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8. Emerging regulatory policy issues

Learn about how MOH tackles new regulatory challenges in healthcare.

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The Ministry of Health (MOH) proactively scans the environment through various channels, like horizon scanning and stakeholder engagements, to identify emerging regulatory issues to enable forward planning and timely regulatory response to such issues. Two such emerging developments are the use of artificial intelligence (AI) and the applications of precision medicine in healthcare.

Artificial Intelligence

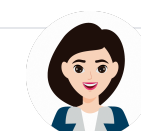
The application of Artificial Intelligence (AI) spans multiple areas, including administration, clinical decision support and research such as drug development. AI has tremendous potential to improve patient care and outcomes. However, the widespread use of AI also includes inherent risks, underscoring the importance of safe and responsible design and use of AI in healthcare.

AI in Healthcare Guidelines

Singapore is committed to adopt AI thoughtfully, prioritising patient safety and clinical effectiveness. MOH continues to develop guidelines to support the safe and responsible use of AI in the healthcare sector. Updated jointly by MOH and the Health Sciences Authority (HSA), the [Artificial Intelligence in Healthcare Guidelines \(AIHGle 2.0\)](#) [↗] (read as 'agile') clarifies that AI should augment and empower our healthcare professionals in enhancing healthcare delivery, with patients at the heart of it.



Building on the 2021 framework, AIHGle 2.0 provides practical guidance to support the safe development, deployment, and use of AI in healthcare, benefitting patients and improving trust. It also complements [HSA's Regulatory Guidelines for Software as Medical Devices](#) [↗]. Key updates include:

- Strengthening accountability through clarity of responsibilities for each stakeholder group – developers (e.g. manufacturers), deployers (i.e. healthcare organisations), and users (i.e. healthcare professionals);
- Improving trust via guidance on transparency to facilitate informed decision-making; and
- Updated guidance on AI deployment, such as assessing and mitigating risks.



DEPLOYERS



Deploy Safely

-  Establish robust governance with multi-disciplinary expertise comprising clinical, technical and legal to inform governance decisions
-  Assess, approve and integrate AI solutions with proper staff training and communication policies
-  Monitor post-deployment performance and maintain incident reporting processes



USERS

Use Wisely

-  Always exercise professional judgment and use AI as a supportive tool
-  Build competencies and use AI in your workflow responsibly

DEVELOPERS

Develop Responsibly

-  Design transparent, fit-for-purpose AI solutions with comprehensive Instructions for Use (IFU)
-  Evaluate model performance, safety and compliance across the product lifecycle
-  Monitor post-deployment performance and implement timely corrective actions

AIHGle is a living document that will be periodically updated to provide appropriate guidance in light of developments and new technologies. Let us work together to enable safe and trusted AI across the healthcare ecosystem.

Download materials

Click the links below to download AIHGle 2.0 materials.

S/N	Name
1	Updated MOH Artificial Intelligence in Healthcare Guidelines (AIHGle 2.0)
2	Infographic summarising the roles and responsibilities for developers, deployers and users
3	Deployers' toolkit that supports new adopters with internal governance and selecting appropriate AI solutions

If you have feedback, please share it with us here: <https://go.gov.sg/aihgle-feedback>.

Precision Medicine



Precision Medicine is a new and evolving field that has the potential to transform healthcare through early detection, targeted prevention and personalised care and management of genetic diseases which may reduce diagnostic testing and treatment costs. Interventions and emerging technologies in Precision Medicine include clinical and non-clinical genetic testing, 'omics'-based biomarkers, pharmacogenomics tests, complex AI-based algorithms, and digital health applications. As technologies become more prevalent in clinical practice and healthcare use, there are also increasing challenges and issues such as:

- Concerns about complexity in interpreting test results;
- Lack of strong scientific evidence in demonstrating safety and efficacy;
- Lack of consumer awareness on novel precision medicine technologies;
- Concerns on data privacy and security; and
- Genetic discrimination in insurability and employment.

MOH is responding to these challenges in a variety of ways, from regulating the provision of clinical genetic and genomic testing, providing guidance on the use of direct-to-consumer genetic test kits, and putting in place a Moratorium on the use of genetic testing results in insurance underwriting.

Regulation of Genetic Testing

MOH issued a Code of Practice (COP) on the Provision of Clinical Genetic Testing in 2018 which sets out the minimum standards and requirements for the provision of clinical and laboratory genetic/genomic testing by healthcare institutions, licensees, and medical practitioners. The COP is currently under review and will be translated to regulations to be implemented under the Healthcare Services Act (HCSA) subsequently.

Read more on the [COP standards \[PDF, 940 KB\]](#).

Non-clinical Genetic Testing

Non-clinical or direct-to-consumer (DTC) genetic test kits are increasingly widespread. They do not address medical conditions and are typically used for general wellness and recreational purposes, such as testing for innate behaviour or talents, fitness, and nutrigenomics. There are several risks of DTC genetic testing, such as unreliability of test results and unauthorised commercialisation of genetic data gleaned from tests.

