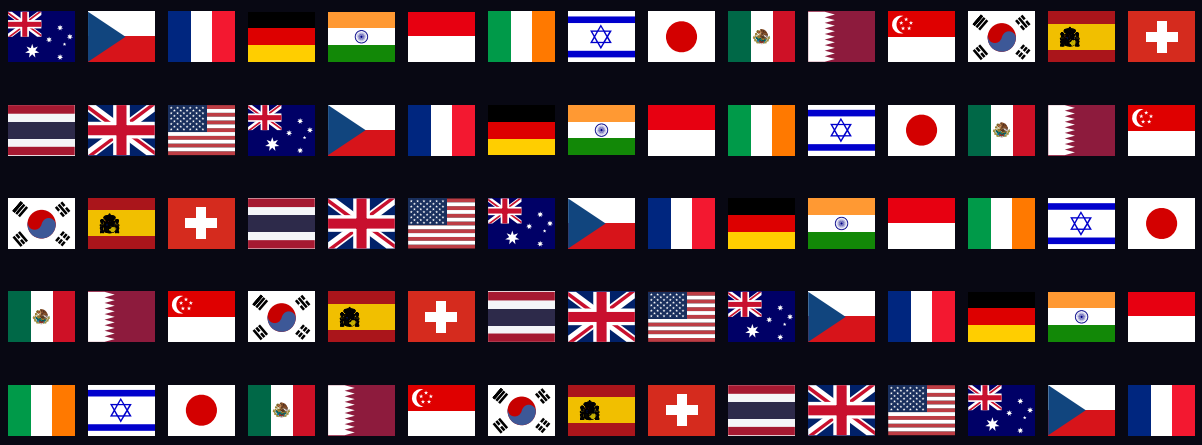
DIGITAL HEALTH

Singapore



LEXOLOGY
Getting The Deal Through

Consulting editor
Latham & Watkins LLP

Digital Health

Consulting editors

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Latham & Watkins LLP

Quick reference guide enabling side-by-side comparison of local insights, including market overview; legal and regulatory framework; data protection and management; intellectual property rights, licensing and enforcement; advertising, marketing and e-commerce; payment and reimbursement; and recent trends.

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Table of contents

UPDATES AND TRENDS

Recent developments

Contributors

Singapore

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MARKET OVERVIEW AND TRANSACTIONAL ISSUES

Key market players and innovations

Who are the key players active in your local digital health market and what are the most prominent areas of innovation?

There are key players in the different sectors of the digital health market in Singapore. In the government sector, the key players are the Ministry of Health (MOH), MOH Holdings, Office for Healthcare Transformation, National Research Foundation, and Singapore Economic Development Board. The key players in relation to healthcare providers are the National University Health System, National Healthcare Group and Singapore Health Services. The key research partners are the Agency for Science, Technology and Research (A*STAR) and Health Technologies Consortium.

The most prominent areas of innovation are artificial intelligence, telemedicine, mobile health (eg, mobile applications and wearable devices), data analytics and digitised and integrated healthcare systems (such as the National Electronic Health Record, which collects patients' health records, and the HealthHub App, which is a national digital healthcare platform).

Law stated - 24 February 2023

Investment climate

How would you describe the investment climate for digital health technologies in your jurisdiction, including any noteworthy challenges?

Medical technology investments and innovations have been a popular focus in the healthcare industry in Singapore given the rapid growth of digital health technology and healthcare research and development. Singapore is an attractive business hub for healthcare innovations with the majority of the population more tech savvy and receptive to digital health innovations than the more hesitant older population.

The covid-19 pandemic created a surge in demand for digital health products and services, which, in turn, catalysed investments in digital health and across the healthcare industry. As such, the adoption of digital healthcare was greatly accelerated. This was an unprecedented opportunity that shifted the default care model to digital health technologies and virtual services; bringing hospital to people's homes and increasing accessibility of an individual's health information and records. The digital demand in Singapore presents great opportunity for businesses to ensure high-quality digital services and to introduce digital healthcare solutions that are more effective and convenient.

