DTx REGULATORY & REIMBURSEMENT PATHWAYS

DIGITAL THERAPEUTICS ALLIANCE

DEVELOPED WITH EVERSANA™

SINGAPORE Regulatory

The Health Sciences Authority (HSA) of Singapore regulates digital therapeutics through the registration of product manufacturing or import, evaluation of technical documentation, and approval of clinical trial plans.

Category Name

Digital Therapeutic (recognized as a subset of Digital Health)

Responsible Regulatory Agency

Health Science Authority (HSA)

Product Risk Classifications

Products are classified into four risk classes: Class A, B, C and D (risk level in increasing order). Several factors affect medical device risk classification. These include:

- The duration of medical device contact with the body.
- The degree of invasiveness.
- Whether the medical device delivers medicinal products or energy to the patient.
- Whether they are intended to have a biological effect on the patient.
- Local versus systemic effects (e.g. conventional versus absorbable sutures).

Based on the product's intended purpose, if two or more risk classification rules apply to the medical device, the medical device is assigned the highest risk class. Risk classification of the product can also be checked by filling a simple questionnaire on HSA's website.

Class A	Class B, C and D
Do not qualify: Class A devices only need notification to the HSA, and registration is not required.	Qualify: Regulatory registration required for medical devices above Class B.

Pre-Submission Opportunities

To facilitate a smooth journey for manufacturers, the HSA offers pre-submission meetings, termed as Pre-Market Consultation Schemes designed to provide guidance, ensure compliance and expedite access to the market.

Guidelines To Be Met

Class A medical devices are exempt from product registration but should still ensure compliance with Essential Principles for Safety and Performance for Medical Devices.

Product Registration

Evaluation routes:

1. Full Evaluation Route
2. Abridged Evaluation Route
3. Expedited Evaluation Route (for Class C and D)
4. Immediate Class B Registration (IBR) & Immediate Class C Registration (ICR) Evaluation Route

The abridged, expedited and immediate registrations are applicable for products that have attained approvals in at least one of the Global Harmonization Task Force (GHTF) founding members (i.e., Australia, Canada, EU, Japan, USA). Certain routes have additionally requirements. For example, immediate evaluation routes additionally require no safety issues associated with use and no prior rejection/withdrawal of the device from any reference agency.

The ICR only applies to standalone mobile applications.

For medical devices that are under Full Evaluation Route, Priority Review Schemes allow for faster processing.

- Route 1: this route is intended for the 5 disease groups, cancer, diabetes, ophthalmic disease, cardiovascular disease and infectious disease, OR for unmet clinical need (no existing alternative and/or provide meaningful advantage over existing technology)
- Route 2 is for medical device that do not meet qualification criteria for Route 1.

more >

SINGAPORE Regulatory *(continued)*

Guidelines To Be Met *(continued)*

Typically, the application process would be as follows:

- Application through MEDICS
- Screening and evaluation of applications
- Regulatory decision and listing on SMDR

For the Immediate Evaluation Routes, the process would be as follows:

- Application through MEDICS
- Listing on SMDR within 1 hour of application submission
- Verification of the documents

Dealer's Licensing must be done in order to supply Class B-D medical devices in Singapore.

Post-market obligations: Dealers are obliged to perform post-market duties, including reporting adverse events, defects and recall to HSA, etc.

Approximate Timing For Process Completion

Risk class	TAT for Registration routes (in working days)				
	Immediate	Expedited	Abridged	Full	Full (Priority Review Scheme)
Class B	Immediate registration upon submission	N.A.	100	160	104
Class C	Immediate registration upon submission (for Class C standalone medical application only)	120	160	220	143
Class D	N.A.	180	220	310	202
Class D (devices incorporating medicinal products)	N.A.	N.A.	220	310	N.A.

Fees For Product Registration

Fees	Class B	Class C	Class D	Class D with a registrable drug
Application fee	$530	$530	$530	$530
Immediate route fee	$950	$3,180	N.A.	N.A.
Expedited route fee	N.A.	$3,180	$5,730	N.A.
Abridged route fee	$1,910	$3,710	$6,050	$10,400
Full route fee	$3,710	$6,050	$11,800	$75,400
Full route (Priority Review Scheme Route 1)	$4,220	$6,800	$13,400	N.A.
Full route (Priority Review Scheme Route 2)	$5,460	$8,800	$17,300	N.A.
Annual retention fee for SMDR listing	$37	$64	$128	$128

DTx REGULATORY & REIMBURSEMENT PATHWAYS

DIGITAL THERAPEUTICS ALLIANCE

DEVELOPED WITH EVERSANA™

SINGAPORE Reimbursement

Prescription Required?	When it comes to digital therapeutics, the prescription requirements can vary significantly based on factors such as whether it is integrated with a device, therapeutic, or service. For reimbursement purposes, a prescription from a medical practitioner is typically necessary.
Public Health Insurance	At present, there is no specific pathway on reimbursement of digital health technologies (DHTs). The subsidy of medical technology is listed in Agency for Care Effectiveness (ACE). The list details the funding status and eligibility of each technology. Currently, there are no DTx products that are under the list.
Private Health Insurance	Digital therapeutics are not widely covered by private health insurers and are typically **considered on a case-by-case basis**, primarily where there are clear cost savings or health benefits. Insurers are increasingly interested in DTx for managing chronic diseases and mental health, but standardized reimbursement pathways remain undeveloped.
Employer Sponsored	Employer-sponsored health coverage is **gradually incorporating digital therapeutics**, especially for mental health and chronic disease prevention. Employers are integrating these technologies into wellness programs to enhance employee health and productivity, supported by government incentives aimed at improving corporate health strategies.
Consumer-Funded	If the specific medical device is not covered by insurance or government subsidies, patients may self-pay out of pocket for registered medical device.

Relevant contact information:

1. **Health Science Authority (HSA)**
   Address: Health Sciences Authority, 11 Outram Road, Singapore-169078
   Telephone: (65) 6213 0838; 1800-2130800 (Quality Service Manager)
   Fax: (65) 6213 0749
   Email: HSA_Info@hsa.gov.sg
2. **MEDICS**
   Address: Health Sciences Authority, 11 Outram Road, Singapore-169078
   Telephone: (65) 6776 0168
   Email: helpdesk@hsahelp.gov.sg
3. **Agency for Care Effectiveness (ACE)**
   Address: College of Medicine Building, 16 College Road, Singapore-169854
   Email: ace_hta@moh.gov.sg

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