

SOUTH KOREA Regulatory

Ministry of Food and Drug Safety regulates digital therapeutics through the approval and certification of product manufacturing or import, evaluation of technical documents, and approval of clinical trial plans.

Category Name	Digital Therapeutic (recognized as a subset of Software as a Medical Device (SaMD), which is a subset of Medical Devices)	
Responsible Regulatory Agency	Ministry of Food and Drug Safety (MFDS)	
Product Risk Classifications	Class I	Class II
Products That Qualify For Regulatory Review	Do not qualify: No approval required for Class I DTx products.	Qualify: Regulatory approval required for Class II DTx products.
Pre-Submission Opportunities	No	
Guidelines To Be Met	There are no examples of Class I DTx products at this time.	Requires evidence-based data, including at least one: <ul style="list-style-type: none"> clinical article published in a peer-reviewed journal clinical trial clinical guideline recognized by Korean Academy of Medical Sciences to support the claim Korean Good Manufacturing Practice (KGMP) Certificate <ul style="list-style-type: none"> Class II devices reviewed by KTR/KTL Class III & IV devices reviewed by KTR/KTL, plus a MFDS Review IEC 82304, IEC 62304, and ISO 14971 National Institute of Medical Device Safety Information's authorization (certification), unless a clinical trial is required for approval. In such case, MFDS is required.
Other Guidelines	Guideline on Review and Approval for Software as a Medical Device (Not translated to English yet.) Guideline on the Application of Real World Evidence of Medical Device (Not translated to English yet.) Guideline on Review and Approval for Cybersecurity of Medical Devices (For industry) <i>Note: Digital therapeutics with treatment purposes cannot be classified as low-risk</i>	
Product Recognition	Approval	
Approximate Timing For Process Completion	6-8 months	
Cost	1,495,000 KRW (approximately \$1,260 USD)	

SOUTH KOREA Reimbursement

Prescription Required?	Required for reimbursement by public health insurance.
Public Insurance Coverage	Product coverage is not provided through the Health Insurance and Review Assessment (HIRA) or National Health Insurance Service (NHIS) agencies yet.
Private Health Insurance	Not at this time.
Employer-Sponsored Healthcare	Not at this time.
Consumer-Funded	Not likely due to universal health insurance coverage. However, consumers may be interested in paying out of pocket for a product that improves quality of life.

Note: This document represents pathways that continue to evolve. It does not provide legal advice.