MINISTRY OF HEALTH
SINGAPORE

Leading Regulatory Transformation in Singapore

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HealthierSG
An initiative of
FORWARD SG

Horizon scanning identified several emerging healthcare services regulatory issues of concern

Changes in Care Models

- More complex care & preventive care will be delivered in community settings
- Greater vertical integration, seamless continuum of care from the hospital to the community
- Emergence of 'One-stop Shop' for care coordination and care management

Complementary & Alternative Medicine (CAM)

- Greater interest in the use of CAM (e.g., Traditional Chinese Medicine, Ayurvedic treatments) in Singapore
- Potential integration of CAM therapies with western medicine.

Digital Technologies shaping the future of healthcare services

- Extension of telemedicine beyond teleconsultations
- Artificial Intelligence-Machine Learning (AI-ML) & Robotics applications replacing direct human care
- Consumer apps / wearables enabling self care

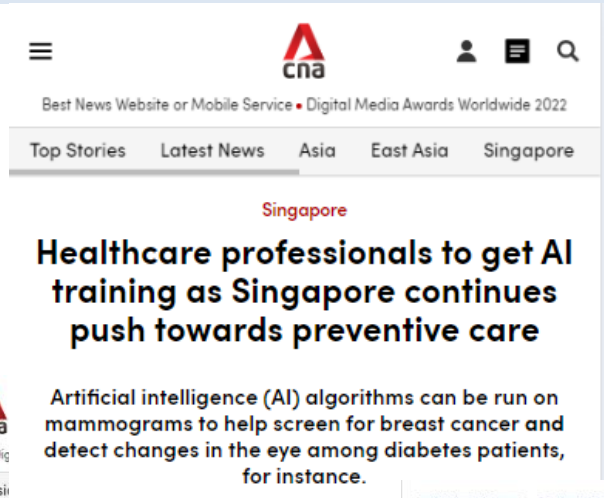
Mainstreaming of personalised novel therapies

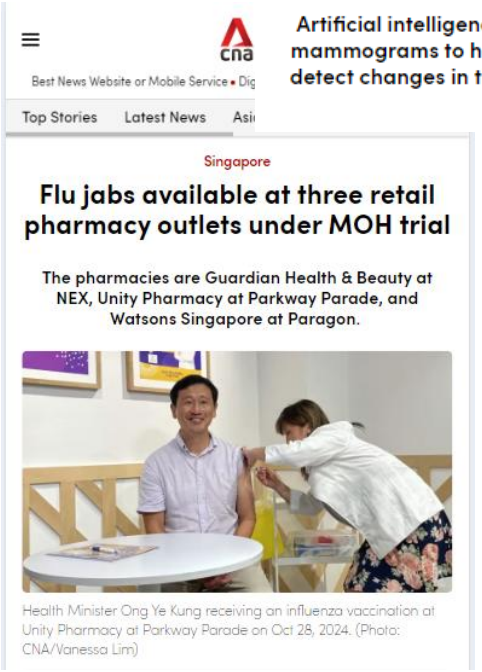
- Use of cell & gene therapies to treat common ailments in the near future.
- Use of mRNA, immune-targeting vectors and nanomaterials to treat cancer or rare diseases in future.
- Use of sophisticated technologies including digital twins and 3D printing.

Broader cross-cutting issues

- Pressures to restructure the healthcare workforce to develop competence in navigating these changes of care models and new skillsets.
- Data privacy and confidentiality concerns from collected data in digital apps, wearables and portable devices.
- Cost concerns related to these innovations and ensuring that healthcare remains affordable and accessible.
- Need for integration of health products, services and professionals regulation with the shifts on the horizon.

New and emerging health technologies and service models introduce complex safety risks that cut across regulatory remits





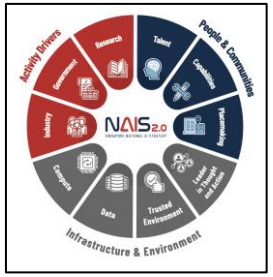
However, these come with challenges

- Financial – High cost for treatment or development
- Regulatory – What regulatory tool do we use?
  - Who regulates which segment?
  - What is safe?
  - What are appropriate cyber and data security standards?
  - How to catch up with the fast-evolving landscape and be future-proof?
- Ethical dilemmas

