

KEYNOTE ADDRESS

Regulatory Innovation as a Catalyst for Global MedTech Growth

Adj Prof (Dr) Raymond Chua,
CEO, Health Sciences Authority &
Deputy Director-General of Health (Health Regulation),
Ministry of Health, Singapore

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A launchpad for healthcare innovation.

Research, Innovation and Enterprise 2030 ·
healthcare sector growth · whole-of-government
support

Singapore's foundation helps ventures move quickly from
strong science to wider market access.

Three pillars to support the MedTech Ecosystem

01

Global Market Access

A regional and global trusted regulator

02

Holistic Value Proposition

Clear route-to-market from clinical trials to adoption

03

Adaptive Regulation

Future-ready frameworks for intelligent MedTech

04

HIGHEST POSSIBLE CLASSIFICATION
IN THE WORLD

WHO MATURITY LEVEL 4

HSA approval gives innovators a global seal of confidence — signalling scrutiny to the highest international standards.

Singapore is a trusted regulatory gateway to regional and global markets.

30

WORKING DAYS

verification route in Malaysia for HSA-registered Class B–D devices, halved from 60 days

60

WORKING DAYS

Thailand review pathway for HSA-approved devices, down from about 150 working days

GLOBAL MARKET ACCESS

Countries that reference HSA's medical device approval

- 01 Australia
- 02 Hong Kong
- 03 Malaysia (New)
- 04 Philippines
- 05 Thailand
- 06 Sri Lanka

Collaborating with agencies to streamline end-to-end pathways

Set up of an industry development arm: engages and supports the industry.

A*STAR · EDB · EnterpriseSG: SCRI: HSA: ACE : support from setup to scale-up and new markets.

END-TO-END VALUE PATHWAY

01
DEVICE
DEVELOPMENT



02
TRIALS



03
REGISTRATION



04
COST
EFFECTIVENESS
ANALYSIS



Leading in the age of intelligent MedTech.

Software as a Medical Device · AI-driven diagnostics · digital therapeutics · brain-computer interfaces

Agile, risk-proportionate frameworks provide clarity without stifling innovation.

MORE INFORMATION



Artificial Intelligence in Healthcare Guidelines (AIHGle 2.0)

EARLY ENGAGEMENT & CONSULTATION

Engage early through HSA Innovation Office

01

30+ HSA Innovation Office consultations
a year on average since 2017

02

Anticipate evidence requirements
and strengthen dossiers

03

Avoid costly rework and
accelerate market access

Bring concepts, clinical plans and regulatory strategy questions to HSA Innovation Office early.

A NEW KIND OF PARTNERSHIP

Regulators who understand your world.

HSA will partner with **Fogarty Innovation** to curate immersion and training programmes so regulators better understand the startup experience and early-stage device development.

The best regulation is shaped close to the innovators it serves.

OPEN INVITATION TO GLOBAL VENTURE CAPITAL

Make regulatory excellence part of your investment thesis.

Speed to market with quality — and predictable, high-trust pathways — reduce execution risk and unlock global expansion.

Vision: HSA aims to enable your investments to deliver success sooner.

FROM REGULATOR TO TRUSTED PARTNER

One ecosystem ("league") One Team. Everyone wins.

Singapore as the home ground for MedTech champions —

- Investors: club owners
- Innovators, entrepreneurs: strikers
- Clinicians, researchers: midfielders
- Manufacturers: defenders
- HSA: referee to play game with trust, consistency and integrity

UPHOLD INTEGRITY · UNITED BY ONE GOAL: LIVES IMPROVE

LOOKING AHEAD · TOGETHER

Launch responsibly, rapidly and successfully.

Singapore is ready for bold ideas. HSA is ready to walk alongside you as a trusted partner

Thank you

Scan to find out more about HSA's initiatives supporting innovation for Singapore's MedTech industry.

MORE INFORMATION



HSA Innovation Office
(Medical Devices)

hsa.gov.sg/medical-devices/md