Digital Health in Asia-Pacific

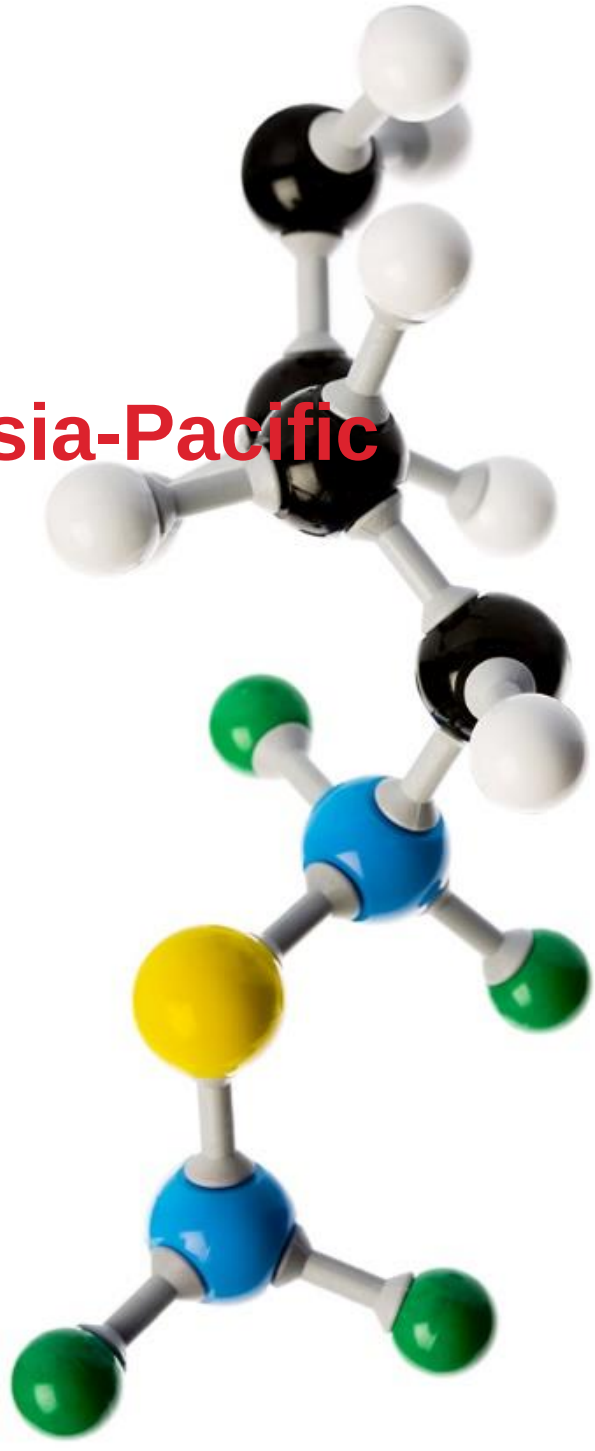
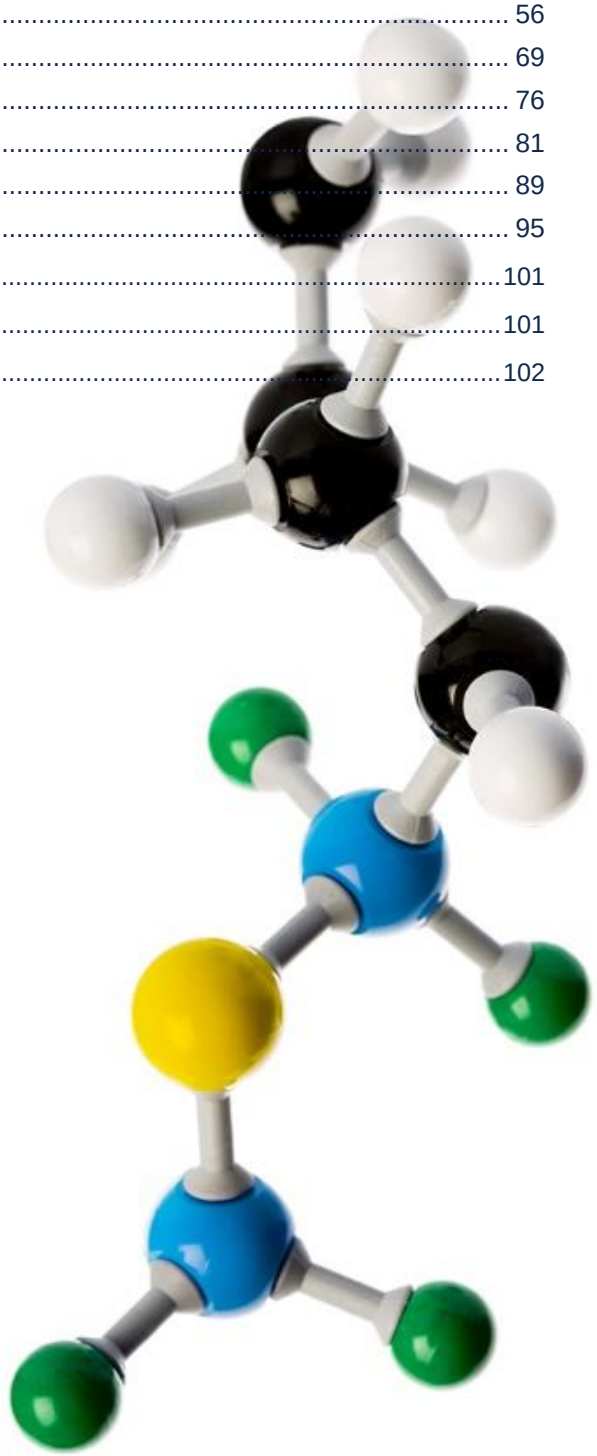


Table of Contents



Introduction

The global drug industry is gradually moving away from traditional drug development and towards integrating the innovations of apps and technologies that provide “overall solutions”. The idea of digital disruption stems from individual autonomy; patients are not just passive recipients but are becoming well-informed and are actively seeking tailored healthcare goods and services that satisfy their particular needs. Ultimately, patients are looking to go “beyond the pill” for greater full-service offerings.

This has led to the emergence of digital health – the convergence of technology with healthcare to deliver healthcare services in a more efficient, personalised and innovative manner. Typical digital health uses include telemedicine, mobile apps, wearable devices, artificial intelligence algorithm software and diagnostic medical devices.

In this guide, we consider the potential legal issues that arise in respect of the digital health technologies emerging within each respective jurisdiction. As a growing area of law, specialists within LAN will provide insight into the interpretation of current regulations, the obstacles to the development of digital healthcare, and the predictions for the future of digital healthcare governance.

Australia

Regulatory Overview

1. What is the main legislation for digital health technology in your jurisdiction?

There is no single piece of legislation which governs digital health technology in Australia. Rather, different laws govern different aspects of digital health technology. In Australia, the main legislation in relation to digital health technology falls into three categories: therapeutic goods law, consumer protection law and privacy law.

Therapeutic goods and medical devices

Therapeutic Goods Act 1989 (Cth)

The legislation regulating 'therapeutic goods' in Australia is the *Therapeutic Goods Act 1989* (Cth) (**Therapeutic Goods Act**), the *Therapeutic Goods Regulations 1990* (Cth) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth). The Therapeutic Goods Administration (**TGA**) is the regulatory body responsible for the administration of this legislation, including administering the regulatory system for medical devices and other therapeutic goods.

In the Therapeutic Goods Act, a 'medical device' is defined as:

(a) *Any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under* whose *name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:*

i. diagnosis, prevention, monitoring, treatment or alleviation of disease;

ii. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;

iii. Investigation, replacement or modification of the anatomy or of a physiological process;

iv. Control of conception;

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means.[1]

Relevantly, software and mobile applications (known as 'apps') can fall within the definition of 'medical device' under the Therapeutic Goods Act. Some examples of software as a 'medical device' (**SaMD**) within the meaning of the Therapeutic Goods Act include:

- Smart phone apps that calculate insulin doses based on a patient's blood glucose levels;
- X-ray image-processing software; andSoftware that uses information about a patient to make a diagnosis.

For clarity, mobile apps that can control or adjust a medical device through Bluetooth or Wi-Fi features are considered to be SaMD because they are accessories to the medical device. Additionally, medical device software that is an integral part of a physical device is considered to be part of that device and is not regulated separately.[2] Digital health devices and software which merely provide a source of information or tools to manage a healthy lifestyle do not fall within the definition of a 'medical device' under the Therapeutic Goods Act. Unless an exemption applies, a SaMD product must be entered into the Australian Register of Therapeutic Goods (**ARTG**) before it can be supplied in Australia.

Consumer protection

Competition and Consumer Act 2010 (Cth)

The Australian Consumer Law (**ACL**), which is found in Schedule 2 of the *Competition and Consumer Act 2010* (Cth), sets out "consumer guarantees" which apply to goods and services supplied to "consumers". At a high level, "consumers" are individuals or corporations who acquire goods or services for their own use (not for re-supply) and where the amount paid for the goods or services is less than $40,000, or where the goods or services are of a kind ordinarily acquired for personal, domestic or household use or consumption.

In the context of digital health technology, the ACL provides that goods (which could include digital health devices supplied to consumers) must:

- Be of acceptable quality;
- Be safe and fit for purpose;
- Match descriptions made by the supplier and manufacturer, on packaging and labels, and in promotions or advertising;
- Match any demonstration model or sample provided;
- Come with full title and ownership;
- Not carry any hidden debts or extra charges;
- Comply with any express warranties provided with the goods;
- Come with undisturbed possession;
- Meet any extra promises made about performance, condition and quality, such as life time guarantees and money back offers; and

[1] Therapeutic Goods Act 1989 (Cth) s 41BD.
[2] Therapeutic Goods Administration, 'Regulation of Software as a Medical Device', available at: https://www.tga.gov.au/regulation-software-medical-device (December 2018).

- Have spare parts and repair facilities available for a reasonable time after purchase unless advised otherwise.

In relation to digital health technology delivered as a service to a consumer, the ACL imposes consumer guarantees that the services must:

- Be provided with due care and skill;
- Be provided within a reasonable time (when no time is specified); and
- Be fit for any specified purpose.

The ACL also contains provisions in relation to product safety of consumer goods, which may be relevant where medical devices (including the software and other technologies in them) are unsafe or defective. Notably:

- It is mandatory for every participant in the supply chain of a consumer product to report any death, serious injury or illness caused by the product;[3]
- Unsafe consumer products can be recalled voluntarily by a supplier, or a recall may be directed by the regulator;[4]
- Consumer products of a kind that may cause injury may be banned;[5] and
- Amanufacturer is liable for safety defects in consumer products that it manufactures. Manufacturers have strict liability, and a "state of the art" defence is available if the manufacturer can prove that the defect could not have been identified given the state of scientific and technical knowledge at the time the goods were supplied.[6]

The ACL allows the Minister responsible for the ACL to publish mandatory standards of particular safety[7] or information features[8] of a class of consumer goods (and product-related services, such as installation services). Presently, there are no mandatory standards prescribed for digital health technologies.

