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[MDREX Newsletter] New Legislation on Digital Health Products

Recently, the National Assembly of Korea enacted new legislation related digital healthcare in Korea (Mar. 16, 2023).

The background of this new legislation ("Laws on Digital Health Products" or "Act") according to the National Assembly is for the local Korean laws and regulations to catch up to satisfying the efficient assessment on the safety and efficacy of digital healthcare products, which has seen a drastic innovation in recent years in development, use and diagnostics, in addition to the rapidly changing environment of overall healthcare stemming from the COVID-19 pandemic. The interest around the world for "digital healthcare" such as AI, wearables etc. has greatly increased recently while the applicable laws and regulations have not caught up to such developments in this field.

Please find the summary of the Laws on Digital Health Products as follows:

- ✓ The law classifies digital health products in categories of either digital medical devices, digital fusion pharmaceuticals or digital health support devices. Based on the purpose of such products and the effects on health of patients/potential risks, this classification allows for assigning classes on digital healthcare products.

- ✓ Manufacturers and importers of digital medical devices must be licensed by the Ministry of Food and Drug Safety ("MFDS") and such companies must also receive the requisite product licenses, certifications, and satisfy cybersecurity requirements etc.

- ✓ Instituted certification on actual-use assessment and management of digital medical devices and also a compatible quality management standard for digital medical device software.

- ✓ Manufacturers and importers of digital fusion pharmaceuticals must also be licensed by the MFDS and such companies must also receive the requisite product licenses for the products.

- ✓ Manufacturers and importers of digital health support device must register with the MFDS in addition to registering the products such companies plan to manufacture/import as digital health support device. Furthermore, these companies will be required to submit materials supporting the functionality of the digital health support device(s) planned for introduction in the Korean market, as well as plans to manage distribution.

- ✓ This Act has also set forth the legal basis to conduct performance evaluations on the components of digital healthcare products as well as train associated personnel on digital health, in addition to supporting digital healthcare products tailored towards individual patients' needs.

If you or your company have any questions on this new legislation on digital healthcare in Korea, please feel free to contact us directly at MDREX(pro@mdrex.co.kr).

Kind regards,

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