Law stated - 24 February 2023

Recent deals

What are the most notable recent deals in the digital health sector in your jurisdiction?

In July 2021, ObvioHealth, a global Virtual Research Organisation, had raised S$31 million in its round of financing. The financing enables ObvioHealth to boost their IT capabilities of its proprietary ecosystem and platform for conducting virtual clinical trials. In June 2022, ObvioHealth signed a new global licensing agreement with Dedalus Group, an international healthcare IT and diagnostic software provider, to obtain access to the latter's data mining technology and analytics tools to carry out its research.

In July 2022, Altera Digital Health signed a multi-year agreement with Singapore's largest public healthcare group, SingHealth, for the use of the SunriseTM suite of healthcare solutions across its network of health services. As part of this deal, Altera will provide SingHealth with ongoing support for its electronic medical record platform.

In November 2022, DocDoc, the world's first patient intelligence company, announced a pan-Asia collaboration to offer its health insurance solutions to clients of Aon, an insurance broker, via insurance partners starting with Singapore. The solutions are powered by DocDoc's AI engine 'HOPE' and will empower employees with the personalised information required to make informed decisions across one of Asia's largest and most data-rich doctor networks.

In November 2022, a digital health platform in Singapore, Speedoc, raised S$28million in pre-Series B round funding, which will be used to scale up Speedoc's virtual hospital model. Speedoc is a virtual clinic that provides a range of mobile home care services, including teleconsultations, onsite doctor and nurse visits, virtual hospital wards and ambulance-hailing services.

Law stated - 24 February 2023

Due diligence

What due diligence issues should investors address before acquiring a stake in digital health ventures?

In a legal due diligence exercise, some of the key areas to examine in a digital health venture are as follows:

- Regulatory approvals: all the necessary licenses, permits, authorisations and approvals have been obtained by the digital health venture for its business, services or product.
- Intellectual property: the digital heath venture has the necessary intellectual property rights, patents, brands, trademark and/or ownerships for the conduct of its business, services or product.
- Privacy and data protection: ensure that the digital health venture's data protection and privacy policies comply with the provisions of Singapore's Personal Data Protection Act 2012 including adequate data protection policies in place, privacy consents and notices.
- Data security, cybersecurity and information technology (IT): examine the data security measures in place, any IT risks that may lead to operational, financial or commercial exposures.

Law stated - 24 February 2023

Financing and government support

What financing structures are commonly used by digital health ventures in your jurisdiction? Are there any notable government financing or other support initiatives to promote development of the digital health space?

Venture capital is a common source of financing in the digital health sector in Singapore. In addition, there are increasing non-dilutive government financings in healthcare to meet the rapid demand for medical digital technology innovations.

Notable government financing

The Research, Innovation and Enterprise Plan (RIE2025) was launched by the Singapore government and holds a budget of around S$25 billion, with plans to support new programmes to respond to future needs and emerging opportunities; funds for postgraduate programmes; innovation & enterprise talent development; and to establish new innovation and enterprise platforms to develop entrepreneurial talent. RIE2025 will be organised across four domains, namely: manufacturing, trade and connectivity; human health and potential; urban solutions and sustainability; and smart nation and digital economy.

Other support initiatives

In October 2022, a Clinical Innovation and Adoption Initiative disbursed up to S$1 million to successful applicants to develop and launch their health technologies in hospitals and clinics islandwide .

Healthcare Innomatch is an annual challenge launched in 2021 to gather technology proposals from startups and small and medium enterprises to change the way healthcare is provided in the future. In 2022, S$2.4 million was awarded in funding to six near market-ready solutions.

Law stated - 24 February 2023

LEGAL AND REGULATORY FRAMEWORK

Legislation

What principal legislation governs the digital health sector in your jurisdiction?

While there is no principal legislation that governs the digital health sector in Singapore, there are regulations and guidelines that may be applicable depending on the area of digital health.

