식품의약품안전처 **Press Release** 국민 안심이 기준입니다

For IMMEDIATE RELEASE		Date	Febulary 15. 2023.(Wed)	
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Digital Therapeutics (DTx) Bring about Wider Treatment Options and Improved Convenience

- Korea's First 'Digital Therapeutic' Approved for Insomnia Symptom Improvement -

- ✓ First approval of domestically developed DTx to be marketed in Korea
- ✓ Expansion of treatment options for patients with insomnia as a new treatment in addition to traditional medications
- ✓ First fruit of the government's effort to support the commercialization of innovative technologies by preemptively establishing review standards
- ✓ 80 percent reduction in the period taken to use at medical facilities thanks to close cooperation with related ministries

□ The Ministry of Food and Drug Safety (MFDS) of the Republic of Korea (Minister Oh Yu-Kyoung) approved cognitive therapy software (Product name: Somzz) developed by AIMMED as a 'digital therapeutic*' for the first time in the Republic of Korea on 15, February.

* Software as a Medical Device (SaMD) that provides evidence-based therapeutic intervention to patients for prevention, control and treatment of medical disorders and/or diseases.

○ ‘Somzz’ is a software medical device that implements ‘Insomnia Cognitive Behavioral Therapy*’ as a mobile application for the purpose of improving symptoms of insomnia.

* Treatment intended for intervention (correction) of psychological, behavioral, and cognitive factors that develop or exacerbate insomnia

○ The MFDS has introduced and provided various support measures for rapid approval and commercialization of Digital Therapeutics (DTx), which are gaining attention as a promising field thanks to the acceleration of digital transformation in the medical field.

○ This first approval of a digital therapeutic paves a way for DTx to be used for the treatment of various disorders or diseases to improve public health.

※ (Global market size and outlook for DTx) The global market size for DTx recorded approximately 3.5 billion dollars in 2020 and we are expected to see an average annual growth rate of 20.6 percent. Accordingly, it is expected that the global market size will reach 23.5 billion dollars by 2030. (released by Allied Market Research (the U.S.) in November 2021)

1 First approval of domestically developed DTx to be marketed in Korea

○ ’Somzz’ is a Software as a Medical Device (SaMD) for improving insomnia symptoms developed by a domestic manufacturer named AIMMED. It is the first digital therapeutic approved in Korea by the MFDS.

○ Its principle is to improve insomnia symptoms and increase the efficiency of sleep by giving patients with insomnia a guide (▲ sleep habit training, ▲ real-time feedback, ▲ behavioral intervention) to follow for 6 to 9 weeks.

- The MFDS reviewed the results of clinical trials conducted at 3 clinical trial institutions in Korea for 6 months and found that the 'Scale for the Assessment of Insomnia Severity' statistically significantly improved after use compared to that before use.
- Moreover, the MFDS convened the Medical Devices Committee consisting of professors from the department of psychiatry or family medicine to get consultation on the safety and effectiveness of DTx and approved through scientific and thorough review.

○ "It is expected that the first approval of DTx will greatly contribute to the expansion of treatment opportunity for patients with insomnia. DTx will serve as a new treatment for various diseases and bring about a paradigm shift in clinical trial." President Jaejin Kim from the Korean Society for Digital Therapy (also a professor of Gangnam Severance Hospital) said.

2 First fruit of the government's effort to support the commercialization of innovative technologies by preemptively establishing review standards

○ The MFDS issued a "Guidance for Review and Approval of Digital Therapeutics" for the first time in the world. The guidance includes ▲ definition, criteria and examples of DTx

and ▲ how to prepare technical documents and the scope of information to be submitted for review and approval.

○ Since then, the MFDS has provided a “Guidance on Safety, Performance Evaluation, and Clinical Trial Design of Digital Therapeutics for Insomnia Improvement“ (December 2021) and other guidances specific to individual DTx for customized technical support.