The ACCC has stated that it wants to see a 'general safety provision' introduced into the ACL by the end of 2019, which may be similar to the general safety provisions introduced in the United Kingdom. A general safety provision would impose an obligation on suppliers not to supply unsafe products to Australian consumers. The practical effect of such a provision is that suppliers must (in order to avoid contravention and penalties) take proactive steps to check the safety of a product before they make a decision about whether to supply it to Australian consumers.

Privacy

Privacy Act 1988 (Cth)

In Australia, Commonwealth government agencies and certain businesses[9] must comply with the requirements of the *Privacy Act 1988 (Cth)* (**Privacy Act**) and the Australian Privacy Principles (**APPs**) contained in Schedule 1 of the Privacy Act in relation to the collection, use and disclosure of 'personal information'.[10] In the digital health space, many applications of digital health technology will involve the collection of personal information, particularly health information.

[3] ACL section 131.
[4] ACL Chapter 3, Part 3-3.
[5] ACL section 114.
[6] ACL Part 3-5, Decision 1.
[7] ACL section 104.
[8] ACL section 134.
[9] In particular, organisations which have an annual turnover of more than AUD $3 million in revenue in a financial year must comply with the Privacy Act. There are certain other entities which are bound, including organisations which deliver a health service.
[10] 'Personal information' is defined as '*information or an opinion about an identified individual, or an individual who is reasonably identifiable whether the information or opinion is true or not, and whether the information or opinion is recorded in a material form or not*'.

'Health information' is classified as 'sensitive information' under the Privacy Act and is subject to strict privacy protections. For example, organisations bound by the Privacy Act must not collect an individual's health information unless the individual consents to the collection of the information and the information is reasonably necessary for the organisation's functions or activities.[11] 'Health information' includes any personal information collected about an individual's health (including an illness, disability or injury) and any personal information collected in relation to a 'health service' that an individual has received or may receive in the future. Examples of 'health information' include details collected by a health service provider about an individual's symptoms or diagnosis, genetic information or any other information about their treatment or proposed treatment.

An organisation is a 'health service provider' if it provides a health service and holds health information. Under the Privacy Act, a 'health service' includes any activity that involves:

- Assessing, maintaining or improving a person's physical or psychological health;
- Where a person's health cannot be maintained or improved – managing the person's health;
- Diagnosing or treating a person's illness or disability;
- Recording a person's health for the purposes of assessing, maintaining, improving or managing the person's health; or
- Dispensing a prescription drug or medicine by a pharmacist.

Many digital health technology providers may be caught by this definition, and therefore bound by the Privacy Act regardless of the size of their business.

The Privacy Act includes a mandatory notification scheme where a regulated entity suffers a data breach of personal information which may give rise to a likely risk of serious harm to affected individuals. Most or all data breaches involving health information will meet this threshold, and will require the entity to notify the Australian privacy regulator (the Office of the Australian Information Commissioner (**OAIC**)) and affected individuals.

The OAIC has published guidelines on its view on what entities should do to comply with the APPs (**APP Guidelines**).[12] Additionally, there is different general privacy legislation for each State and Territory in Australia, which binds State and Territory government agencies,[13] as well as additional legislation in New South Wales, Victoria and the Australian Capital Territory that applies to health information handled by public sector organisations and private sector organisations in those jurisdictions.[14]

My Health Records Act 2012 (Cth)

Where digital health technology involves the use of My Health Record information, the *My Health Records Act 2012* (Cth) (**MHR Act**) will apply. The My Health Record system is the Australian Government's digital health record system for Australian individuals who have not opted-out of that system. The My Health Record system contains online summaries of individuals' health information, such as medicines they are taking, any allergies they may have and treatments they have received. The MHR Act, *My Health Records Rule 2016* (Cth) and *My Health Records Regulation 2012* (Cth) comprise the legislative framework for this system.

The MHR Act imposes strict limits on when and how health information in a My Health Record can be collected, used and disclosed. Unauthorised collection, use or disclosure of My Health Record information is both a breach of the MHR Act and an interference with privacy under the Privacy Act.

[11] *Privacy Act 1988 (Cth) APP 3.3.*
[12] Office of the Australian Information Commissioner, 'APP Guidelines', available at: https://www.oaic.gov.au/agencies-and-organisations/app-guidelines/ (as at March 2018).
[13] See, for eg, *Privacy and Personal Information Protection Act 1998* (NSW); *Information Privacy Act 2014* (ACT); *Privacy and Data Protection Act 2014* (Vic); *Information Privacy Act 2009* (Qld); *Information Act* (NT); *Personal Information and Protection Act 2004 (*Tas).
[14] *Health Records and Information Privacy 2002* (NSW); *Health Records (Privacy and Access) Act 1997* (ACT); *Health Records Act 2001* (Vic).

2. What are the main regulatory bodies for digital health in your jurisdiction and what is their corresponding regulatory scope?

There is currently no single regulatory body for digital health in Australia. The relevant bodies involved in matters relevant to digital health and their remits are summarised below.

Therapeutic goods

The TGA is the regulatory body responsible for regulating the import, supply, manufacture, export and advertising of therapeutic goods (including medical devices) under the Therapeutic Goods Act. Digital health devices that fall within the definition of 'medical device' under the Therapeutic Goods Act would fall within the regulatory scope of the TGA.

The TGA also manages recall of therapeutic goods supplied in the Australian market that suffer from deficiencies or defects in relation to their safety, quality, performance or presentation.

Competition and consumer protection

The Australian Competition and Consumer Commission (**ACCC**) is Australia's competition and consumer protection regulator.[15] The ACCC has extensive powers to investigate, regulate and prosecute suspected breaches of the ACL.[16] Digital health goods and services which do not comply with the consumer guarantees set out in the ACL would fall within the regulatory scope of the ACCC.

Privacy

The OAIC regulates the handling of personal information (including health information) by Australian Government agencies, private sector organisations and some state and territory agencies. The Information Commissioner is responsible for investigating breaches of the MHR Act and the Privacy Act.

Each State and Territory in Australia also has its own regulatory authority that is responsible for the protection of individuals' personal information held by public sector entities.

Digital Health

The Australian Digital Health Agency (ADHA) is responsible for the operation of the My Health Records system and focuses on improving health outcomes for Australians through the delivery of the National Digital Health Strategy. The Digital Health Cyber Security Centre also works alongside the ADHA to provide a range of cyber security capabilities to support secure national digital health operations across Australia.[17]

[15] Australian Competition and Consumer Commission, 'About the ACCC', available at https://www.accc.gov.au/about-us/australian-competition-consumer-commission/about-the-accc.
[16] Ibid.
[17] https://www.digitalhealth.gov.au/about-the-agency/digital-health-cyber-security-centre/about.

3. Are there specific rules relating to digital health and compliance/dealing with HCPs in your jurisdiction?

Health care professionals may use digital health technology in clinical practice, provided that they comply with the regulations set out in the Therapeutic Goods Act and the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth).[18] The TGA requires that all digital health devices which constitute 'medical devices' are registered on the ARTG before they can be 'supplied' in Australia. Health care professionals who import medical devices for use in clinical practice are considered to be 'supplying' the medical device to the general public. The term 'supply' is defined to include supply 'by way of administration to, or application in the treatment of, a person'.[19]

4. Are there any current government initiatives promoting digital health technology?

In 2016, the Australian Government established the ADHA to lead the development and implementation of the National Digital Health Strategy.[20] The National Digital Health Strategy focuses on developing the My Health Records system to allow all Australians and their health service providers to access their health information through digital apps and tools. The National Digital Health Strategy proposes to support the introduction of accredited health apps into the digital health market and deliver an improved developer program to enable entrepreneurs to expand existing services and create new services that meet the evolving needs of both patients and providers.[21]

The National Digital Health Strategy identifies seven key priorities for digital health in Australia:

- Health information is available whenever and wherever it is needed;
- Health information can be exchanged securely;
- High-quality data with a commonly understood meaning that can be used with confidence;
- Better availability and access to prescriptions and medicines information;
- Digitally-enabled models of care that drive improved accessibility, quality, safety and efficiency;
- A workforce confidently using digital health technologies to deliver health and care; and
- A thriving digital health industry delivering world-class innovation.

Further, in 2018 the Commonwealth Scientific and Industrial Research Organisation (**CSIRO**) released its 'Future of Health' report, which explores the use of digital health technology in Australia.[22] The CSIRO undertook a consultative process to identify the key challenges facing the Australian health system and how digital health technology can be applied to address these challenges. In the context of digital health, the CSIRO has identified that key barriers to the widespread adoption of a digitised health system include consumer trust in data sharing, digital and health literacy, data ownership, system interoperability and Australia's current digital infrastructure.

---

[18] Therapeutic Goods Administration, 'Importing and supplying medical devices – information for health professionals', available at: https://www.tga.gov.au/importing-supplying-medical-devices.
[19] *Therapeutic Goods Act 1989* (Cth) s 3.
[20] Australian Digital Health Agency, 'Health Ministers approve Australia's National Digital Health strategy' (4 August 2017), available from: https://www.digitalhealth.gov.au/news-and-events/news/health-ministers-approve-australia-s-national-digital-health-strategy.
[21] Australian Digital Health Agency (2018) *Australia's National Digital Health Strategy: Safe, seamless and secure: evolving health and care to meet the needs of modern Australia*, available from: https://conversation.digitalhealth.gov.au/australias-national-digital-health-strategy.
[22] CSIRO, 'Future of Health: Shifting Australia's focus from illness treatment to health and wellbeing management' (September 2018), available at: https://www.csiro.au/en/Showcase/futureofhealth.

5. Please provide a brief regulatory regime for digital health in your jurisdiction.

See the answers to questions 1 and 2, above.

6. What are the regulations governing the transfer of technology, both domestically and cross-border?

Technology transfer is the process of moving new technology from one person or organisation to another to enable sharing of resources or to facilitate further development and commercialisation. This may include transfers of materials, information or the details of new technologies. As part of the commercialisation process, patents may be sought and, if obtained, the technology may be transferred to other researchers or industry for further development through patent licensing or assignment. In the context of digital health, technology transfer is important because research is only the first stage in the development and commercialisation of marketable digital health products.

