

## **Republic of Singapore**

### **Agenda No. 15**

### **Harmonization of regulatory approaches, governance and standards for data, digital health and artificial intelligence in the health sector**

#### **Written Statement**

Singapore commends the Director-General for this comprehensive report. The emphasis on building robust foundational systems aligns with Singapore's approach to healthcare innovation.

2 Singapore recognises that technological breakthroughs in healthcare represent double-edged swords. Whilst genomics, artificial intelligence, and precision medicine offer unprecedented opportunities to transform care delivery, they also present significant risks around data security, ethical use, and equitable access. Our experience has taught us that innovation can only reach its full potential when robust safeguards protect against these risks.

3 Singapore has developed national platforms that serve to secure data sharing to enable innovation whilst protecting privacy. Our Health Empowerment through Advanced Learning and Intelligent eXchange (HEALIX) platform enables secure sharing of anonymised clinical, socio-economic, and genomic data across public healthcare institutions. HEALIX serves as our AI development factory, allowing institutions to create and train machine learning models for clinical decision-making.

4 Complementing this, our Trusted Research and Real-World Data Utilisation and Sharing Tech (TRUST) platform provides a secure environment where anonymised patient data may be shared for research purposes. The platform supports health data analytics and innovation between public institutions, and between the public and private sectors to improve health outcomes. Through the appointment of a Data Access Committee and the adoption of the Five Safes Framework (Safe Purpose, Safe People, Safe Settings, Safe Data, Safe Output) for governance, TRUST protects the privacy and confidentiality of individuals while enabling expeditious access to data for research.

5 Singapore has established regulatory sandboxes for AI software-as-medical devices (AI-SaMDs), allowing licensed public healthcare institutions to deploy AI solutions rapidly whilst maintaining robust clinical oversight and appropriate governance. This approach treats our entire public healthcare system as one entity, enabling proven AI solutions developed in one institution to be quickly adopted system-wide. Our fundamental philosophy approaches healthcare as AI-

enhanced rather than AI-decided. Human healthcare professionals maintain central roles in patient care, with AI augmenting rather than replacing clinical judgement.

6 Building on these foundations, Singapore is implementing predictive preventive care programmes, beginning with genetic testing for Familial Hypercholesterolemia (FH). This demonstrates how robust data governance enables precision medicine whilst ensuring equitable access through subsidised testing and cascade screening of family members.

7 Singapore believes that harmonised regulatory frameworks and coherent governance are essential for sustainable digital transformation. We stand ready to share our experiences and learn from others as we collectively navigate this technological revolution whilst maintaining patient safety, data security, and equitable access to innovation.