The broad scope of digital health includes categories comprising telehealth and telemedicine, mobile health, wearable devices, health information technologies and personalised medicine. Medical devices are defined by the Health Sciences Authority (HSA) as health products which have a physical or mechanical effect when used on human bodies. Some examples of medical devices which incorporate digital health technology are software used by healthcare providers to screen or diagnose, tele-monitoring such as wearable devices, tele-treatment, and digital therapeutics such as software or mobile applications. Medical devices in Singapore are regulated under the Health Products Act and Health Products (Medical Devices) Regulations 2010 and there are regulatory guidance documents issued by the HSA as well for medical devices. Furthermore, the Artificial Intelligence in Healthcare Guidelines was published in October 2021 and serves as a guide for developers and implementers of AI in healthcare and complements the existing HSA regulatory requirements of AI Medical Devices.

The Private Hospitals and Medical Clinics Act 1980 will be gradually replaced by the Healthcare Services Act 2020 (HCSA) and under the HCSA, telemedicine services will be licensable healthcare services from the end of 2023. The HCSA aims to transition from the previous premises-based regulatory framework adopted by PHMCA to a services-based regulatory framework.

Law stated - 24 February 2023

Regulatory and enforcement bodies

Which notable regulatory and enforcement bodies have jurisdiction over the digital health sector?

In Singapore, the healthcare sector in Singapore is generally overseen by the Ministry of Health (MOH). MOH also has a dedicated national health-tech agency, Integrated Health Information Systems (IHiS), that focuses on developing and integrating technology within Singapore's public healthcare sector.

Digital health products (as long as they qualify as medical devices) are principally regulated by the Health Sciences Authority (HSA). The HSA administers and enforces the Health Products Act 2007 and its subsidiary legislation. Whereas telemedicine services are regulated by the Private Hospitals and Medical Clinics Act 1980 (PHMCA) which will be gradually replaced by the Healthcare Services Act 2020 (HCSA). The PHMCA and HCSA are administered and enforced by MOH.

There are several regulatory instruments that relate to data protection and privacy in the digital health sector such as the PHMCA and the HCSA, which contain provisions relating to the protection of confidential information such as patients' medical records, diagnosis or treatment, and the Healthcare Cybersecurity Essentials, which provides intermediate and long-term care services in adopting basic safeguards for IT assets and data.

Law stated - 24 February 2023

Licensing and authorisation

What licensing and authorisation requirements and procedures apply to the provision of digital health products and services in your jurisdiction?

Medical devices in Singapore, including digital health products and services, are regulated under the Health Products Act (HPA) and Health Products (Medical Devices) Regulations 2010, which are governed by the Health Sciences Authority (HSA).

In relation to the registration of medical devices, the registration process will differ depending on the device's risk classification and evaluation routes. The risk classification of devices may fall under four classes, Classes A, B, C and D, whereby Class A devices are exempted from product registration. The evaluation route, which determines whether an application for a licence is necessary, depends on three factors: the risk classification, the number of prior approvals by HSA's overseas reference regulatory agencies and the duration of safe marketing history for the device.

As for the licensing requirements, all medical device dealers are required to apply for a dealer's licence (includes importer's, manufacturing and wholesaler's licences) before importing, manufacturing and supplying devices in Singapore, which includes the distribution of digital health products. In granting a dealer's licence, the HSA will also take into consideration whether these dealers have conformed to the requirements of the Good Distribution Practice for Medical Devices (GDPMDS), which apply to medical devices incorporating digital solutions (sensors). Information on the software version being registered and to be supplied in Singapore is to be clearly presented on the device labelling (if supplied in physical form) or software graphical interface (if supplied without physical form), depending on the mode of supply of the software. Further guidelines on licensing requirements specific to software medical devices (such as software embedded in medical devices, standalone mobile applications, standalone software and web-based

software) are set out in the Regulatory Guidelines for Software Medical Devices dated April 2022.