MOH has developed [guidance on the provision of non-clinical or DTC genetic testing](#), which provides information to providers of non-clinical genetic testing who are operating or wish to operate in Singapore to ensure safety, welfare, and privacy of the consumers. The guide also informs and guides the expectations of potential consumers of non-clinical genetic testing.

Find out more about [non-clinical or DTC genetic testing](#).

Moratorium on the Use of Genetic Test Results in Insurance Underwriting

MOH and the Life Insurance Association (LIA) developed the 'Moratorium on Genetic Testing and Insurance' to support Precision Medicine (PM) in Singapore. The Moratorium aims to give individuals the assurance to undergo clinical genetic testing for medical care and to participate in PM research, by protecting genetic test results from use by insurers in underwriting. It applies to all LIA members that includes life insurers and reinsurers that are licensed to operate in Singapore.

The Moratorium prohibits the use of genetic test results in insurance underwriting. The Moratorium was first introduced in 2021 ("2021 Moratorium") and was later amended and re-signed in 2025 ("2025 Moratorium") to enhance protections for individuals undergoing genetic testing for FH under the National Familial Hypercholesterolaemia (FH) Genetic Testing Programme. This aims to support early identification and interventions for individuals with FH and forms part of MOH's broader preventive care efforts.

[For more information please click here for the Moratorium and the Consumer Guide](#)

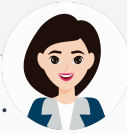


Download documents

Table 2: Documents regarding clinical and non-clinical genetic testing

S/N	Name
1	Code of Practice on the Standards for the provision of Clinical Genetic/Genomic Testing Services and Clinical Laboratory Genetic/Genomic Testing Services [PDF, 940 KB] ↗
2	Guidance Document on the Provision of Non-clinical Genetic Testing [PDF, 359 KB] ↗
3	Circular on Updates on Proposed Regulatory Framework for Clinical Genetic Testing Services (CGTS) ↗
4	<p>Competency Framework for the Provision of Clinical Genetic/Genomic Testing (CGT) Services:</p> <ol style="list-style-type: none"> 1. Introduction Document [PDF, 210 KB] ↗ 2. Base Template [PDF, 202 KB] ↗ 3. Obstetrics & Gynaecology (O&G) specialty-specific templates: <ul style="list-style-type: none"> ◦ Alpha Thalassaemia [PDF, 314 KB] ↗ ◦ Beta Thalassaemia [PDF, 312 KB] ↗ ◦ Low-Risk Pregnancy [PDF, 336 KB] ↗ 4. Paediatrics specialty-specific templates: <ul style="list-style-type: none"> ◦ Alpha Thalassaemia [PDF, 314 KB] ↗ ◦ Beta Thalassaemia [PDF, 312 KB] ↗ ◦ Common Chromosomal Aneuploidies [PDF, 310 KB] ↗ ◦ Global Developmental Delay/ Intellectual Disability [PDF, 342 KB] ↗ ◦ Epilepsy [PDF, 333 KB] ↗ 5. Oncology (with Haematology) specialty-specific templates: <ul style="list-style-type: none"> ◦ Cancer (Solid Tumours) [PDF, 375 KB] ↗ ◦ Cancer (Haematological) [PDF, 364 KB] ↗ 6. Cardiology specialty-specific templates: <ul style="list-style-type: none"> ◦ Dilated Thoracic Aorta [PDF, 297 KB] ↗ ◦ Arrhythmia [PDF, 299 KB] ↗ ◦ Familial Hypercholesterolemia [PDF, 298 KB] ↗ ◦ Primary Cardiomyopathy [PDF, 299 KB] ↗ 7. Neurology specialty-specific templates: <ul style="list-style-type: none"> ◦ Epilepsy [PDF, 333 KB] ↗ ◦ Huntington Disease [PDF, 302 KB] ↗ ◦ Myotonic Dystrophy [PDF, 299 KB] ↗ ◦ Spinocerebellar Ataxia [PDF, 300 KB] ↗ 8. FAQs for Competency Framework [PDF, 128 KB]* ↗ <p><i>*Please note that FAQ 14 is no longer applicable. For enquiries, please email HCSA_Enquiries@moh.gov.sg.</i></p>

Table 3: Documents regarding moratorium on genetic testing and insurance

S/N	Document Name
1	For policies signed on or after 30 June 2025, please refer to the 2025 Moratorium. 

	Download the 2025 Moratorium ↗
2	For policies signed from 27 October 2021 (inclusive) to 29 June 2025, please refer to the 2021 Moratorium. Download the 2021 Moratorium ↗
3	[English] Consumer Guide on the Moratorium ↗ [Chinese] Consumer Guide on the Moratorium ↗ [Malay] Consumer Guide on the Moratorium ↗ [Tamil] Consumer Guide on the Moratorium ↗
4	Infographic for Moratorium ↗

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