Case example: Artificial Intelligence Governance Approach in Singapore

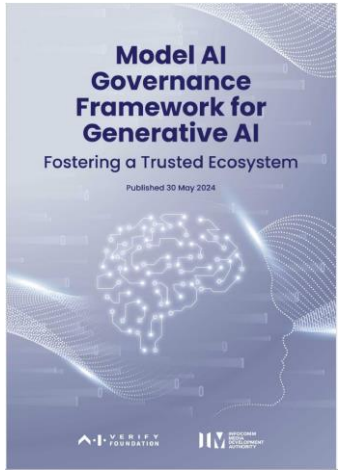
National Guidance

Singapore National AI Strategy 2.0 (NAIS 2.0) (2023)



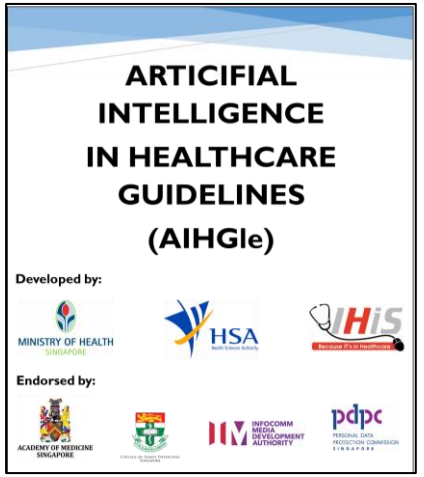
Model AI Governance Framework Second Edition (2020) for traditional AI

Model AI Governance Framework for Generative AI (2024)



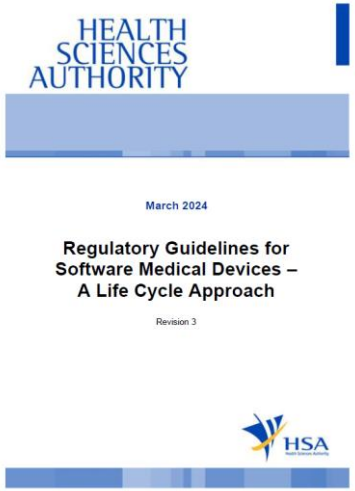
Healthcare Sector's Guidance

AIHGle (2021)



BDAI in Human Biomedical Research (2023)

Regulatory Guidelines on AI-MD (2024, first published 2022)



However, Artificial Intelligence governance has its challenges

- AI Regulatory controls can be divided into **4 siloed pillars**

Services *Healthcare Services Act (HCSA)*	**Professionals** *Medical Registration Act, Ethical Code and Ethical Guidelines (ECEG)*	**Products** *Health Products Act*	**Data** *Health Information Bill, Human Biomedical Research Act*
• Regulation of **healthcare service providers**. • Focuses on governance and accountability at the licensee, key appointment holders, principal officer and clinical governance officer level.	• Regulation of **individual healthcare professionals**. • Focuses on professional standards and ethical behaviour of individual medical practitioners.	• Regulation of medical devices, specifically for AI – **Software as a Medical Device (SaMD)**. • Focuses on ensuring the quality, safety and efficacy of AI medical devices	• Regulation of **health information**. • Focuses on data collection, sharing, access and protection (e.g. usage of NEHR data to train AI models under HIB)

National AI in Healthcare Guidelines (AIHGle)

- Sharing good practices with AI developers (e.g. manufacturers or companies) and AI implementers (e.g. healthcare institutions – hospitals, clinics, laboratories).
- Complements existing regulatory frameworks.

Challenges faced / feedback

- Liabilities should there be errors or complications
- Regulatory process slowing down innovation (e.g. requirements to obtain ISO, various licenses, etc)
- Difficulty to determine if products are medical devices or not (i.e. if software intended direct medical purposes (e.g. detection, screening, diagnosis, treatment, monitoring or management of any medical condition or disease))

Singapore takes a layered and coordinated healthcare regulation approach to ensure safe and effective delivery of care

SG Wide Legislation
(e.g. Penal Code, *Penal Code, Personal Data Protection Act, Cyber Security Act)*

Health Data
(Health Information Bill)

Healthcare Services
(Healthcare Services Act)

Health Products & Devices
(Health Products Act)

Healthcare Professionals
(various professional registration acts e.g. Medical Registration Act, Ethical Code and Ethical Guidelines)