It is Australian Government policy to support research organisations working with the industry to commercialise the products of their research.[23] This policy is based on the view that patenting by research organisations and licensing of technologies to the private sector will increase the rate of commercial application of knowledge.[24] As such, where patents are involved in the technology transfer process, the *Patents Act 1990* (Cth) and the *Patents Regulations 1991* (Cth) will be relevant. In Australia, the *Patents Act 1990* (Cth) is administered by the Patents Office, which is part of IP Australia. With respect to the cross-border transfer of technology, intellectual property (**IP**) rights are territorial. As such, the registration or grant of a patent in Australia does not provide protection overseas. Generally, in order to enforce IP rights in digital health technology in jurisdictions outside Australia, the IP rights need to be registered in the relevant overseas jurisdictions. However, this is not the case for copyright in digital health technology (such as copyright subsisting in software code), because copyright works automatically vests in Australia in the creator and does not require registration. Copyright is recognised internationally by jurisdictions (including Australia) that are a contracting party to the Berne Convention.

7. What are the licencing requirements for personal and clinical use?

Personal use

The TGA regulates all medical devices that are imported into, supplied to or exported from Australia under the Therapeutic Goods Act. Unless a specific exemption applies, a medical device must be registered on the ARTG before it can be lawfully supplied in Australia. Under the "personal importation scheme", medical devices imported for personal use by an individual or their immediate family member do not need to be registered on the ARTG where:

- The device is for the individual's own treatment or the treatment of immediate family;
- The individual does not supply (sell or give) the device to any other person; and
- The other conditions of personal importation are met as part of the personal importation scheme.[25]

In addition, the TGA has issued guidelines which provide practical guidance on how individuals can import medical devices for personal use.[26]

[23] Commonwealth of Australia, 'Backing Australia's Ability: An Innovation Action Plan for the Future' (2001).
[24] Commonwealth of Australia, 'Backing Australia's Ability: An Innovation Action Plan for the Future' (2001), 18.
[25] These conditions are set out in Schedule 5 of the Therapeutic Goods Regulations 1990. See also https://www.tga.gov.au/personal-importation-scheme.
[26] Therapeutic Goods Administration (2004) *Access to unapproved therapeutic goods: personal importation*, available from: https://www.tga.gov.au/sites/default/files/access-personal-import-guidelines.pdf.

Clinical use

Health care professionals may use digital health technology in clinical practice, provided that they comply with the regulations set out in the Therapeutic Goods Act and the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth).[27]

The TGA requires that all digital health devices which constitute 'medical devices' must be registered on the ARTG before they can be 'supplied' in Australia. Health care professionals who import medical devices for use in clinical practice are considered to be 'supplying' the medical device to the general public. The term 'supply' is defined to include supply 'by way of administration to, or application in the treatment of, a person'.[28]

The TGA applies a risk-based approach to assessing and approving medical devices for use in Australia and reviews the evidence to determine whether the benefits of the medical device outweigh any possible risks. By way of example, digital health devices which pose a low health risk to the user (i.e a smartphone app that calculates insulin doses based on a patient's blood glucose levels) may be approved based on the applicant's certification of compliance with regulatory requirements, whereas higher risk devices (i.e 3-D printed skin patches) would require direct evaluation of the available evidence by the TGA.

Data Protection Overview

1. Can any types of data be shared with companies for the development of digital health technologies? Which kinds of data are permitted or prohibited?

While there is no specific legislation that governs the development of digital health technologies, the disclosure of personal information (including sensitive information and health information) is governed by Australian privacy laws, as set out in Question 1 of the Regulatory Overview. As a general rule, where an entity holds personal information about an individual that was collected for a particular purpose, the entity may only disclose the information for that purpose unless the individual, has consented to disclosure for another purpose. There are other exceptions but they vary between States and Territories.

In addition to collecting and storing personal health information, the *MHR Act* (as set out in Question 1 of the Regulatory Overview) allows My Health Record data to be made available for secondary purposes; for example, for research or public health purposes, law enforcement or System Operator functions.[29] This means that approved Australian and international companies can apply to access this data. By default, de-identified My Health Record data will be made available for public health and research purposes unless the individual takes active steps to unsubscribe from these secondary uses.[30] However, applications can also be made by approved third parties to access identified data, in which case specific consent will need to be obtained from the individual.

To assist with data protection concerns, the Australian Government has released a framework guiding secondary uses of My Health Record data.[31] This framework indicates that My Health Record data disclosed for secondary purposes is not to be sold or used solely for commercial and non-health related purposes. Further, My Health Record data cannot be used by social welfare organisations to assess eligibility for benefits or by the Australian Tax Office to make determinations in relation to an individual.

---

[27] Therapeutic Goods Administration, 'Importing and supplying medical devices – information for health professionals', available at: https://www.tga.gov.au/importing-supplying-medical-devices.
[28] *Therapeutic Goods Act 1989* (Cth) s 3.
[29] *My Health Record Act 2012* (Cth) ss 15, 16, 70
[30] *My Health Record Act 2012* (Cth) Sch 1, cl 13; https://www.myhealthrecord.gov.au/for-you-your-family/howtos/choose-how-your-data-is-used-for-research
[31] Commonwealth of Australia as represented by the Department of Health (2018) Framework to guide the secondary use of My Health Record system data ("MHR Framework"), accessed 1 July 2019, available from https://www.health.gov.au/internet/main/publishing.nsf/Content/F98C37D22E65A79BCA2582820006F1CF/$File/MHR_2nd_Use_Framework_2018_ACC_AW3.pdf

The Australian Government expects that My Health Record data will be made available for public health and research purposes from 2020. Each application for access to My Health Record data will undergo a merits assessment by a governance board and will be subject to ethics committee approval on a case by case basis.

2. Are there any regulations or restrictions on use of data collecting or sharing digital health technologies by or in collaboration with medical institutions or doctors?

As with Question 1 of the Data Protection Overview, while there is no specific legislation that governs digital health technologies, the use and disclosure of personal information (including sensitive information and health information) is governed by Australian privacy laws, as set out in Question 1 of the Regulatory Overview. Where an entity holds personal information about an individual that was collected for a particular purpose, the entity may only use or disclose the information for that purpose unless the individual has consented to use or disclosure for another purpose. There are other exceptions but they vary between States and Territories.

Intellectual Property Overview

1. What types of digital health technology can be patented and describe the general patent registration, if any, structure of your jurisdiction?

General patent registration structure

In Australia patent protection is provided through a system of registration governed by the *Patents Act 1990* (Cth). Registration of a patent gives the holder of the patent the legally enforceable right to exploit (or licence another to exploit) an invention for the term of the patent. There are two types of patents in Australia: the standard patent and the innovation patent.

- The standard patent lasts up to 20 years (or 25 years for pharmaceuticals) and has mandatory examination before the patent is granted. As Australia is a signatory to the Patent Cooperation Treaty (PCT), a standard patent can be applied for via the PCT system, thereby allowing the patentee to seek patent protection in Australia and other PCT countries.
- The innovation patent lasts for 8 years and is appropriate for incremental advances on existing technology, usually having a shorter development and commercialisation cycle than standard patents. An innovation patent has a lower inventive threshold and it is granted if the formalities of the application are satisfied. Whereas standard patents require examination, innovation patents are examined upon request, after which the patent right can be enforced. As noted below, the innovation patents will be abolished in the near future.

Types of patentable digital health technologies

In order to be patentable, digital health technology must be an 'invention' (or ‘innovation’), that is a ‘manner of manufacture’, novel, inventive (or innovative) and useful, in that it meets its promise. The ‘manner of manufacture’ requirement raises issues for digital health technologies. Whereas copyright is more likely to protect coding and user experience forms of art, and trade mark registration will protect a new app or product names or logos, patents will protect the technology itself.

In the digital health technology context, the invention is likely to relate to the hardware and software in cloud-based and online systems, email/text platforms, smart device apps, clinical management and tele-monitoring devices and business methods, where the method directly involves a physical form or device to bring about a useful product.

(a) Software or methods that are unconnected to a physical form or device are unlikely to be suitable for a patent (*Grant v Commissioner of Patents*[32]). However, when technical means are employed resulting in an improvement in computer technology, for example, technology such as in the form of a programmed computer, it is possible that a method can be patented (*Rokt Pte Ltd v Commissioner of Patents*[33]). This area remains unsettled under Australian law, with recent cases following Grant to state that an abstract idea unconnected to any material or tangible product is unlikely to attract a patent protection,[34] while others suggest artificial steps requiring human interaction in the method may take a method beyond a merely abstract, intangible situation to make it patentable.[35]

(b) While there can be overlap between the categories, patentable digital health technologies can be broadly divided into mechanical, chemical, electrical and software categories. These include:

(i) Mechanical: devices such as Bluetooth exoskeleton, wearable sensors, and wearable fall monitors;

(ii) Chemical: portable gluten detector, Bluetooth pulse oximeter, automated dosing systems, and automated insulin pump with blood glucose monitor;

(iii) Electrical: wearable devices with low-level electrical brain stimulation, wearable transcutaneous nerve stimulation (TENS) device for pain management, smart glasses with augmented reality function, Bluetooth ECG/atrial fibrillation detector, wearable UV monitor, wearable bioimpedance monitor; and

(iv) Software: mobile medical apps, posture analysis app using phone accelerometer, orthodontic monitoring apps.

2. What types of digital health technology can be copyrighted and describe the general copyright registration, if any, structure of your jurisdiction?

While there is no system of registration for copyright protection in Australia, copyright in digital health technology is governed by the *Copyright Act 1968* (Cth). The central tenant of copyright is that it protects the particular expression – copyright does not protect facts, information or ideas.

To be protectable, digital health technology must be original, created by a human author, reduced to material form and be capable of being classified into one of the recognised categories of "works". As noted below, in the digital health space, copyright protectable works are likely to be literary works or artistic works.

Copyright system in Australia

The legislation regulating copyright in Australia is *Copyright Act 1968* (Cth) and *Copyright Regulations 2017* (Cth). Copyright protection is automatic once the work is put into material form and unlike other jurisdictions, is not dependent on a copyright notice.

Copyright protects original literary, artistic, dramatic and musical works, as well as another subject matter which are not relevant to digital health technology. To be 'original' the creation of the work must have involved 'independent intellectual effort' and at a minimum, not be copied. It is also a requirement that the work originate from a human author. It follows that the emergence and increased prominence of artificial intelligence (AI) and the reliance on machine learning raises new issues as to whether certain digital health technologies can be protected by copyright.

[32] (2006) 154 FCR 62 at [66] (Heerey, Kiefel and Bennett JJ).
[33] [2018] 139 IPR 1 at [201] (Robertson J).
[34] *Watson v Commissioner of Patents*[2019] 1015 at [29] (Rares ACJ).
[35] *Sequenom, Inc. v Ariosa Diagnostics, Inc.* [2019] FCA 1011 at [494] (Beach J).

Owners of a work enjoy a number of exclusive rights, including the right to reproduce the work, communicate the work to the public and licence others to do so. Copyright provides a relatively long period of protection in that in general, it lasts 70 years from death of the author.