The covid-19 pandemic has accelerated the use of digital health technologies in clinical trials. The development of e-consent systems and patient portals has made the enrolment process much smoother, whereby patients are able to access all the information in connection with the clinical trial and provide their consent digitally. HSA would have to be consulted prior to implementation of any digital clinical trial. For instance, an AI-driven digital medicine platform called Quadratic Phenotypic Optimisation Platform (QPOP) was developed by researchers from the Cancer Science Institute of Singapore, which is helping doctors make better clinical decisions when treating cancer patients. QPOP has already proved to be successful in current and past cancer patient trials.

Law stated - 24 February 2023

Soft law and guidance

Is there any notable 'soft' law or guidance governing digital health?

There are notable 'soft' laws and regulations governing digital health. For instance, medical devices in Singapore are regulated under the Health Products Act and Health Products (Medical Devices) Regulations 2010 and there are regulatory guidance documents issued by the Health Sciences Authority (HSA). Furthermore, the Artificial Intelligence in Healthcare Guidelines (AIHGle) were published in October 2021 and serves as a guide for developers and implementers of AI in healthcare and complements the existing HSA regulatory requirements of AI Medical Devices. Separately, telemedicine services are regulated under the MOH's 2015 National Telemedicine Guidelines, the SMC Ethical Code and the 2016 Handbook on Medical Ethics.

There are further key regulations in Singapore that apply to digital health applications that are considered medical devices:

- Medical Devices Regulations: these regulations deal with the manufacture, import, supply requirements and exemptions for medical devices, presentation, advertisement and registration of medical devices, and various duties and obligations of manufacturers and importers of medical devices.
- National Telemedicine Guidelines (January 2015): these non-legally binding guidelines were issued by the MOH as a guide setting out best practices in implementing telemedicine solutions. They govern the use of technology and equipment in telemedicine.
- Regulatory Guidelines for Telehealth Products (April 2019): these guidelines describe telehealth products, which may include digital health applications that are categorised as medical devices, and set out the risk classification and regulatory controls for telehealth medical devices and standalone mobile applications that are categorised as medical devices.
- A regulatory guidance issued by the HSA in June 2018 that provides guidance on medical device advertisements and sales promotion.
- Guidelines for Telepharmacy 2009 that are issued by the Pharmaceutical Society of Singapore.

Law stated - 24 February 2023

Liability regimes

What are the key liability regimes applicable to digital health products and services in your jurisdiction? How do these apply to the cross-border provision of digital health products and services?

In Singapore, contractual and tort law would be the key liability regimes applicable to digital health products and services. For example, a contractual claim may arise where there is a breach of contract pertaining the digital health product or service provided. Actions for injuries or damage due to faulty digital health products will be founded on the tort of negligence and breach of contract (if there is privity of contract). Another instance would be actions for breach of patient confidentiality or data breaches which could amount to tort of breach of confidence.

There are also general liability regimes for consumer protection that would be applicable to digital health products and services. For instance, the Consumer Protection (Fair Trading) Act 2003 protects consumers from unfair practices by commercial suppliers (including suppliers of digital health products). In the event of a breach or unfair practices, consumers or customers may obtain civil remedies against these suppliers under contract and tort law and legislations, such as the Unfair Contract Terms Act 1977 and under the Sales of Goods Act 1979 (for example, if the digital health product does not correspond with the description, quality, sample provided or is not fit for purpose).

With regards to cross-border provision of digital health products and services, liability under the law of contract would depend on the laws that the contract is governed by. As regards cross-border tort disputes, this would depend on the country in which the damage occurs or where in substance the tort had occurred. Legal liability issues could arise especially in situations of freelance registered doctors in telemedicine negligence or claims against foreign telemedicine providers. In any event, the common law of the tort of negligence will continue to apply to telemedicine in connection with the diagnosis, advice and treatment by a doctor.

Law stated - 24 February 2023

DATA PROTECTION AND MANAGEMENT

Definition of ‘health data’

What constitutes ‘health data’? Is there a definition of ‘anonymised’ health data?