MINISTRY OF HEALTH
SINGAPORE

HSA
Health Sciences Authority

SINGAPORE MEDICAL COUNCIL
SINGAPORE DENTAL COUNCIL
SINGAPORE PHARMACY COUNCIL
SINGAPORE NURSING BOARD
AHPC
ALLIED HEALTH PROFESSIONS COUNCIL
Optometrists & Opticians Board
TRADITIONAL CHINESE MEDICINE PRACTITIONERS BOARD

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Health Professionals are regulated by respective professional Boards & Councils

Regulators of Healthcare Professions in Singapore

i. To protect the health & safety of the public

ii. To uphold standards of practice of healthcare professionals

Registration and regulation of healthcare professionals governed by the Professional Boards (PBs)

All PBs have full autonomy and independence over professional and statutory matters, as provided for under their respective professional registration Acts

Health Products are regulated by our Health Sciences Authority (HSA)

- For example, medical devices are classified as a health products under Singapore law
- The HSA ensures that health products in Singapore are wisely regulated to meet appropriate standards of safety, quality and efficacy throughout the product life cycle
- Ensure timely access to good quality, safe & efficacious health products
- Support the healthcare and biomedical sciences industry and facilitating its development

HSA's Regulatory Philosophy

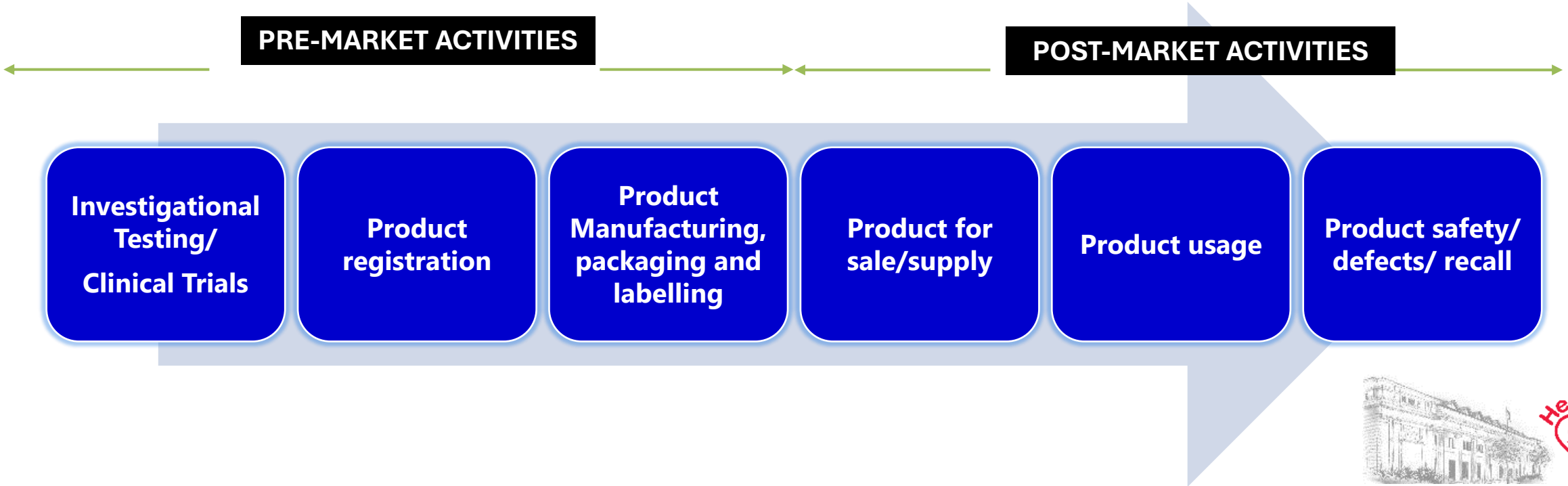
1. Benefits outweigh foreseeable risks
2. Risk-based, fit-for-purpose approach
3. Confidence-based approach
4. Adoption and judicious adaption of international standards & best practices
5. Forging strategic partnerships both regionally in ASEAN and internationally