In the context of digital health technology there are two further points to note:

- The copyright / design overlap prevents dual protection for things which should only be protected under the *Designs Act 2003* (Cth), ie if something is registered as a design, then it cannot also be protected by copyright. For example, if the user interface of digital health software is registered as a design, copyright protection of the artistic aspects of the user interface will cease to exist. Note that copyright will still be maintained in the 'literary aspect' of the software source code, as this is not covered by the design registration.
- Any subsistence of copyright in software code that is based on open source software is likely to be fragile as it raises questions as to whether the software code is original. Additionally, the ability to use the open source code in health based software may depend upon the conditions of the open source licence. For example, a condition of using that open source code may be to keep any resulting software products freely accessible. This may impact the usefulness of using that open source code as part of paid digital health software.

Copyrightable digital health technology examples

Digital health technology may include a range of copyright protectable work. The key consideration is whether the technology is original, created by a human author and can be categorised as a 'literary work' or 'artistic work'. Some broad examples of technology for digital health that may be protected by copyright include:

(a) Software which can be classified as a 'literary work' (the definition of literary work under the *Copyright Act* specifically includes a computer program). Examples of software in the digital health space that may be protectable include:

  (i) Predictive software to manage patient admission;

  (ii) Automated image analysis software package to measure and report on cell features for drug discovery; or

  (iii) Software to assist in the design of 3D printed replacement joints.

(b) User experience / user interfaces of digital health technologies may be protectable as an 'artistic work'. As artistic work copyright protects the 'look and feel' and the juxtaposition of the elements, artistic work copyright may be available to protect the visual aspects of a digital health technology app.

  For example, artistic work copyright may be able to protect user interfaces for:

  (i) Health management apps – e.g. the artistic aspects of period trackers, apps that connect to wearable health devices

  (ii) Surgical training software / simulators

  Copyright as an artistic work may also subsist in the image / design of the 3D printing model for an artificial implant

3. What are the main intellectual property issues arising in digital health technology development?

The main intellectual property issues arising in digital health technology development relate to the nature of the industry and the way in which the technology is developed. The industry is fast-paced, with a variety of competing new entrants, of which many are small start-up businesses. These companies are developing digital health technology products to enter the market which are likely to require overlapping forms of IP protection in order to reach their full medical and economic potential. Managing this IP portfolio

from the outset can be a challenge for small businesses, as it is not always high on the agenda for start-ups. The development of an effective IP strategy may therefore provide a competitive edge in digital health technology development.

Patentability

For the reasons discussed below, some digital health technologies may be difficult to patent, exposing their creators to business risks. The fast-moving nature of the digital health industry means inventors may face the following issues around patentability:

(a) **Patentable subject matter**

(i) Not all inventions or ideas are patentable. The High Court of Australia in the *NDRC Case* has said that patentable subject matter must be a manner of manufacture that results in an artificially created state of affairs that has utility in the field of economic endeavour.[36] The subject matter also has to be novel and inventive.

(ii) Consider, for example, health-related mobile apps. Apps are computer programs, which may not always satisfy the manner of manufacture test from *NDRC* as easily as tangible products, though a 2018 Federal Court decision in *Rokt* has provided some comfort for business looking to patent computer implemented inventions.[37] Nonetheless, in a world where there are so many similar apps developing concurrently, it may be challenging for an app creator to show that the software is novel and inventive compared to all the other apps emerging in the field at the same time.

(b) **Prior public use** by the inventor (patent applicant)

(i) Many technologies, especially things like digital health apps, are developed by start-ups who may not be familiar with the law around patentability, or where investment in capital (rather than IP) is a top priority.

(ii) Often inventors are focussed on getting their product to market as soon as possible in order to establish market presence. This is often prioritised over filing for an Australian standard patent protection, a process which generally takes up to 18 months until the patent is granted (or longer in the case of PCT applications). In Australia, applying for an innovation patent is quicker and easier to achieve, making it a good option for businesses that need to move quickly and for technology with a relatively short lifespan. However, innovation patents are soon to be abolished in Australia, with a Bill to this effect introduced to Parliament in July 2019.

(iii) Businesses that put their product on the market before filing for patent protection run the risk of ineligibility by way of their prior public use of the invention. However, a 12 month grace period may apply if the prior public disclosure of the invention was accidental or otherwise ill-timed.

(c) **A technological arms race**

(i) In a similar vein, the start up space is highly competitive and often when one start up has had an idea for a digital health technology, a number of others have too, including in other jurisdictions.

(ii) This may mean that a start-up may invest in significant R&D hoping for a patent protection, only to be 'pipped at the post' by a competitor developing the same technology in parallel. In this case, the competitors invention may be prior art making it difficult to obtain a patent.

[36] *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252.
[37] *Rokt Pte Ltd v Commissioner of Patents* (2018) 139 IPR 1.

(iii) In addition, some competing companies may have to agree to license their patents to each other in order to further develop their digital health technologies. This was an issue in smart phone development, notably between Apple and Samsung, who had to license each other to use their respective patents so that they could each develop their own (competing) products. This resulted in substantial litigation over reasonable license fees and royalties, and it is not unforeseeable that a similar situation could arise between competitors in medical technology.

(iv) Licensing may also be an issue between co-inventors. It is not unforeseeable that issues of co-ownership and licensing between inventors will develop. Digital health technology is often developed collaboratively and disputes may arise between co-inventors as a result.

(v) The lifespan of both the technology and the patent may also be an issue. A single patent may be insufficient to provide ongoing protection as the technology continues to advance and the product evolves over time. For example, changes based on user feedback, ongoing medical research and bug fixes are part and parcel of the maintenance of a health app. This can be contrasted against classic pharmaceutical treatments – once a drug is found to be safe and effective, it is usually marketable without significant change for a number of years. Innovation patents can assist with protecting technology that is regularly updated, but as mentioned above, they are soon to be abolished in Australia.

(d) **Intentional protection is not automatic**

(i) Should a digital health technology inventor succeed in obtaining an Australian patent, it is still at risk of overseas exploitation. This is especially true of products that are available over the internet (such as mobile apps or products for sale via e-commerce platforms).

(ii) Australian inventors may want to access the international market for their products. If this is the case, patentees should consider applying for international protection under the Patent Cooperation Treaty (**PCT**) which will afford the patentee protection in most international jurisdictions.

(iii) As with any patent infringement, it may be harder to identify foreign infringers and enforce against them than it is to do so against local infringers.

Designs

In Australia, a registered design can be used to protect the visual features (specifically features of shape, configuration, pattern or ornamentation) of the technology, but not the technology itself. Thus designs provide only **limited valuable protection to inventors of new digital health technology** and cannot effectively prevent competitors from entering the market with the same idea (as long as it is visually presented in a different way).

However, this has not stopped both large and small companies in the digital health space from registering designs for digital health products in Australia. For example, designs have been registered for:

- Automated staining apparatus or portion thereof with graphical user interface (registered by Leica Biosystems Melbourne Pty Ltd);
- Transcutaneous electrical nerve stimulation (TENS) device (GSK); and
- Robotic system for assisting surgical installations (MEDTECH).

Using the first example, the digital health provider can protect the Graphical User Interface with which users interact in using the apparatus, but the value of the product is more likely to be in the functionality, which would need to be protected by patent or trade secret. The design registration does not prevent a competitor from manufacturing and selling an automated staining apparatus that is presented in a different way.

Confidential information

This issue is not necessarily specific to digital health technology as opposed to other new technologies, but the risk of unauthorised access and distribution of information is ever-increasing.

As mentioned above, start-up enterprises are again at greater risk due to their often informal research and development phase, in which sufficient protection of confidential information may not be a high priority. At the very early stages of a start-up business, it may be necessary to discuss the idea with third parties, and it is not always common practice of such small businesses to have a confidentiality agreement in place when doing so.

In addition, stealing of confidential information is also a risk. This could happen in a number of ways, notably:

- Hackers accessing a poorly secured databases storing information about an idea or invention;
- Inadvertent disclosure of the idea or invention to an untrustworthy party; or
- Reverse engineering of an idea or invention from a prototype developed during the R&D phase.

The Future of Digital Health

1. Have there been any recent updates to the regulatory regime governing digital health in your jurisdiction?

The creation of the ADHA and introduction of the My Health Record are significant recent additions to the digital health regulatory regime in Australia. The ADHA was established in 2016 to improve health outcomes for Australians by developing digital healthcare systems, developing a National Digital Health Strategy and overseeing the My Health Record.[38]

The My Health Record is an online summary of an individual's healthcare records, which is accessible by all of the individual's healthcare providers. It aims to promote efficient, high-quality healthcare by allowing medical professionals across different fields to coordinate their services. This is particularly important for patients who suffer from complex medical problems and lack the expertise necessary to accurately track their various treatments. The My Health Record switched to an opt-out system from late 2018, meaning that individuals can now choose to permanently delete their My Health Record at any time. The My Health Record system now has a participation rate of approximately 90.1 percent of the Australian population eligible for Medicare.[39]

Controversy surrounding the privacy requirements of the My Health Record led to the introduction of tougher privacy and security protections in 2018. As a result of the changes, individuals are now able to have their My Health Record permanently deleted and third parties like insurers and employers are prohibited from accessing the data.[40]

2. Are we likely to see any reforms or new regulations relating to digital health?

[38] *Public Governance, Performing and Accountability (Establishing the Australian Digital Health Agency) Rule 2016* (Cth) s 9; https://www.digitalhealth.gov.au/about-the-agency
[39] https://www.myhealthrecord.gov.au/statistics
[40] *My Health Records Amendment (Strengthening Privacy) Act 2018* (Cth) https://www.myhealthrecord.gov.au/about/legislation-and-governance/summary-privacy-protections

Digital Health Subsidies

The Australian Government operates a public healthcare scheme called Medicare, which provides free or subsidised treatment for specific services. Medicare operates alongside the Pharmaceutical Benefits Scheme (**PBS Scheme**), which subsidises a range of pharmaceutical products. With the growth of digital health, there is scope for digital health technologies to be subsidised through Medicare and/or the PBS Scheme.

Expansion of Data Sharing

The Australian Government has introduced the Consumer Data Right Scheme (**CDR**) in 2019, which would allow individuals to require organisations to transfer their data to accredited third parties. The CDR is being rolled out in the banking sector initially, before being introduced to other sectors. In a recent report, the CSIRO suggested that applying the CDR to health data could provide a cost-effective alternative to the My Health Record and help facilitate health literacy and consumer empowerment.[41] For example, the CDR could allow patients to have pathologists transfer their data directly to health apps, which could then track, manage or diagnose their condition in real time.

Regulatory Reforms for Medical Device Software

In early 2019, the TGA consulted on proposed reforms to the regulations governing medical device software.[42] The TGA was particularly concerned about how to regulate apps that function as medical devices in their own right, for example, by diagnosing conditions through electrocardiogram (ECG) data, or calculating dosages of medications.