- In particular, these guidances provide specific information regarding product design, documents on assessment of safety and performance and consideration for clinical trial plan to reduce the preparatory period for rapid commercialization

< List of DTx Guidances >

① Guidance for Review and Approval of Digital Therapeutics (August 2020)
② Guidance on Safety, Performance Evaluation, and Clinical Trial Design of Digital Therapeutics for Insomnia Improvement (December 2021)
③ Guidance on Safety, Performance Evaluation, and Clinical Trial Design of Digital Therapeutics for Alcohol Use Disorders Improvement (December 2021)
④ Guidance on Safety, Performance Evaluation, and Clinical Trial Design of Digital Therapeutics for Nicotine Use Disorder Improvement (December 2021)
⑤ Guidance on Safety, Performance Evaluation, and Clinical Trial Design of Digital Therapeutics for Panic Disorder Improvement (December 2022)
⑥ Guidance on Safety, Performance Evaluation, and Clinical Trial Design of Digital Therapeutics for Depressive Disorder Improvement December 2022)

○ The MFDS is committed to creating an environment in which diversified competitive DTx can be developed and marketed in Korea by taking advantage of its competitiveness as an ICT powerhouse.

- To this end, the MFDS will take the lead in establishing international regulatory standards with the development of

additional 10 types of guidances on review and approval of customized DTx by 2027 and strengthen support for manufacturers to meet the standards.

* (Currently) 5 types including insomnia developed → (By 2023) 2 types including ADHD, eating disorder to be developed → (By 2027) Additional 8 types to be developed

3 80 percent reduction in the period taken to use at medical facilities thanks to close cooperation with related ministries

○ The government has developed the 'integrated review and assessment system for innovative medical devices*' (implemented since October 2022) so that excellent DTx can be promptly used at the medical facilities.

- The MFDS designated a digital therapeutic developed by AIMMED as the first target product for the 'integrated review and assessment system for innovative medical devices' on 15 December 2022, reducing the period taken from approval to use by approximately 80%.

✓ **Integrated review and assessment system for innovative medical devices (implemented since October 2022)**

▸ It is possible for innovative medical devices to be approved and marketed at the same time by simultaneously implementing processes (❶Innovative medical device designation by the Ministry of Food and Drug Safety ❷ Determination whether it is eligible for health care benefit item or non-benefit item by the Health Insurance Review & Assessment Service ❸ Innovative medical technology evaluation by the National Evidence-based Healthcare Collaborating Agency) that were carried out sequentially by institution.

⇨ Reduced period : (Previous) 390 days → (Improved) 80 days

ㅇ “The government and the MFDS have actively engaged in the approval of a digital therapeutic that had not yet been approved in Korea“, President Jinhwan Im of AIMMED said.

- He also added, “The MFDS provided substantial assistance in promptly reviewing and approving the product to be available at the medical facilities by preemptively establishing DTx-related standards on its clinical trial and approval and developing a new system such as an integrated review and assessment system.”

□ The minister stated, “ The MFDS will strive to devise a new way to facilitate the commercialization of DTx with the aim of improving public health by putting top priority on public confidence and actively promoting scientific and technological innovation.“

ㅇ “The MFDS will align our regulations with global standards so that domestic manufacturers can develop innovative products and take the lead in the global market.“ the minister added. It is also highlighted that we will provide a range of support such as R&D coordination, close consultation with regulatory experts and application of global standards to increase the success rate of commercialization and speed up the launch of innovative products.

□ The MFDS expects that this first approval of a digital therapeutic in Korea will contribute to achieving one of national tasks ’Leap Toward a Global Key Player in Digital and Bio-health Sector’ and will spare no effort to facilitate commercialization of DTx that are proven to be safe and reliable.

Attachment	Description of SaMD for cognitive behavioral therapy for insomnia

The protocol of CBT-I (Cognitive Behavioral Therapy for Insomnia), a standard therapeutic in clinical practice, is implemented by sequentially applying systematic algorithms to mobile applications. It provides patients with insomnia with education, real-time feedback, behavioral intervention and push notification for 6 to 9 weeks.

Login(Start)	Writing a sleep diary	Checking the sleep diary	Sleep restriction therapy
			

Sleep habit training	Stimulus control and relaxation therapy	Cognitive therapy	End of Training