



식품의약품안전처

# Press Release

국민 안전이 기준입니다

**For IMMEDIATE RELEASE**

Date

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Medical Device  
Evaluation Department  
Digital Health  
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## MFDS Strengthens Bilateral Cooperation with HSA to Lead Global Digital Health Medical Devices

- The Ministry of Food and Drug Safety (MFDS) of the Republic of Korea (Minister Oh Yu-Kyoung) held a bilateral meeting with Health Sciences Authority (HSA) of Singapore on December 6 at COEX (located in Gangnam-gu, Seoul) in order to support the advancement of domestic medical devices into the global market and strengthen bilateral cooperation in the field of digital health medical devices.
- MFDS and HSA have agreed to exchange knowledge on approval policy for digital health medical devices including artificial intelligence healthcare and build a close cooperation system by holding regular meetings in the future. The next meeting is scheduled in March next year.
- The key points of this meeting were ▲ Introduction of fast track system on approval for digital health and artificial intelligence(AI)-enabled medical devices ▲ Introduction of the “Guidance for Review and Approval of AI-Enabled Medical Devices” published by the MFDS for the first time in the world ▲ Sharing information on AI-enabled medical device-related

guidelines published in Singapore ▲ Discussion on how to promote joint clinical research to verify clinical effectiveness of AI-enabled medical devices.

- In addition, representatives of Singapore had an opportunity to acknowledge the high level of domestic digital medical infrastructure and AI technology after visiting a medical site (Seoul National University Bundang Hospital) and a manufacturing site (Vuno) where artificial intelligence medical devices were applied.

- ☐ MFDS will continue to strengthen the cooperation system between countries in order to lead international regulations in digital health medical devices and actively support excellent domestic companies of digital health medical devices for advancing into the global market.

## Contact Persons

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