To give one example of the problems involved with the current regulations, the TGA currently classifies medical devices according to the risk of harm to users. However, the current regulations only consider the risk of harm caused by the physical interaction between the medical device and human user.[43] This approach is not apt to assess the risks posed by medical device software, which is more likely to cause harm by making an incorrect diagnosis or calculation. The TGA has therefore proposed a change to its risk categorisation guidelines, to take into account factors such as the significance of information provided by medical device software, the context in which it is used and the seriousness of the condition being treated.[44]

Mandatory safety and information standards

While there are currently no mandatory safety or information standards applicable to digital health technologies, if there are safety concerns applicable to this kind of consumer goods (or a subset of them), the Minister may prescribe mandatory standards applicable to safety or information features of such goods. This may include standards to ensure medical devices can be used safely and/or requirements in relation to the instructions given to users of the device.

It is worth noting that 'safety' standards generally refers to physical safety.[45] To date, there is no indication to suggest that cyber security or information security is a 'safety' issue about which standards may prescribe requirements. As concerns about cyber security increase, the mandatory standards power could be broadened to allow minimum cyber security requirements to be prescribed.

---

[41] CSIRO, Future of Health Report, pg 34.
[42] Therapeutic Goods Administration, Consultation: Regulation of Software, including Software as a Medical Device (February 2019) https://www.tga.gov.au/sites/default/files/consultation-regulation-software-including-software-medical-device-samd.pdf
[43] Ibid, 5.
[44] Ibid, 7.
[45] ACL section 104(2) and 104(3) refer to standards being made where they are 'reasonably necessary to prevent the risk of injury to any person.'

Application

Medical Devices

1. What types of digital health technologies need to be registered as medical devices?

Any digital health technology which meets the definition of "medical device" under section 41BD of the *Therapeutic Goods Act 1989* (Cth) (**TG Act**) will be subject to regulation as a medical device.

In essence, section 41BD captures:

(a) Any "instrument, apparatus, appliance, material or other article" (ie any technology including hardware and software);

(b) Which is intended to be used (for human beings) for at least one of the following purposes:

  (i) Diagnosis, prevention, monitoring, treatment or alleviation of disease;

  (ii) Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;

  (iii) Investigation, replacement or modification of the anatomy or of a physiological process; or

  (iv) Control of conception; and

(c) which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means.

The above definition is extremely broad and will capture a range of digital health technologies such as:

(a) Desktop or cloud-based software – for example, applications which analyse diagnostic images of a patient to make a diagnosis of disease or injury;

(b) Smart phone apps – for example, an app which calculates correct insulin dose based on a patient's blood glucose levels;

(c) Computing platforms – for example, a handheld device which connects wirelessly to a smartphone to display body function measurements through an app interface;

(d) wearable body function monitors; and

(e) personalised 3D printed orthopaedic or dental appliances.

2. What types of digital health medical devices can be used and how do they work in practice?

For example, would a digital health wearable device be classed as a medical device?

Digital health devices can come in various forms, such as software itself, wearables, or combinations of software, monitors and smartphones. They key consideration is whether the technology meets the definition of "medical device", as discussed above.

3. What are the main legal issues surrounding digital health medical devices?

Regulation under the *Therapeutic Goods Act 1989* (Cth) (**TG Act**):

(a) A “medical device” needs to be registered on the Australian Register of Therapeutic Good (ARTG) before it can be supplied in Australia.

(b) Manufacturers and sponsors of medical devices have numerous obligations under the TG Act.

(c) Advertising, labelling and packaging must comply with the TG Act and regulations.

Product Liability:

(a) Various laws apply at both Commonwealth and State and Territory level which govern product liability claims.

(b) Under the Australian Consumer Law (ACL) for example, a manufacturer of goods will be liable to compensate an individual for injury caused by a product with a safety defect.

(c) Liability under the ACL is extended to any person who suffers loss or damage due to such injury caused to another person.

Cyber security and privacy:

(a) Digital health technologies are becoming increasingly reliant upon personal data – such as through the collection and analysis of personal data, the generation and presentation of personal data, or the storage of personal data. The collection and handling of personal data is regulated at both Commonwealth and State and Territory level.

(b) Privacy and data protection laws require certain minimum standards to be maintained, and provide certain conditions when disclosing personal data to persons located outside Australia.

(c) The Therapeutic Goods Administration has also proposed new additions concerning cyber security to the Essential Principles, which underpin the assessment for inclusion of medical devices on the ARTG. The proposed requirements are based on the EU requirements and are that:

    (i) The features, capabilities and risks of the computing platform be taken into account during design and manufacturing;

    (ii) The cyber security risks associated with network connectivity be minimised;

    (iii) Software be designed and produced using best practice software engineering principles;

    (iv) Medical devices indicate when critical features and connections are or are not enabled, and provide appropriate alarms;

    (v) Best practice cyber security principles be used regarding the risk of unauthorised access to the device;

    (vi) Medical devices be designed to facilitate software updates, and information about the clinical risk of an update is provided to the user; and

    (vii) Requirements relating to the computer platform, operating system, accessories and network security be provided in the instructions for use.

Consumer guarantees in the Australian Consumer Law:

The ACL provides for a number of implied guarantees in relation to consumer goods, including that goods (which includes software) must be:

(a) Safe and fit for purpose;

(b) Match descriptions made by the salesperson, on packaging and labels, and in promotions or advertising;

(c) Match any demonstration model or sample provided;

(d) Come with full title and ownership;

(e) Not carry any hidden debts or extra charges;

(f) Come with undisturbed possession;

(g) Meet any extra promises made about performance, condition and quality, such as life time guarantees and money back offers; and

(h) Have spare parts and repair facilities available for a reasonable time after purchase unless advised otherwise.

4. What kinds of marketing activities are permitted or prohibited?

Advertising must comply with:

(a) The Australian Consumer Law – advertising and marketing communications must not:

  (i) Be likely to mislead or deceive consumers; or

  (ii) Make false or misleading claims or statements.

(b) The Therapeutic Goods Advertising Code (No.2) 2018 – which applies specifically to therapeutic goods (including medical devices) and provides that advertising must include:

  (i) An accurate description of the device;

  (ii) Either:

    (A) If the trade name for the device is available—a reference to that name;

    (B) Otherwise—a reference to another name for the device;

  (iii) The intended purpose of, or indications for, the device, as they appear on the device's label or primary packaging, as appropriate to the device; and

  (iv) Any specifically required statements such as "ALWAYS READ THE INSTRUCTIONS FOR USE" etc.

The Medical Technology Association of Australia (MTAA) also publishes a non-mandatory industry Code of Practice for medical technology companies which sets out the ethical framework within which they must work, in their relationships with healthcare professionals and also, where relevant, with the consumer. The Code is not law. It is a guide to industry best practice and all companies in the industry are encouraged to comply with it, including provisions related to advertising and marketing of medical devices.

m-Health

1. What types of m-Health can be used and how do they work in practice?

There is no definitive definition of m-Health in Australia and there are no specific regulations dealing specifically with m-Health.

We understand that the definition of m-Health is unsettled. However, the World Health Organisation has described m-Health as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices".

In Australia, m-Health has traditionally been used in telemedicine, where practitioners use teleconference and videoconference to facilitate consultations remotely. However, digital technology is starting to be used in the area of diagnosis, where software applications based on image analysis are being developed in order to support practitioners with disease diagnosis.

Apps have also been developed in the pharmacy space by certain vendors, which allow the customer to order medicines and track medicine usage.

2. What are the main legal issues surrounding m-Health?

There are no specific legal issues in the context of m-Health over and above those outlined above for digital health devices.

3. Are there any regulations or restrictions on use of m-Health by or in collaboration with medical institutions or doctors?

There are no specific regulations dealing with m-Health.

However, at a general level, practitioners and institutions are regulated by a variety of sources, which may impact whether or not m-Health may be used in the delivery of healthcare.

4. What kinds of marketing activities are permitted or prohibited?

Advertising of m-Health devices that are also medical devices should comply with the requirements discussed above.

Artificial Intelligence

1. What are the main legal issues surrounding artificial intelligence and digital health?

One of the main legal issues surrounding artificial intelligence (AI) and digital health is the absence of a robust legal framework to guide its implementation in Australia. While there are no specific laws dealing with AI in Australia, the Federal Department of Industry Innovation and Science have published a draft ethical framework which proposes eight guiding principles for the use of AI in Australia:[46]

- The AI system must generate net-benefits;
- The AI system must not be designed to harm or deceive civilians;
- The AI system must comply with all relevant state, local and federal government obligations, regulations and laws;
- The AI system must ensure private data is protected;
- The AI system must not result in unfair discrimination towards individuals, communities or groups (ie must be free from bias);
- Information must be provided to impacted individuals about how the algorithm makes decisions (ie transparency and accountability);
- There must be an efficient process to challenge the use or output of the AI system (ie contestability); and
- People and organisations responsible for the creation and implementation of the AI system should be accountable for both the intended and unintended impacts of the system.

At this stage, this framework has not proceeded beyond public consultation.

[46] Dawson D and Schleiger E , Horton J, McLaughlin J, Robinson C, Quezada G, Scowcroft J, and Hajkowicz S (2019) *Artificial Intelligence: Australia's Ethics Framework*. Data61 CSIRO, Australia.

Key legal issues in relation to artificial intelligence and digital health include:

- Data protection and privacy; particularly in relation to the use of health information and the Australian government's "My Health Record" ("MHR") – an online summary of an individual's key health information, for which a profile was automatically created for every Australian who did not opt out prior to 31 January 2019; and
- Liability: Australia's Draft Ethical Framework suggests that because an AI system has no moral authority, a human must be held accountable for the consequences of decisions made by the AI; however, which entity should ultimately be responsible is unclear.

2. What types of artificial intelligence digital health technology can be used and how do they work in practice?

There are a number of applications of artificial intelligence – either in the pipeline or currently on the market – in Australian digital health technology. A few examples of these are set out below:

(a) An experimental influenza vaccine thought to be the first completely designed by artificial intelligence, by presenting an AI program with examples of successful and failed drugs;

(b) Artificial intelligence functionality in an Australian-designed smart stethoscope called "Stethee" to automatically tag geolocation, patient position and environmental factors (eg humidity, temperature or pollen count) when analysing heart and lung data.

(c) An artificial intelligence tool called PainChek to detect pain and assess its severity in patients with dementia who can no longer self-report their symptoms, based on the patient's face and muscle movements.

(d) An automated decision support tool which uses general practice clinical and billing data from over 500 practices to accurately predict a patient's risk of presenting to an emergency department within the next 30 days.

