DTx REGULATORY & REIMBURSEMENT PATHWAYS

DIGITAL THERAPEUTICS ALLIANCE

DEVELOPED WITH EVERSANA™

SOUTH KOREA Regulatory

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–IV**
Regulatory Review	Do not qualify: No approval required for Class I devices.	Qualify: Regulatory approval required for medical devices above Class II.
Pre-Submission Opportunities	No	
Guidelines To Be Met	DTx products are generally classified Class II or higher as they have the purpose of treatment.	To qualify as a DTx, following conditions have to be met: • Device must be a digital software device, which can be installed in the PC, Mobile, HMD (Head Mounted Display), etc. hardware. • Device must be used for disease prevention, management and/or treatment. • There must be scientific (clinical) evidence for the mechanism of action of the treatment. The evidence may include Clinical Practice Guidelines from the Korean Medical Association, clinical papers published in academic peer-reviewed journals, exploratory clinical trial data, etc. Safety Evaluation Safety is evaluated through risk analysis and evaluation. Safety of DTx can be classified as • Class A: Low risk of injury or damage from use; Class A is equivalent to Class I of the general medical device risk classification. • Class B: Possibility of non-serious injury; Class B is equivalent to Class II-III of the general medical device risk classification. • Class C: Possibility of serious injury or death; Class C is equivalent to Class IV of the general medical device risk classification Depending on each class, discussion on risk control and the evaluation of residual risk acceptability should be done between the manufacturer and MFDS. Cybersecurity Data must abide by "", meeting below conditions: 1. Availability: data must be available to authorized users when and where needed and in the form needed. 2. Confidentiality: data must not be disclosed to unauthorized persons. 3. Integrity: data must not be converted or destroyed in unauthorized ways. The risk of cybersecurity breach can be classified as high, medium or low based on comprehensive consideration of the harm that may occur to the user when breached. Manufacturers must take measures to prevent and control these risks.

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SOUTH KOREA Regulatory *(continued)*

Guidelines To Be Met *(continued)*		Requires real world evidence-based data, including at least one: • 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 • Class II devices reviewed by NIDS and one of the 8 consignment agencies, including KTR and KTL. • Class III & IV devices reviewed by MFDS Medical Device Review Department 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 Review and Approval for Software as a Medical Device 2023 (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) *Note: Digital therapeutics with treatment purposes cannot be classified as low-risk*	
Product Recognition	Approval	
Approximate Timing For Process Completion	Immediate	• Within 80 days for review of technical documents and clinical data
Cost	1,495,000 KRW for electronic submission (approximately $1,100 USD) 1,662,000 KRW for mail submission (approximately $1,200 USD)	

SOUTH KOREA Reimbursement

Prescription Required?	Required for reimbursement by public health insurance.
Public Insurance Coverage	In 2023, DTx has been given 3 year temporary registration for national reim-bursement under Health Insurance and Review Assessment (HIRA) or National Health Insurance Service (NHIS). Reimbursement will be selective for prescribed patients within research or clinical trial institutions that was appointed by NECA. Temporary registration is for select medical instructions to establish clinical evi-dence, such as effectiveness. Upon evaluation after these 3 years, the final deci-sion on official registration for national reimbursement will be made.
Private Health Insurance	Not at this time.
Employer-Sponsored Healthcare	Not at this time.
Consumer-Funded	For DTx products that has not been approved for reimbursement, patients may choose to pay out of pocket for improved quality of life. The non-reimbursed product price should be disclosed by medical institutions on the HIRA website.

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