Health Products Regulation adopts a product lifecycle approach

Health products e.g., **medicines, medical devices, cell, tissue and gene therapies** in Singapore are wisely regulated, through risk calibration, to meet appropriate standards of:

i) Safety,
ii) Quality, and
iii) Efficacy

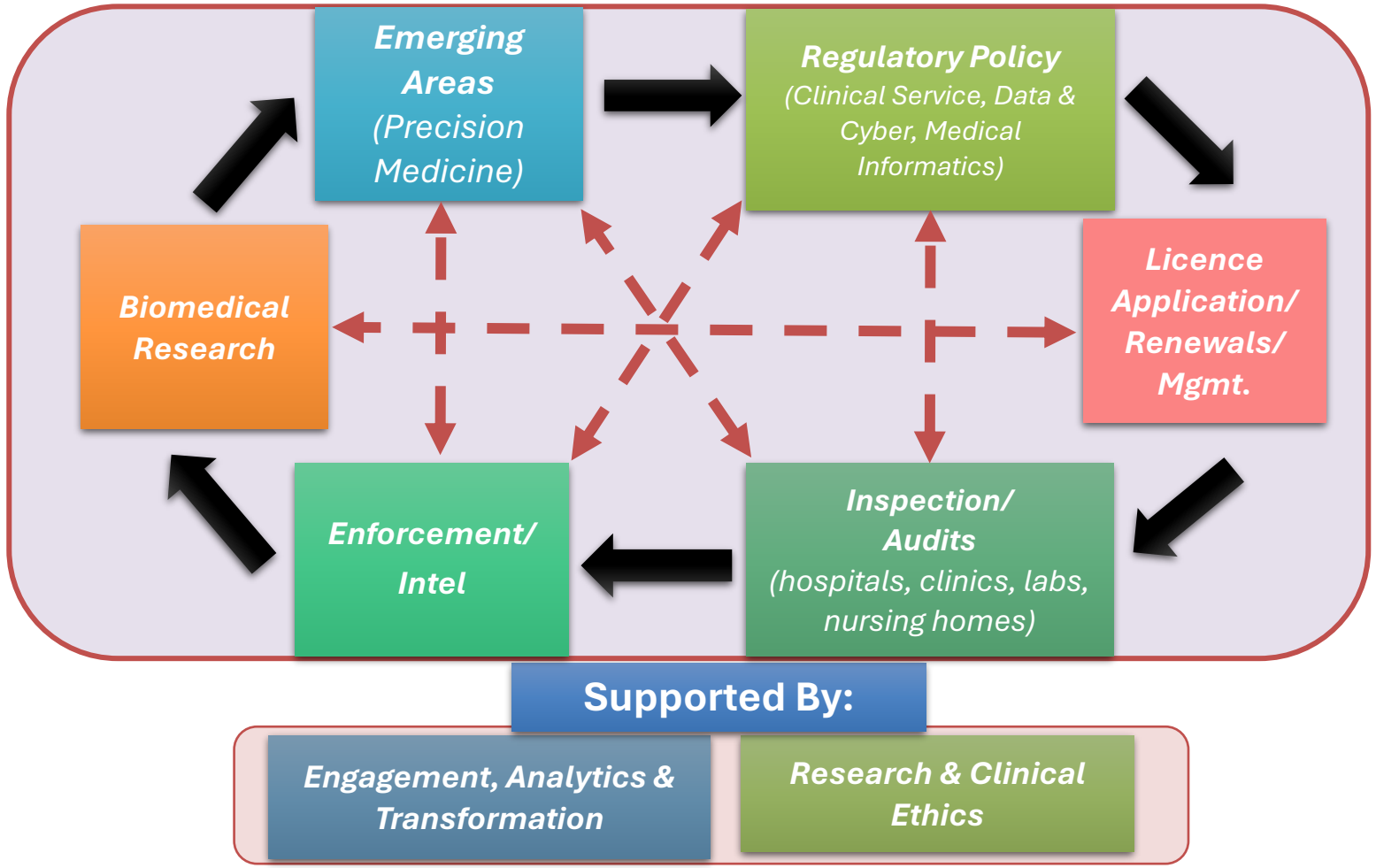
throughout the product life cycle



Healthcare Services are regulated by the Ministry of Health – Health Regulation Group

HRG's Mission: To safeguard and improve the safety and welfare of the public in our evolving healthcare landscape, through an effective and efficient regulatory regime

