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Korea, Singapore strengthen bilateral cooperation over digital health medical devices

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Supporting potential domestic companies in entering the global market for digital health medical devices through bilateral relations



South Korean Ministry of Food and Drug Safety (MFDS) recently held a bilateral meeting with Health Sciences Authority (HSA) of Singapore at COEX, 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 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.

The next meeting is scheduled in March 2023.

To lead international regulations in digital health medical devices and actively support potential domestic companies of digital health medical devices in entering the global market, MFDS will continue to strengthen the cooperation system between countries.