.772.4711
E: jinhwan.chung@leeko.com

Eileen Jaiyoung SHIN

T: +82.2.772.4831
E: eileen.shin@leeko.com

New Administration Displays Its Strong Will to Promote Digital Health

Further to the 110 national initiatives for the new administration announced on May 3, 2022 (see our newsletter dated May 10, 2022), the government released a more detailed plan to promote digital health on July 27, 2022 (the **Plan**). The Plan was jointly prepared by the Ministry of Health and Welfare, the Ministry of Economy and Finance, the Ministry of Science and ICT, the Ministry of Trade, Industry and Energy, and the Ministry of Food and Safety.

1. Improvement in Regulation of Innovative Digital Medical Devices

Since the Act on Nurturing Medical Devices Industry and Supporting Innovative Medical Devices was implemented in May 2020, 19 medical devices including SaMDs (Software as a Medical Device) have been designated as innovative medical device (**IMD**) by the Ministry of Food and Drug Safety (the **MFDS**) as of July 2022. However, even though a medical device is designated as IMD, it usually takes at least an additional 3 years for such medical device to be used at medical institutions with the coverage, if eligible, by the national health insurance program. In order to reduce such time lag, the government plans to introduce a new regulatory system for IMDs, and the proposed plan consists of two main components :

- A non-invasive digital IMD obtaining market authorization from the MFDS will be permitted to be used for patient care or treatment without undergoing the evaluation process required under the National Health Insurance Act. Under this proposed scheme, an IMD can be first used as a non-covered or selectively covered product for purposes of the national health insurance for a certain period and later be re-evaluated for eligibility under the national health insurance with the clinical data accumulated during such preliminary launch period. For this purpose, an expert evaluation committee for digital health will be established at the Health Insurance Review & Assessment Service; and

- The innovation evaluation and the safety evaluation will be conducted simultaneously when the MFDS designates a medical device as IMD and the expedited innovative medical technology assessment track will be introduced for IMDs, whereby the current evaluation period of around 390 days can be reduced to 80 days.

Although the Plan will apply to a limited scope of ICT-based medical devices designated as IMD under the Act on Nurturing Medical Devices Industry and Supporting Innovative Medical Devices, the Plan represents a significant shift in regulatory scheme. Since the national health insurance system was introduced in mid-1970s, the government has developed multiple layers of approval and evaluation processes under which a medical device is approved for market access and evaluated for coverage under the national health insurance. Such system ensures that a clinically effective and safe medical device is available for patient care and treatment at an affordable price; however, the system was often criticized by the industry for being excessively time consuming and lagging behind the pace of rapid technical development in the industry. Under these circumstances, the government has adopted certain evolutionary measures allowing innovative medical devices to be used at the front line of medical care in a speedy way (e.g., the innovative medical technology evaluation track introduced in March 2019), and the Plan seems to make progress based on past efforts. The Plan adopts a concurrent review and assessment process (as opposed to traditional lineal, step-by-step process), which is anticipated to result in a meaningful reduction of the government's review period for innovative digital medical devices, and thereby practically benefit patients, healthcare professionals as well as medical devices industry.

2. Increasing Foreseeability in Regulation

The Plan also includes measures to increase foreseeability in regulation :

- The government will re-design the regulatory scheme for digital health products to reflect product's peculiar characteristics and provide the industry with more practical services for the successful commercialization of digital health products;
- For new business areas not clearly covered by current regulations, the government will provide guidance in the form of policy directives in advance so as to reduce the uncertainty in the industry. Further, the government will prepare a roadmap for renovation of the current regulatory scheme by the end of this year; and
- The government will introduce regulation sand-boxes customized for bio-health products.

Rapid development in the digital health field often tends to make existing regulations out of date and reduces the foreseeability of the government's regulatory decisions or policies. Such being the case, this government's agenda is opportune. However, as the Plan still lacks specific details (e.g., timeline and scope of application), close attention should be paid to government's next step.

3. Regulatory Change in Use of Health Data

Huge volumes of personal health data are stored at medical institutions and relevant government bodies (e.g., National Health Insurance Service, Health Insurance Review & Assessment Service), and discussions by stakeholders are undergoing as to the utilization of such data (e.g., so-called **MyData**).

However, such demand for utilization is difficult to satisfy under current legislations.

Therefore, the Plan announces that the government will introduce new legislation and develop a sophisticated regulatory scheme which provides clear guidance to enable the industry's use of personal health data without infringing the data subject's privacy.

Given that the healthcare paradigm is shifting from healthcare service provider-focused disease treatment to patient-focused disease prevention and everyday life health management, and that rapid progress is made in the field of digital health technology, the demand to share and utilize health data is increasing while concern for protection of privacy is also increasing. As a part of the government's efforts to reconcile these conflicting interests, the Ministry of Health and Welfare organized the Policy Review Committee for Healthcare Data in March 2022 so as to build social consensus among stakeholders upon which new policies will be based. The health data agenda included in the Plan may be viewed as a part of the government's ongoing efforts to set up a new regulatory system to utilize personal health data without infringing data subject's privacy.

Lee & Ko's Healthcare & Life Sciences Group and TMT Group, whose members are attorneys specializing in healthcare, pharmaceuticals, medical devices, privacy & cyber security and ICT matters, as well as experts with experience working at government bodies including the Ministry of Health and Welfare, the Ministry of Science and ICT and the Health Insurance Review & Assessment Service, offers seasoned and insightful professional services to our precious clients. If you have any questions on this newsletter or need any assistance on these matters, please feel free to contact the attorneys introduced in this newsletter.

For more information pertaining to this newsletter, please contact the attorneys identified on the left.

More L&K Newsletters

Lee & Ko

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