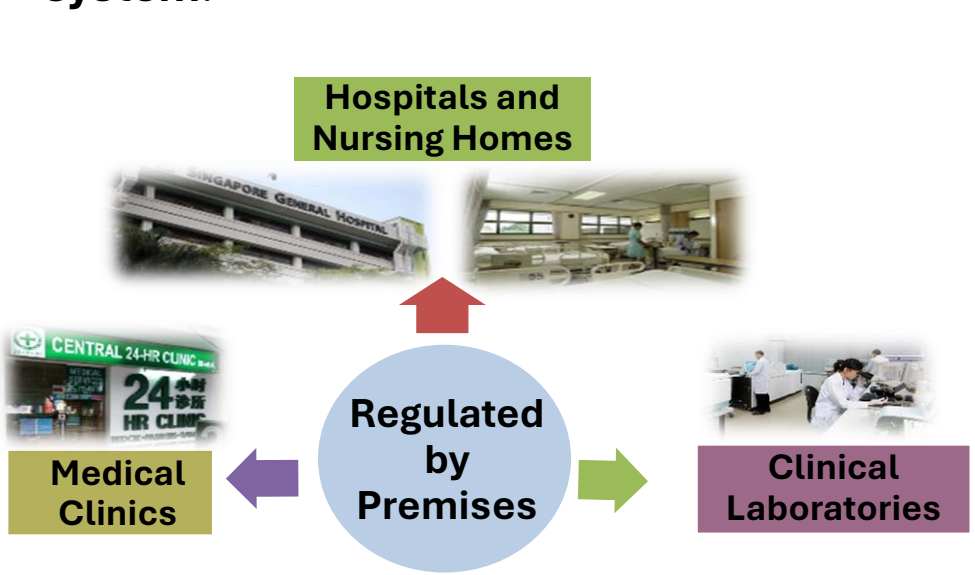
Within HRG, our regulatory functions are closely linked and integrated to enable feedback and improvements

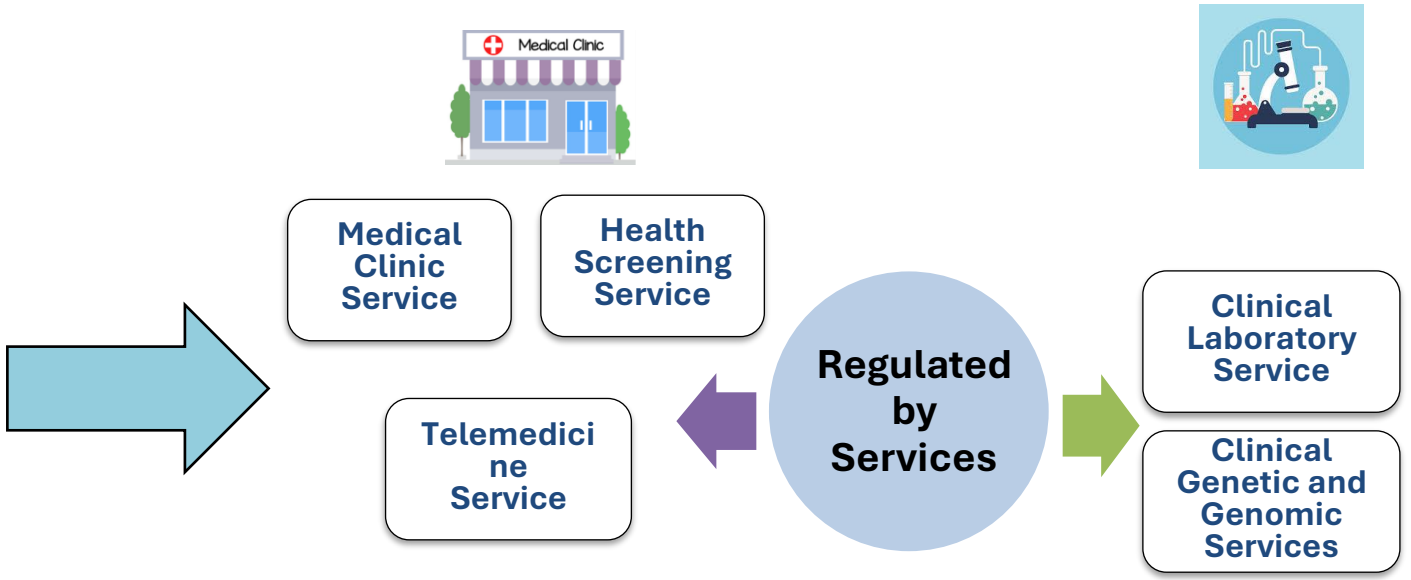


Feedback across the regulatory lifecycle, contributing to a robust regulatory system

Healthcare Services regulation adapting with new care models for a more flexible regulatory approach

- **New care models for patients have emerged**, and healthcare services are increasingly delivered through different modes, such as mobile and online channels.
- This has necessitated a shift towards a **more flexible approach in the regulation of Singapore's healthcare system**.