The term ‘health data’ is not specifically defined under any Singapore legislation. However, the Personal Data Protection Act 2012 (PDPA) in Singapore governs the collection, use, disclosure, retention and care of personal data. The PDPA applies to all industries, including the healthcare industry. As such, ‘health data’ would be covered under the umbrella term of ‘personal data’. Even though the PDPA does not have a special or separate category of ‘sensitive’ personal data, the PDPC does take a stricter view when considering a case where the personal data compromised is of a sensitive nature. It is conceivable that the data of a person’s health and medical condition, together with other identifying information, can constitute ‘sensitive’ personal data.

There is no legal definition of anonymised personal data. The PDPA has issued Advisory Guidelines on PDPA for Selected Topics in which the general term ‘anonymisation’ is referred to as the process of converting personal data into data that cannot identify any particular individual and, depending on the specific process used, can be reversible or irreversible. This would be the best aid to the interpretation as to what constitutes ‘anonymised data’.

Law stated - 24 February 2023

Data protection law

What legal protection is afforded to health data in your jurisdiction? Is the level of protection greater than that afforded to other personal data?

As 'health data' falls under personal data that is governed under the Personal Data Protection Act 2012 (PDPA), the provisions of the PDPA apply. The Personal Data Protection Commission (PDPC) and Ministry of Health have issued Advisory Guidelines for the Healthcare Sector (revised on 28 March 2017), which aim to address the unique circumstances faced by the healthcare sector in complying with the PDPA. There is a greater emphasis in the level of protection afforded to health data in Singapore in view of the importance placed on health data (such as medical records, contact information and financial details) and increases in data breaches, cyberattacks and cybercrime activity. As health data may in some circumstances be considered as 'sensitive' data, the PDPC expects a higher standard of protection for sensitive personal data.

Law stated - 24 February 2023

Anonymised health data

Is anonymised health data subject to specific regulations or guidelines?

The Personal Data Protection Commission and Singapore Digital issued a Guide to Basic Anonymisation on 31 March 2022 which includes references to anonymisation of health data. In relation to healthcare data, the right choice of anonymisation techniques would have to be applied. For instance, the organisation would likely require someone with sufficient healthcare knowledge to assess a record's uniqueness, namely, to what degree that it is identifiable or re-identifiable. Another instance is when data attributes are swapped between records and it takes a healthcare expert to recognise if the anonymised records make sense. Anonymised health data is also subjected to the Advisory Guidelines for the Healthcare Sector (revised on 28 March 2017).

Law stated - 24 February 2023

Enforcement

How are the data protection laws in your jurisdiction enforced in relation to health data? Have there been any notable regulatory or private enforcement actions in relation to digital healthcare technologies?

The data protection laws in Singapore are governed under the Personal Data Protection Act 2012 (PDPA), which includes health data. The Personal Data Protection Commission (PDPC) oversees the compliance and enforcement of the PDPA. In relation to health data, the Personal Data Protection Commission and Ministry of Health have issued Advisory Guidelines for the Healthcare Sector (revised on 28 March 2017) that aim to address the unique circumstances faced by the healthcare sector in complying with the PDPA.

In June 2018, the nation's worst data breach occurred, with a cyber-attack on SingHealth that resulted in the personal information of 1.5 million patients being compromised. Due to the breach, the technology vendor for Singapore's healthcare sector, Integrated Health Information Systems was fined S$750,000 for lapses in securing patient data and SingHealth, who was the owner of the patient database system, was fined S$250,000 by the PDPC.

In November 2022, Farrer Park Hospital was fined S$58,000 over a data breach that resulted in medical records of individuals being leaked. The PDPC warned of the risks of such data breach involving sensitive personal data and the need for stronger security arrangements.

Law stated - 24 February 2023

Cybersecurity

What cybersecurity laws and best practices are relevant for digital health offerings?

To the extent that digital health offerings are closely intertwined with Critical Information Instructure, as defined under the Cybersecurity Act, the provisions of the Cybersecurity Act will apply.