(e) A Patient Admission Prediction Tool that forecasts the demand on hospital resources using historical data to predict with 90% accuracy:

  (i) How many patients will present at emergency departments and when;

  (ii) The medical needs of those patients;

  (iii) Urgency of care; and

  (iv) The number of patients that will be admitted or discharged.[47]

(f) Researchers at the University of Adelaide have applied artificial intelligence to predict mortality rates in individuals who had undergone chest CT imaging, using "deep learning" (a subset of artificial intelligence) to automatically discovers low-level and high-level visual features, discover new biomarkers without human input. The program predicted – with 70 percent accuracy – which of the 48 subject patients would die within five years.

3. Can artificial intelligence digital health diagnostic services provide medical advice?

Australia does not expressly prohibit independent diagnosis through artificial intelligence; however, the recent development of digital products with diagnostic capabilities suggest this may be an area for future regulation. At this stage, however, AI digital health diagnostic services would be regulated as any diagnostic device under the *Therapeutic Goods Act*.

[47] *PwC: Adopting AI in healthcare*, p 10.

China

Regulatory Overview

1. What is the main legislation for digital health technology in your jurisdiction?

The legislation which is relevant to digital health is broad and can generally be divided into three subsets. The first subset relates to legislation which regulates “healthcare”. The second subset relates to “technology.” The final subset is a hybrid of the two first subsets and relates to new legislation enacted to regulate the new field of digital health. Legislation from all three subsets will be equally relevant moving forward, however, it is expected that more laws and regulation relating to digital health specifically will be released as this field continues to develop.

Key relevant legislation regulating healthcare include the:

- Drug Administration Law of the of the People’s Republic of China (“PRC”)
- Regulations for the Supervision and Administration of Medical Devices;
- Medical Device Classification Catalogue;
- Law of the PRC on Medical Practitioners; and
- Administrative Regulations on Medical Institutions.

Key relevant legislation regulating technology include the:

- Cybersecurity Law of the PRC;
- Provisions on Protection of Personal Information of Telecommunication and Internet Users; and
- National Standard Entitled Information Security Technology - Personal Information Security Specifications (GB/T 35273—2017）.

Key relevant legislation regulating the new field of digital health include the:

- Internet Diagnosis Administrative Measures;
- Internet Hospital Administrative;
- Administrative Measures for Remote Healthcare Services (Trial for Implementation);
- Measures for the Management of Population Health Information;

- Management Measures for Standards, Safety and Service for the National Healthcare Big Data;
- Technical Guiding Principles for the Cybersecurity Registration of Medical Devices;
- Technical Guiding Principles for the Registration of Mobile Medical Devices;
- Opinions on Advancing telemedicine services in medical institutions;
- Circular on Making Sound Work on the Measures for Administrating the Internet Medical and Health-Care Information Services; and
- Opinions of the General Office of the State Council on Promoting the Development of "Internet Healthcare".

2. What are the main regulatory bodies for digital health in your jurisdiction and what is their corresponding regulatory scope?

Relevant regulatory bodies for traditional healthcare include:

- The National Medical Products Administration (NMPA, 国家药品监督管理局), which is the authority to administer all affairs in relation to drugs, medical devices and other medical products. In particular, it is in charge of the registration of medical devices which are commonly used in the digital health arena; and
- The National Health Commission (NHC, 中华人民共和国卫生健康委员会), which is the administrative authority for all medical institutions and persons, both in the digital and traditional health arena. In particular, it is in charge of approving the establishment of 'internet hospitals' and of the qualification of doctors and nurses involved therein.

Relevant regulatory bodies for technology include:

- The Ministry of Industry and Information Technology (MoST,中华人民共和国工业和信息化部), which administers how the digital technologies are applied in the health industry from a general perspective, such as collecting, using and protecting data;
- The Ministry of Public Security (公安部), which focuses more in the protection of information. It designs the regulations and standards to ensure that digital health technologies are applied in safe way; and
- The Cyberspace Administration of China (also called the Office of the Central Cybersecurity Affairs Commission 中华人民共和国国家互联网信息办公室, 中共中央网络安全和信息化委员会办公室), which is in charge of cybersecurity and internet related affairs, in particular, supervising the transmission of data.

There is currently no specific umbrella regulatory body established for digital health. The above authorities regulate the industry within their own independently authorised regulatory scopes.

3. Are there specific rules relating to digital health and compliance/dealing with HCPs in your jurisdiction?

The Internet Diagnosis Administrative Measures and Internet Hospital Administrative Measures mentioned above set-out a reasonably comprehensive framework of rules which regulate HCPs in relation to digital health.

- *Internet Diagnosis Administrative Measures* – Internet Diagnosis refers to medical institutions that, together with their registered doctors, use the internet or other information technology to operate referrals of common and chronic diseases and the engagement service of the "Internet +" family doctors. Providers must be qualified medical institutions, they must have internet diagnosis and

treatment management rules, equipment and facilities, information systems and relevant security systems and the correct technical personnel. Further, the physicians and nurses providing these services must be licensed to practice medicine or dispense patient care in China. Physicians must have at least 3 years independent medical experience.

These measures are also designed to ensure patient safety and ensure that internet diagnostic services are limited to diagnose common or chronic diseases and the patient's first visit must be made in person. Further, if the patient's condition changes over time, they must revisit their doctor for a physical examination.

Under these measures, doctors are also allowed to provide prescriptions following online consultations, however, this must be prescribed using an electronic signature. In addition, the online prescription must be reviewed by a pharmacist. Currently, very few doctors have registered their signature electronically.

- *Internet Hospital Administrative Measures* – Internet Hospitals refer to online hospital services operated by and based on real hospitals or medical institutions. The establishment of an internet hospital must be approved by the authority. An existing hospital that extends its services to provide online services needs to apply to the local authority to add an internet hospital to its current medical license. If a new internet hospital is to be established, it should be supported by a real hospital and file an application to the local authority to obtain the approval for establishment.
- *Administrative Measures for Remote Healthcare Services* – Examples of remote healthcare services include: hospital A inviting hospital B to provide remote healthcare services for a patient of hospital A via the internet or via other technologies; and hospital A or a third party establishing a remote healthcare service platform, where other hospitals can register and provide remote healthcare services to hospital A's patients. In these cases, all parties should agree on the allocation of liabilities.

4. Are there any current government initiatives promoting digital health technology?

The Chinese government recently published multiple policies and initiatives to support general technological innovation in the healthcare industry, including:

(a) *The Opinions of the Communist Party of China Central Committee and the State Council on Deepening the Healthcare System Reform 2009*, emphasising a 4-target reform plan:

  (i) To build a practical, medical information system;

  (ii) To push forward healthcare information standardisation;

  (iii) To establish a public healthcare service platform; and

  (iv) To construct telemedicine networks in rural and remote areas.

(b) *Made in China 2025*, emphasising hi-tech dominance to propel its biomedical and medical device manufacturing industries. The plan focusses on improving production of high-end medical devices, including wearables and telemedicine.

(c) *The National Planning Guideline for the Healthcare Service System (2015 – 2020)*, the first comprehensive five-year blueprint targeting key areas for development in the healthcare industry by 2020, including increased access and investment in technology for digital health projects;

(d) The *Opinions on Promoting the Development of* "*Internet + Healthcare*", which includes a number of policies and measures aimed to strengthen the synergy between the internet and healthcare services;

(e) The *Three-Year Action Plan to Encourage the Industrial Development of the New Generation of AI*, which aims to achieve a scaled development of key AI products including creating medical imaging diagnosis systems which are able to detect 95% of common diseases;

(f) The *13th Five-Year Plan*, in which the government has recognised the challenge it faces with an aging population and general increase in the demand for healthcare. It encourages the private sector to participate in healthcare and produce a "fully integrated system."; and

(g) *Healthy China 2030*, which looks to make significant changes to the overall health of the population in China. The government announced that they are looking to develop new industries, new forms and models of business in the healthcare sector and also to grow internet-based health services.

5. Please provide a brief regulatory regime for digital health in your jurisdiction.

The digital healthcare sector in China, alike most of the world, is still relatively young. The regulatory regime stems largely from separate regulations from healthcare and technology which could fall behind the technology's development and therefore bring uncertainties in regulatory practice. For example, the Technical Guiding Principles for the Cybersecurity Registration of Medical Devices and Technical Guiding Principles for the Registration of Mobile Medical Devices set outs the technical standards that NMPA's examiners used to examine digital health-related medical devices during the products' registration processes. On the other side, considering the key role that data collection and sharing have in developing digital health technology, especially in relation to sensitive personal health information, it is telling that there is still no uniform law or national authority providing a regulatory framework on privacy and data protections laws in China. For now, medical health devices that collect information within China are subject to regulation under the *Cybersecurity Law of the People's Republic of China* ("**Cybersecurity Law**") and the various related technical guiding principles. The Cybersecurity Law also introduces the concept of Critical Information Infrastructure ("**CII**") operators, a broad term that may include private companies providing cloud computing, big data or other food and drug-related services, whereby storage of all personal information collected during operations within China are to be exclusively kept within the territory. As the Chinese government are trying to really drive the progression of digital health, it can likely be expected that more regulations will be realised in the near future as the government aims to reach goals by 2020, 2025 and 2030 respectively.

6. What are the regulations governing the transfer of technology, both domestically and cross-border?

The regulations covering domestic transfer of technology include the:

- Law of the People's Republic of China on Science and Technology Advancement;
- Law of the People's Republic of China on Promoting the Transformation of Scientific and Technological Achievements;
- Contract Law of the People's Republic of China;
- Patent Law of the People's Republic of China;
- Provisions on Promoting the Transformation of Scientific and Technological Achievements;
- Opinions on Accelerating the Development of the Technology Market; and
- Implementation Plan on Promoting National Technology Transfer.

The PRC law covering cross-border transfer of technology include the:

- Foreign Trade Law of the People's Republic of China;
- Administrative Regulations of the People's Republic of China on Technology Import and Export;
- Administrative Measures of Registration of the Contracts for Import or export of Technologies; and
- Measures on the Administration of Technologies Prohibited and Restricted from Import.

7. What are the licencing requirements for personal and clinical use?

In practice, most personal use digital health technologies are in the form of mobile medical devices. Under Chinese law, all medical devices shall be recorded or registered with the NMPA or its local branches before they can be marketed to the public.

Digital health technologies for clinical use mainly cover medical devices used in medical institutions. Most of these medical devices are considered to be high risk and therefore subject to registration with the NMPA before they can be marketed and used. Digital health technologies can also be used in remote diagnosis and treatment processes. As clarified in question 3 above, such remote health services can only be provided in qualified medical institutions and by qualified healthcare professionals. Such medical institutions and healthcare professionals should obtain qualification approvals from the local branch of the NHC.

Data Protection Overview

1. Can any types of data be shared with companies for the development of digital health technologies? Which kinds of data are permitted or prohibited?