Private Hospitals and Medical Clinics Act (PHMCA)
Premises-based

Healthcare Services Act (HCSA)
Services-based

- Hence, to cope with the rapidly changing healthcare environment, the Healthcare Services Act (HCSA) was conceptualized to:
  - Replace the PHMCA
  - **Better safeguard patient safety and well-being**; and
  - **Enable the development of new and innovative healthcare services.**

Protecting health data to allow retrieval of accurate, up-to-date information for better care delivery

Health Information Bill

This Bill will mandate licensed healthcare providers contribute a copy of selected key health information (as determined by MOH) to the NEHR.

It will also ensure our healthcare data is well protected, by mandating cyber and data security requirements for healthcare providers and third-party data intermediaries.

NEHR
National Electronic Health Record Singapore

The NEHR system captures selected key health information in a central platform, for easy access by licensed healthcare providers and healthcare professionals.

1. **Mandatory contribution** of **selected key health information** to NEHR by healthcare licensees (e.g. hospitals, clinics, laboratories) and retail pharmacies; and enabling access for direct patient care

2. "**Green Lane" sharing** of identifiable data across prescribed entities in the healthcare ecosystem without prior consent, for **prescribed purposes** and with safeguards in place

3. Putting in place **cybersecurity and data security** to safeguard health information

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Multiple Safeguards will be Put in Place to Ensure Appropriate Use of NEHR

Access to NEHR **prohibited for insurance and employment purposes** (unless permitted by law).

Statutory medical reports are not considered patient care and thus NEHR access is generally prohibited to protect patient privacy, with exceptions only for **selected statutory medical examinations** where lack of access could significantly harm individual health or public interest.

Patients can view in HealthHub Access Logs which institution has accessed their NEHR records.

Patient may **place restrictions on NEHR access**, and block data sharing with healthcare providers. Other features include:

1. Break glass for medical emergencies
2. Double log-in for Sensitive Health Information
3. Cyber and data breach incident reporting and management

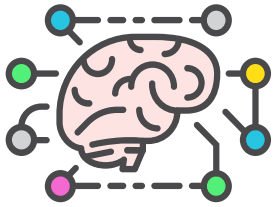
All access to NEHR are **audited** backend, and **inappropriate accesses are flagged for review**. Any unauthorised access to NEHR may be referred for investigation under the Computer Misuse Act.

Ensuring our regulatory frameworks are pragmatic, balanced and future proofed

1) *Ensure that **patient safety and quality of care continue to be of utmost importance***

2) *Enhance and introduce appropriate laws and regulatory frameworks to **enable and support upstream preventive care***

3) *Ensure we **stay ahead of the curve and develop fit-for-purpose regulatory tools to support the growth of new and innovative services** that benefit patients and our healthcare ecosystem*



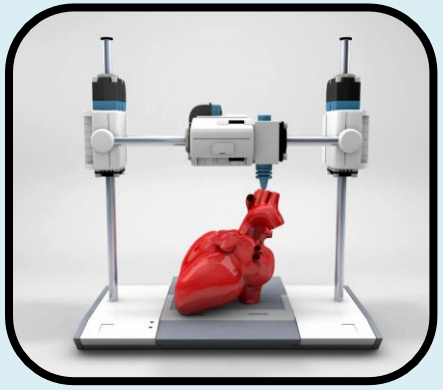
How Do We Support Safe and Timely Adoption of New Technologies?

Leveraging Increased Connectivity and Data

Artificial Intelligence and Cross-Boundary Care

Safe Deployment of Non-Digital Technologies

Gene Testing & Editing



3D-Printed Organs, Tissues & Medicine

Robotics

Regulatory Tools

Low Compliance Burden → **High Compliance Burden**

Stakeholder Education	Guidelines / Standards	Industry Self-Regulation	Regulatory Sandbox	Accreditation	Regulations/ Legislations

Supporting Enablers:
Data Analytics, Behavioural Insights, Stakeholder Consultation, Horizon Scanning

Transforming Our Health Regulatory Ecosystem

- To ensure our healthcare system progresses in tandem with technological advancements and is able to best serve our populations' evolving health needs, our regulations will need to:

Think out of the box

Be **premise-neutral** and more **service-centric**

Safeguard and Protect

Moratorium to **govern genetic data**

Protect against overcharging

Experiment

Sandboxes to support safe and innovative pilots

Review and Enhance

Change to **better embrace new technologies** – AI , Cellular Therapies

Create Bridges

Enable **safe data sharing** - HIB

Collaborate with partners and stakeholders

Future Proof

Resilient and Future-Ready – **"One-stop" Regulatory Hub**

Are we future-ready as health regulators as we are today?