The Ministry of Health (MOH) has issued a guideline on the Healthcare Cybersecurity Essentials (HCSE) in August 2021. The aim of the HCSE is to provide guidance to all healthcare providers on basic cybersecurity measures that can be adopted to ensure the security and integrity of their IT assets, systems, and patient data. While the HCSE is non-binding, healthcare providers are strongly encouraged to adopt the recommended measures. The key recommended measures that healthcare providers can implement are split into three steps: (1) to create an IT assets inventory, (2) to secure the data, detect, respond to, and recover from breaches and (3) to implement the measures into practices.

The MOH issued the Cybersecurity Advisory 1/2019 in view of the 2018 SingHealth data breach that involved the health data of 1.5 million individuals being leaked. This Advisory set out the cybersecurity best practices arising from the recommendations in the Committee of Inquiry (COI) report to the cyber-attack on SingHealth. In the report, the COI made 16 recommendations to protect SingHealth and other public sector IT systems which contain large databases from cybersecurity attacks.

The MOH and other agencies in Singapore have in 2022 begun a consultation into the proposed cybersecurity labelling scheme for medical devices (CLS (MD)), which describes a four-tier cybersecurity rating scale. The scope of CLS (MD) would apply to medical devices that handle health-related data or connect to other devices, systems and services.

Law stated - 24 February 2023

Best practices and practical tips

What best practices and practical tips would you recommend to effectively manage the ownership, use and sharing of users' raw and anonymised data, as well as the output of digital health solutions?

Digital health companies and businesses handling raw and anonymised data should ensure that they comply with the Personal Data Protection Act 2012 (PDPA) of Singapore and the relevant guidelines issued by the Personal Data Protection Commission (PDPC) such as the Guide to Basic Anonymisation issued on 31 March 2022 and the Advisory Guidelines for the Healthcare Sector revised on 28 March 2017. Digital health companies and businesses should also carefully consider the personal information that they require and the purpose for such information and evaluate the need for transfer or sharing of this personal data.

Digital health companies should ensure there is adequate protection and security of users' raw data and anonymised data, whether stored in-house or with external parties.

In a scenario where data has to be transferred out of Singapore, there is a need to ensure compliance with section 26 of the PDPA (Transfer Limitation Obligations), which limits the ability of an organisation to transfer personal data

outside of Singapore.

Law stated - 24 February 2023

INTELLECTUAL PROPERTY

Patentability and inventorship

What are the most noteworthy rules and considerations relating to the patentability and inventorship of digital health-related inventions?

In relation to digital health-related inventions, the general rules under the Patents Act 1994 and Trade Mark Act 1998 would be applicable. Patents and trademarks are given and protected under the Intellectual Property Office of Singapore. When applying for patents in Singapore, the digital health-related invention must meet certain legal requirements for a patent to be filed. Firstly, the invention must be novel and this fact may be ascertained by applying a worldwide test of novelty that contains two steps: (1) whether it was anticipated by a previous patent and (2) whether it was published or used anywhere in the world. Second, the invention must involve an inventive step, which means that such inventive step used in creating the invention must not have been obvious to a person skilled in that particular field. Third, the invention must be capable of industrial application, meaning that the invention can be made or used in any kind of industry, including medicine, and serves a useful purpose.

Law stated - 24 February 2023

Patent prosecution

What is the patent application and registration procedure for digital health technologies in your jurisdiction?

The registration of IP works in a manner that higher priority is accorded to the applicant who files the earliest. This also prevents a similar invention from obtaining the rights and precedence before said applicant.

In May 2022, the Intellectual Property Office of Singapore (IPOS) had launched the SG Patent Fast Track programme (now renamed as SG IP FAST) to support the acceleration of patent applications in all technology fields, including digital health technologies. To begin filing for a patent, the applicant must submit a patent application to the IPOS online and ensure the conditions to qualify or remain on the SG IP FAST programme are met.