Enterprises share data from their applications with other users for a variety of business needs. For example, pharmaceutical or healthcare organizations share patient data with medical researchers to assess the efficiency of clinical trials or development of digital health. To protect the privacy rights of the shared data, laws, regulations and business policies have been instigated by the government and enterprises which require the protection and confidential handling of protected health information. Any information that can be used to distinguish one person from another will be considered as personally identifiable information which may be protected by privacy rights and direct sharing for business purposes should be avoided. After a data masking process, such information can become anonymised and can then be used for business purposes, such as the development of digital health technologies.

2. Are there any regulations or restrictions on use of data collecting or sharing digital health technologies by or in collaboration with medical institutions or doctors?

The collection of healthcare data in China complies with the principle of “a piece of information must correspond to a unique source” and must minimize the information to be collected to the extent necessary. For healthcare data which contains private information, the consent of the recipient must be obtained before the information is directly obtained. Express consent should be obtained for sensitive information of the individual. When collecting indirectly, the personal information provider should be required to explain the source of personal information and confirm its legality, and should understand the scope of authorization for the processing of the personal information that has been obtained.

The state has strict control over electronic medical records. It is forbidden to disclose patient medical records for non-medical, teaching and research purposes. Apart from specific subjects (patients, medical staff, departments or personnel authorized to be responsible for medical records management/medical management, etc.), no other institution or individual may access the patient’s medical records without authorization. If foreign entities want to use Chinese genetic resources, they should cooperate with the Chinese entities in a cooperative manner and at the same time be approved by the MoST.

Intellectual Property Overview

1. What types of digital health technology can be patented and describe the general patent registration, if any, structure of your jurisdiction

The digital health technology which can be patented shall be novel, inventive and practically applicable in the PRC. There are only four technology topic types which can be patented, including method, product, device and material. The state provides that no patent shall be granted for an invention that contravenes any law or social moral or that is detrimental to public interests. No patent will be granted for an invention based on genetic resources if the access or utilization of the said genetic resources is in violation of any law or administrative regulation. In addition, methods for the diagnosis or for the treatment of diseases and rules and methods for mental activities also cannot be patented. It is worth noting that under PRC Patent Law, computer programs can also be patented. In order for a computer program to constitute a technical solution it must solve technical problems and the features of the program have been designed in such a way in order to achieve this. This is important in the field of digital health as most projects will involve computer programs.

There are two methods for registering a patent in the PRC. Companies can apply directly to the National Intellectual Property Administration (NIPA) for patent registration. If an individual is already a patent holder in a country which is a signatory of the Paris Convention then the individual can apply for patent registration under the Patent Cooperation Treaty with NIPA.

2. What types of digital health technology can be copyrighted and describe the general copyright registration, if any, structure of your jurisdiction?

China is a signatory of the Berne Convention for the Protection of Literary and Artistic Works ("**Berne**") and also the Agreement on Trade-Related Aspects of Intellectual Property Rights ("**TRIPS**"). If works have been created in another signatory country to Berne or TRIPS they will receive automatic protection in China. Despite receiving automatic protection, it is recommended to register copyrights in China.

In accordance with the *Copyright Law of the People's Republic of China (2010 Amendment)*, works covering the digital health technology can enjoy copyright including written works, computer software, etc. The most significant area here is computer software. China has also released specific regulations dealing with the protection of computer software, namely the Regulations on Computer Software Protection. This regulation will apply to software developed by Chinese citizens, legal persons or organisations. The regulation also applies to software developed by foreigners if their initial software release is in China or if the Copyright is protected under and International treaty that China is a signatory of, such as Berne or TRIPS. In addition to computer programs, data products such as data bases can also be protected under the PRC Copyright Law. In order to receive this protection the data product must be original in terms of its selection or arrangement of its content.

Author of the creative work (be this a natural person, a legal entity or an organisation who created the work) or by other copyright owners who obtain the right through transfer or inheritance from the author can file the copyright registration with the Copyright Protection Centre of China. The Copyright Protection Centre of China is the institution that is authorized by the National Copyright Administration of China to administer computer software registration, and the registration of copyrighted works.

3. What are the main intellectual property issues arising in digital health technology development?

Under the PRC intellectual property regime, certain AI processes can enjoy copyright rights in accordance with the *Copyright Law of the People's Republic of China (2010 Amendment)*. New methods or products in the field of AI also can be patented in accordance with the PRC Patent Law. One of the biggest hurdles for these types of applications are that they could fall into the scope of "methods of diagnosis and treatment of

diseases" which are not patentable. In response to this limitation, besides avoiding any "diagnosis or treatment" terms in the application, an applicant should stress the technical idea of the patent application. That is, the applicant should stress that they have technical expertise in the logic, diagnosis and treatment of diseases and that this can be used in the medical field.

Under the *Special Administrative Measures for Access of Foreign Investments* (the "**Negative List**"), investment in medical institutions by foreigners is restricted. The restriction means that all investment must be conducted by way of a joint venture or cooperative operation. While the new Foreign Investment Law has prohibited forced technology transfer, there are key considerations with regards to IP when entering a joint venture or cooperation.

When entering a cooperation involving the development of technologies, unless otherwise agreed, the right of the application of patent protection will be jointly held by both parties to the cooperation. This is problematic as if one party refuses to apply for patent protection, the technology cannot be patented.

With regards to joint ventures, if IP is registered in the joint ventures' name, problems may be encountered when trying to export the IP out of China. There are certain restrictions on technology transfers out of China, and certain kinds of IP will be placed under examination before they are allowed to be transferred.

In addition to these issues, there may also be some IP issues depending on the source of funding for the digital health technology. If the project has received Chinese public funding it is likely that the IP generated will be considered "national property." If this is the case, there are certain regimes which take force which may make IP ownership for a foreign party or transfer of IP out of China difficult.

The Future of Digital Health

1. Have there been any recent updates to the regulatory regime governing digital health in your jurisdiction?

The most recent updates to the digital health regulatory regime are outlined in question 3 of the Regulatory Overview section above. The government have released regulations covering telemedicine, internet diagnosis and internet hospitals. These are also the most important regulations introduced in China which specifically relate to digital health.

2. Are we likely to see any reforms or new regulations relating to digital health?

Yes, the Chinese government have been extremely ambitious with regards to setting themselves digital health targets, as outlined in policies such as *Made in China 2025* and *Healthy China 2030*. Given these ambitions, it is highly likely that if this sector is to expand rapidly in China, this will have to be accompanied by an appropriate regulatory framework.

Application

Medical Devices

1. What types of digital health technologies need to be registered as medical devices?

Under Chinese law, medical devices refer to instruments, equipment, appliances, in-vitro diagnostic reagents and calibrators, materials as well as other similar or relevant articles, including necessary computer software.

The utility of medical devices are assessed via looking at their purpose, which includes the:

- Diagnosis, prevention, monitoring, treatment or relief of diseases;
- Diagnosis, monitoring, treatment, relief or functional compensation of injury;
- Inspection, substitution of, adjustment to, or support of physical structures or physical processes;
- Support or maintenance of life;
- Control of pregnancy; and
- Inspection of the human body to provide information for medical treatment or diagnosis.

If such device falls into any of the above scopes, it will be regulated as a medical device in China and must be registered or recorded with the NMPA or its local branches.

2. What types of digital health medical devices can be used and how do they work in practice?

After registration with the NMPA, the medical devices can be marketed and used.

Currently, most of the digital health medical devices are wearable fitness trackers which are used for health management, such as the Huawei Talkband B5 and Xiaomi Mi Band 3, enabling the monitoring of fitness and activity levels, sleep patterns, heart rate and other features.

Similarly, some medical devices can collect patient data and transfer such data to doctors who can monitor the patient's disease. For example, the MGIUS-R3 Remote Ultrasound System is a robotic and real-time ultrasound system developed by Shenzhen MGI Tech Co., Ltd. Here, doctors control the ultrasound robotic manipulator and can see the ultrasound images transmitted back to the doctors in real-time. Further, medical service robots developed by IFLYTEK use face and speech identification technology to provide patients with appointment services and recommend appropriate clinics in accordance with the symptoms described by patients.

3. What are the main legal issues surrounding digital health medical devices?

Local laws and regulations will need to keep up with the rapidly evolving technology landscape. For example, whilst the *Regulations on the Supervision and Administration of Medical Devices* set strict procedures and standards for the registration and approval of medical devices, the NMPA has not yet formulated enough registration technical guidelines for different kinds of digital health devices, meaning that the relevant approval authorities will not be able to accurately review the technical standards of devices filed for registration.

4. What kinds of marketing activities are permitted or prohibited?

The Chinese legal system does not classify types of marketing activities or even clarify which activities are permitted, restricted or forbidden. In practice, several laws and regulations will be applied to judge whether marketing activities are allowed. Content or forms of the market activity can also influence the activities' legality.

We have summarized some common marketing activities below for reference:

(a) Permitted:

(i) Advertisements for common consumers;

(ii) Exhibiting devices at events; and

(iii) Patient education.

The above activities are generally permitted in China. These practices will be illegal if bribery or other illegal factors are involved, e.g., the content of the advertisement is wrong or misleading.

(a) Restricted:

(i) Advertisements of medical devices may not target children. Adverts must not be published in children publications, media channels, programs or columns.

(b) Forbidden:

(i) Cash and/or personal gifts;

(ii) Adverts for specific devices are forbidden by NMPA from manufacturing or trading; and

(iii) Adverts for devices for internal use in a medical institution.

m-Health

1. What types of m-Health can be used and how do they work in practice?

Examples of m-Health:

- Ping An Good Doctor: The platform lets users consult doctors for a diagnosis and to set up appointments. It has recently obtained an online hospital license, which will eventually let it provide prescriptions too. In April this year, Ping An Good Doctor became a listed company in Hong Kong, valued at US$1.1bn. The app is looking to expand into the Southeast Asia region to give users in the region access to AI-assisted online medical consultations, medicine delivery and appointment bookings. Good Doctor claimed, in 2017, that it had 27m active monthly users who receive up to 400,000 diagnoses in a day, although some analysts estimate users were closer to 20m.
- WeDoctor: The platform allows users to book appointments, make payments, and more at hospitals and other medical facilities through WeChat public accounts. As of 2017, over 38,000 medical facilities in China have WeChat accounts (in Chinese). 60% of those provide online consultation and appointments, and 35% support medical bill payments by WeChat pay. The company now provides health care support services to more than 2,700 hospitals, 240,000 doctors and 160 million platform users in China.