Health Services & Data

MINISTRY OF HEALTH

To safeguard and improve the safety and welfare of the public in our evolving healthcare landscape, through an effective and efficient regulatory regime for health services & data

Health Products

HSA

To ensure standards of safety, quality and efficacy throughout the product life cycle are met.

Health Professionals

AHPC

To uphold standards on professional conduct and ethics, supported by the Secretariat of Healthcare Professional Boards (SPB).

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2026 Goal: “One-Stop” Future-Ready Centre of Regulatory Excellence

Enable greater policy & operations alignment across regulatory domains to address issues more holistically, expeditiously & efficiently.

✓ *Our Stakeholders*

Streamline stakeholder journeys with a **single regulatory touch point** for our stakeholders (e.g. licensees, registrants, citizens)

✓ *Our Partners*

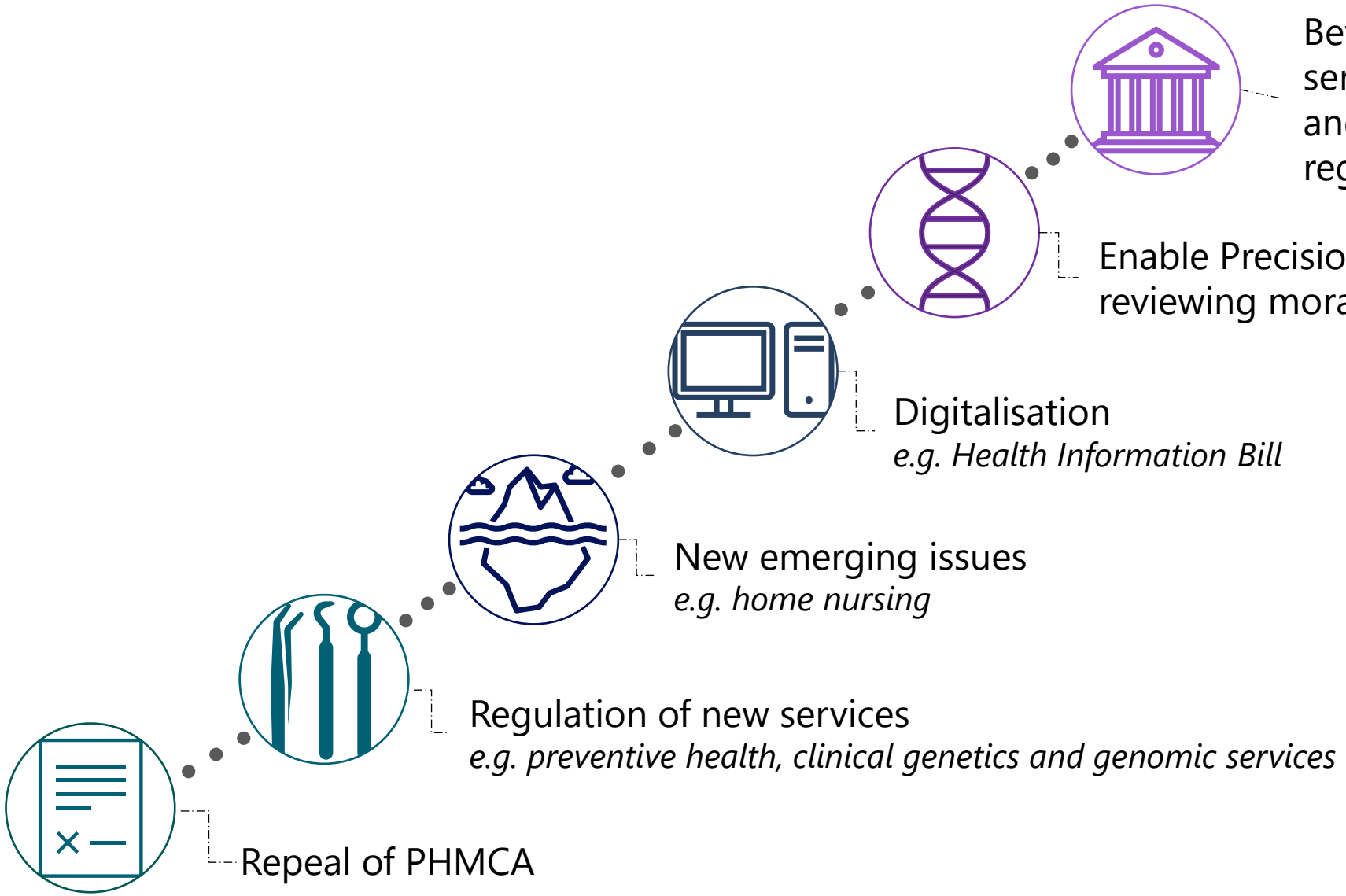
Single touchpoint for our partners (i.e. other government agencies & statutory boards) for all health regulatory matters.