While obtaining a patent in Singapore generally takes about two to four years from the date of filling, the accelerated timelines under the SG IP FAST programme grants straightforward patent applications as fast as six months and grants non-straightforward patent applications as fast as nine months. Once granted, the patent takes effect immediately and lasts for 20 years starting from the date that the patent application was filed.

Law stated - 24 February 2023

Other IP rights

Are any other IP rights relevant in the context of digital health offerings? How are these rights secured?

To the extent a medical device is involved in the service offering, then Registered Design protection may be relevant to

protect the shape of the design. A registration for the design would protect the external appearance of the article and have the right to control its use. Similarly, if the digital health offering is performed under a brand, then trademarks to protect this brand may be relevant.

Law stated - 24 February 2023

Licensing

What practical considerations are relevant when licensing IP rights in digital health technologies?

There are only two major practical considerations to take into account when licensing IP rights in digital health technologies:

- whether the licensing terms comply with any regulatory requirements; and
- what is the optimal tax position for the structure of the licence.

Law stated - 24 February 2023

Enforcement

What procedures govern the enforcement of IP rights in digital health technologies? Have there been any notable enforcement actions involving digital health technologies in your jurisdiction?

The usual court procedures under Singapore Intellectual Property (IP) law generally would be available to IP owners to enforce their rights in digital health technologies.

For any infringement of patents or trademarks, applicants could bring an infringement action to obtain damages in a civil claim. For trademarks, trademark owners would be able to bring a claim and obtain relief for infringement in accordance with section 26(2) of the Trade Marks Act 1998.

In Singapore, the Ministry of Law has announced that in the new Supreme Court of Judicature (Intellectual Property) Rules 2022 that have come in force on 1 April 2022, a new optional track for IP litigation will be implemented. The new optional track is streamlined and aims to lessen time costs and for IP dispute resolutions to be more cost-effective. The new track would be mainly for disputes involving an IP right where the monetary relief claimed by each party in the action does not or is likely not to exceed S$500,000 or all parties agree to the application of this simplified process to their case.

There have not been any notable reported cases concerning enforcement actions and digital health technologies in Singapore.

Law stated - 24 February 2023

ADVERTISING, MARKETING AND E-COMMERCE

Advertising and marketing

What rules and restrictions govern the advertising and marketing of digital health products and services in your jurisdiction?

In relation to advertisements for digital health products and services that qualify as medical devices, the Health Sciences Authority has issued a regulatory guidance in June 2018 on medical device advertisements and sales promotion. It is the responsibility of the advertiser to ensure compliance with the legislations and guidelines for advertisement and promotions of medical devices. The advertiser has to take note of the advertisement prohibitions (for instance, advertising to the general public that claim, indicate or suggest that the medical device will prevent, alleviate or cure some diseases or conditions is not allowed) and general principles of advertisements (such as truthfulness, substantiation, accuracy, claims of safety, etc). It is an offence to advertise false or misleading information relating to therapeutic products or medicinal products and these would include digital health products and services.

Law stated - 24 February 2023

e-Commerce

What rules governing e-commerce are relevant for digital health offerings in your jurisdictions?

The general rules governing e-commerce are applicable to digital health offerings. Electronic payments in Singapore are regulated under the Payment Services Act 2019 (PSA). Payment services can only be offered by licensed payment service providers under the PSA, regulated by the Monetary Authority of Singapore (MAS). As such, providers of digital healthcare can work with various licensed service providers to provide electronic payments options, increasing accessibility of healthcare to all consumers in Singapore.

In addition, the Health Sciences Authority has set out certain regulatory requirements for licensed retail pharmacies to satisfy if they wish to supply registered therapeutic products, prescription-only medicine and pharmacy only medicines, through e-pharmacy service. An applicant who qualifies to supply registered therapeutic products through the mode of e-pharmacy must implement good governance and practices in operations and operate an effective system to ensure high-quality medicines are supplied to patients. Guidance documents are issued to better understand the specific regulatory requirements to supply registered therapeutic products through e-pharmacy service such as Guidance Notes on Supply of Registered Therapeutic Products through e-pharmacy and Guidance Notes on Good Distribution Practice.