✓ *Our People*

Greater opportunities to take on new roles, develop new skills and access a wider range of resources for professional growth and career progression as regulatory specialists and leaders.

Greater ease of collaboration and cooperation across regulatory domains to tackle complex regulatory issues holistically

Beginning of an Exciting Healthcare Regulatory Transformation Journey



Repeal of PHMCA

Regulation of new services
e.g. preventive health, clinical genetics and genomic services

New emerging issues
e.g. home nursing

Digitalisation
e.g. Health Information Bill

Enable Precision Medicine through reviewing moratorium and legislation

Better aligning regulations of services, products, data and professionals through regulatory transformation

Our Regulatory Advisory Panel insights to emerging areas

Artificial Intelligence

1. Risk based supervision of professionals - Develop a framework of responsibilities for deploying AI systems in patient care
2. Differentiated regulation approach toward AI (i.e. structured AI vs unstructured AI require different levels of human oversight, thus regulatory approach)
3. Incorporating real-world evidence through post market surveillance (in additional to sensitivity and specificity)
4. Adopting generative AI requires cultural readiness – through enabling transparency, ensuring data privacy and educating users (e.g. AI labels)

Wellness Services Regulation

1. Ensure informed consent and provision of cost-based analyses to consumers

Indirect care providers (e.g. concierge services/platforms)

1. Guidance to clearly define relationships between providers, insurers and stakeholders
2. Banning commissions-based payments (i.e. prioritise patient welfare)

Regulatory processes

1. Prevent duplication of licensing across different regulators for overlapping requirements
2. Incorporation of outcome-based collaboration and regulation to transform regulation to be more sustainable and adaptable
3. Equitable and consistent standards across all healthcare providers was critical, regardless of licensing status (i.e. to include wellness/non evidence-based treatment)

A Collective Approach Towards Transforming Regulation

Healthcare Products Industry

Patients

- There is **no one-size-fits-all solution** to regulating healthcare
- Always **be agile and be prepared for change** as the healthcare landscape will continue to evolve at a rapid pace
- It is important to **continue engaging and collaborating with various stakeholders** to co-create policies, regulations and tools while safeguarding patient safety and welfare

Insurance Providers

International Regulators

Healthcare Institutions & Professionals

CHANGE

is hard at first,
messy in the middle
and gorgeous at
the end. ~Robin Sharma

Lets review how the upcoming healthcare transformation is impacting us

Share with us your thoughts

https://go.gov.sg/regtransformation

Discussion Questions

1. Are the emerging areas in your horizon scanning areas similar? How are you approaching regulating these?
   - [Recap of emerging areas: 1. Change in Care Models; 2. Complementary & Alternative Medicine; 3. Digital Technologies shaping future of healthcare services; 4. Mainstreaming of personalised novel therapies]

2. Do you observe a rise in wellness/alternative facilities (e.g. wellness spas that provide weight loss treatment or homeopathy services that also prescribe medications)? How do you approach regulation of these?

3. With ongoing disrupters in healthcare, should we remain status quo (i.e. silo-ed regulator) or evolve and move towards integrated regulatory agency?

4. In your view, how might the convergence of healthcare domains (services, professionals, products & data) impact international regulatory harmonisation efforts?

Thank you

Contact us
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