Law stated - 24 February 2023

PAYMENT AND REIMBURSEMENT

Coverage

Are digital health products and services covered or reimbursed by the national healthcare system and private insurers?

Certain digital health products and services are covered or reimbursed by Singapore's healthcare system and private insurers.

In 2015, the Health Promotion Board (HPB) under Singapore's healthcare system, launched the National Steps Challenge to members of public where Singapore residents may collect a digital health product, HPB Fitness Tracker, to

track the number of steps that they have taken and are rewarded instantly for meeting various milestones stated in the Challenge.

Private insurers have been active in the digital healthcare space and have partnered with various telemedicine services to provide digital healthcare services. For example, under the AIA HealthShield insurance, individuals under the plan would be able to leverage the partnership that AIA has with White Coat (a Singapore-based healthcare provider that offers on-demand telemedicine services through a mobile app) to have a video consultation by Singapore-registered doctors at low costs.

In April 2020, Prudential Singapore launched an artificial intelligence-powered mobile app called Pulse by Prudential that provides Singapore residents with 24/7 access to healthcare services and updates on their health information (for example, being able to check their symptoms, conduct digital health assessments and seek health advice when required).

Law stated - 24 February 2023

UPDATES AND TRENDS

Recent developments

What have been the most significant recent developments affecting the digital health sector in your jurisdiction, including any notable regulatory actions or legislative changes?

In April 2022, Biofourmis, Singapore's healthtech startup (and now US-headquartered) surpassed unicorn status with a S$300 million Series D investment. With this investment, Biofourmis intended to scale up its virtual care offerings. This includes delivering personalised and predictive in-home care to a growing number of acutely ill patients and expanding its recently announced virtual specialty care services, Biofourmis Care, to those patients with complex chronic conditions.

In 2018, the Ministry of Health (MOH) launched a regulatory sandbox initiative called the Licensing Experimentation and Adaptation Programme to explore new digital health innovations in areas of telemedicine and mobile medicine. In February 2021, the objectives were fulfilled and MOH closed the sandbox, with multiple telemedicine applications created that also gained popularity, especially during the covid-19 pandemic. This allowed MOH to better understand the risks of direct telemedicine providers and provide a transition approach in issuing more concrete regulations and measures for the telemedicine sector prior to regulating telemedicine as a licensed healthcare service under the Healthcare Services Act.

Several telemedicine applications have picked up speed in recent years, with digital health applications such as Speedoc and Doctor Anywhere raising funds in various series of funding. Furthermore, Speedoc is MediSave-accredited and Community Health Assist Scheme-accredited (CHAS-accredited), which makes the application more attractive to Singapore residents as they will be able to use CHAS subsidies and MediSave to subsidise part of their healthcare bills.

The Ministry of Health Office for Healthcare Transformation (MOHT) launched a one-year pilot digital healthcare initiative in September 2018 specifically for hypertension patients to better self-manage their conditions where patients enrolled would receive a Bluetooth-enabled home blood pressure device to monitor their blood pressure at least once

weekly. The readings from the device would be automatically transmitted from a mobile application to the polyclinic care team and the team would follow up on teleconsultations where they could adjust the patient's medication if required, without the need for physical visits. The pilot was successful and the programme was scaled up to include several polyclinics in Singapore.

Law stated - 24 February 2023

Jurisdictions

Australia	Gilbert + Tobin
Czech Republic	dubanska & co
France	Intuity
Germany	Ehlers Ehlers & Partner
India	Chadha & Chadha Intellectual Property Law Firm
Indonesia	ABNR
Ireland	Mason Hayes & Curran LLP
Israel	Naschitz Brandes Amir
Japan	Anderson Mōri & Tomotsune
Mexico	Galicia Abogados SC
Qatar	Al Marri & El Hage Law Office
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