2. What are the main legal issues surrounding m-Health?

Although m- health technologies offer benefits to patients and healthcare providers, they also attract new threats. Considering the key role data collection and sharing has in developing m-health technology, especially in relation to sensitive personal health information, it is telling that there is still no uniform law or national authority providing a regulatory framework on privacy and data protections laws in China. Thus, cybersecurity represents one of the main legal issues facing the rise in digital disruption. Issues for cybersecurity include: weak or non-existent access controls, inadequate software protection, non-existent encryption, improper or unsafe operation and no guidance for new technologies. A new cybersecurity law was enacted in China last year setting out a number of compliance requirements, including formulating internal cybersecurity management policies and procedures, assigning qualified staff to be in charge of cybersecurity matters, taking the necessary technical measures to protect operational security, manufacturing and using safe and controllable products, and complying with certain obligations when collecting, processing and using personal information.

3. Are there any regulations or restrictions on use of m-Health by or in collaboration with medical institutions or doctors?

As clarified in Q3 of the Regulatory Overview part above, only qualified medical institutions and doctors can provide m-health services to operate common and chronic diseases under specific regulatory requirements.

4. What kinds of marketing activities are permitted or prohibited?

There is currently no specific regime in China relating to the advertisement of m-health services. These services will still fall under the scope of the *Advertising Law of the People's Republic of China* (the "**Advertising Law**").

Generally, advertisements cannot be misleading. If the information is incorrect with regards to function, origin, usage, quality, ingredients or price, in an advertisement, it will be deemed as misleading. Companies are also banned from using superlatives in their advertising material. If the regulator finds any advertisement to be misleading or in breach of any of the other provisions of the Advertising Law they can demand that publication of the advert ceases. Advertisers may also have to take steps to mitigate the effect of the misleading advert. If the breach is considered serious enough, companies may have their business licences revoked.

Please also note the marketing activities should also comply with other applicable laws and regulations, such as the anti-bribery obligations defined in legislation regarding competition Law.

Artificial Intelligence

1. What are the main legal issues surrounding artificial intelligence and digital health?

Similar to m-health, the development of AI technology and utilization also need to rely on a significant amount of data, thus cybersecurity is also a main legal issue for AI.

2. What types of artificial intelligence digital health technology can be used and how do they work in practice?

AI in disease diagnosis:

- PereDoc: A Beijing-based start-up. Their AI software is installed in more than 20 hospitals in China, with a network of more than 180 hospitals serving as research collaborators to craft algorithms that process medical images in order to assist with diagnosing and identifying potential diseases and signs of cancer using scans.
- AI Medical Innovation System (AIMIS): An AI-powered diagnostic medical imaging service developed by Tencent. AIMIS labs have been established in over 10 hospitals across the country, with signed agreements to deploy AIMIS to around 100 hospitals in China. The technology currently has accuracy rates of over 90% for preliminary diagnoses of esophageal cancer, 95% for lung sarcoidosis and 97% for diabetic retinopathy.
- Babylon AI app: When a user describes his or her symptoms or conditions to the system, Babylon's AI can analyse and form a personal assessment based on those inputs, while making recommendations as to whether the user should seek further consultation with a doctor which can take place online with GPs via text or video messaging. Earlier this year, Babylon announced that it is providing its artificial intelligence (AI) technology to Tencent's WeChat social messaging platform, with a potential reach of 1 billion in the pharma market to allow the WeChat users to enter their symptoms to the app to receive healthcare advice.

AI and data mining:

- iCarbonX: Created in 2015, iCarbonX is an AI-enabled health data mining start-up backed by Tencent, having raised over USD600 million at more than a USD1 billion valuation. Its ambition is to apply deep learning algorithms in analysing reams of data to provide medical and health advice to consumers directly through a real time app platform called “Meum”. Collaboration is key when data sharing forms the foundation of an AI product, and iCarbonX has formed alliances with leading health technology and application companies around the world, including HealthTell (US), which specialize in gathering different types of healthcare data. Together, the “Digital Life Alliance” as they call themselves, iCarbonX are working to help people better understand the medical, behavioural and environmental factors in their lives that may accelerate or mitigate disease and optimize health. Within China, another AI competitor is WuxiNextCODE, backed by Alibaba, which has developed a special database designed to collect and identify genomic data.

AI and Robotics:

- Combining AI and robotics together can result in beneficial clinical use. For instance, the Chinese TiRobot system used in Beijing’s Jishuitan Hospital can be used to create a 3D scan of a patient’s torso and plot a surgical path to the affected area where required, as well as being deployed to drill holes for surgery. The use of robotics provide a solution to the physical limits of a surgeon’s sight and steadiness of hand, in addition to the precise calculations given to it, or even such calculations the AI robotic’s has made itself following deep learning procedures. The main leader in the field for medical robotics is the Da Vinci Surgical System, a robotic apparatus made in California but used in China since 2006.

3. Can artificial intelligence digital health diagnostic services provide medical advice?

Currently, despite the lack of specific laws and regulations on AI health services, existing laws permit the use of AI in assisting doctors in the diagnostics process. However, AI software is itself prohibited from being used to provide diagnosis advice independently. Thus, AI chatbots such as Baidu’s “Melody the Medical Assistant” would only be able to provide general medical consultancy services, rather than diagnostic services.

India

Regulatory Overview

1. What is the main legislation for digital health technology in your jurisdiction?

Digital health technology is governed under a patchwork of legislation in India. Like many other jurisdictions, different kinds of digital health offerings/products are covered by different laws, although there may be some overlap between categories.

Key legislation regulating digital health include:

- The Information Technology Act, 2000 ("**IT Act**") read with the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011 ("**Data Protection Rules**"), and the Information Technology (Intermediaries Guidelines) Rules, 2011 ("**Intermediary Guidelines**");
- The Drugs and Cosmetics Act, 1940 ("**DC Act**") read with the Medical Device Rules, 2017 ("**MDR**") and the Drugs and Cosmetics Rules, 1945 ("**DC Rules**");
- The National Medical Commission Act, 2019 ("**NMC Act**") read with the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 ("**Ethics Code**");
- Telemedicine Practice Guidelines;
- The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, and Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955 ("**DMRA**");
- Telecom Commercial Communication Customer Preference Regulations, 2018 ("**TCCP Regulations**"); and
- Consumer Protection Act, 2019 ("**CPA**").

2. What are the main regulatory bodies for digital health in your jurisdiction and what is their corresponding regulatory scope?

- There is currently no specific umbrella regulatory body established for digital health.
- Ministry of Health and Family Welfare ("**MoHFW**"): This is the primary regulatory authority governing traditional, as well as digital, health in India. While there is no specific sub-regulatory body governing all

kinds of digital health products, there are a number of regulators that operate within their scope, for different types of digital health products.

- Central Drug Standards Control Organization ("**CDSCO**"): Medical device software i.e., software that is embedded within a physical device, as well as software having medical applications that are independent of any physical device regulated by the CDSCO, and is formed under the MoHFW.
- National Pharmaceutical Pricing Authority ("**NPPA**"): This is the primary agency established under the DPCO 2013 and is responsible for setting drug prices.
- National Medical Commission and Board of Governors: Medical education and the medical profession in India is regulated by the National Medical Commission (which replaced the erstwhile Board of Governors), instituted by the Indian government. Prior to the constitution of the National Medical Commission, the Board of Governors issued Telemedicine Practice Guidelines that must be followed by doctors and healthcare professionals who provide such services. Telemedicine is defined as 'the delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies'.
- Ministry of Communications and Information Technology: This is the primary regulatory body for technology and regulates data protection, namely, how service providers/intermediaries collect, use and protect data. Given that digital health products routinely deal with personal data, they would be covered by this authority as well.
- Department of Telecommunications: This body is one of the two main governing bodies of the Indian telecommunication industry and requires "Application Services" providers to be registered with the Department of Telecommunications. This would include telemedicine services which use telecom resources.

3. Are there specific rules relating to digital health and compliance/dealing with HCPs in your jurisdiction?

- The NMC Act currently regulates the medical profession and medical education in India. The professional and ethical standards set out in the Ethics Code are to be followed by all doctors in India. In light of the Covid-19 pandemic and the difficulty faced in providing in-person healthcare services the MoHFW has issued the Telemedicine Practice Guidelines to encourage and enable registered medical practitioners to provide healthcare using telemedicine. These guidelines are annexed to the Ethics Code and broadly set out the requirements to be followed during tele-consultations, such as:
  a. A registered medical practitioner is required to exercise their professional judgment in deciding whether a telemedicine consultation is appropriate, or if an in-person consultation is required for a given situation.
  b. The registered medical practitioner or doctor must then choose the appropriate medium of teleconsultation i.e., audio, video or text.
  c. The doctor should verify and confirm a patient's identity by name, age, address, email address, phone number, registered ID and seek proof of age in cases of doubt, for issuing a prescription.
  d. Patient consent is necessary for any telemedicine consultation, such consent may be implied or explicit, as set out in the guidelines.
  e. A telemedicine consultation would entail the same standard of care and accountability as a traditional in-person consultation. Doctors are permitted to issue prescriptions for medicines set out in the list of drugs in Annexure 1 of the guidelines.**
- The Telemedicine Practice Guidelines also make data protection and privacy laws binding on registered medical practitioners who would need to be mindful of protecting patient privacy and confidentiality during the handling and transfer of such personal patient information. For more information regarding Indian data protection laws, please refer to the Data Protection section below.

- In cases of professional misconduct, a patient may raise a complaint with the relevant state medical council. If such complaint has merit and the doctor is found guilty of violating the Ethics Code i.e., the ethics rules, they may be suspended from practice of have their medical license cancelled.

4. Are there any current government initiatives promoting digital health technology?

India has taken several initiatives in recent years to support and promote digital health systems in India, including:

- *The National e-Health Authority ("**NeHA**")*: The MoHFW is in the process of setting up the NeHA, which will act as a promotional, regulatory, and standards-setting body for creating guidelines, frameworks and regulations for interoperability/standardisation of digital health information and promotion of e-health.
- *National Digital Health Blueprint ("**NDHB**") and the National Digital Health Mission ("**NDHM**"):* The Ministry of Health has, as part of the NDHB, initiated efforts in the direction of a comprehensive, nationwide integrated e-health system that seeks to, *inter alia*, establish and manage core health data, and infrastructure for its exchange, establish national and regional registries relating to clinical establishments, healthcare professionals and health and pharmacies, and create personal health records based on international standards, which are easily accessible to citizens and service providers, based on consent. In August 2020, the Government announced the NDHM, which in furtherance of the NDBH, seeks to create core digital systems to increase access to healthcare, such as a health identification, a single, updated repository of all doctors, a repository of health facilities in the country, and interoperable health records.
- *Aarogya Setu App*: The Government of India recently released the app to spread awareness of Covid – 19 by using the user's smartphone GPS and Bluetooth features to track the spread of infection. Users are required to add their status (i.e., whether they have been infected). Using location information, the app provides information on positive cases in the neighbouring areas and provides real time updates on positive cases nationally. However, there are still several privacy concerns surrounding the Aarogya Setu App.
- *Proposed Legislation – The Digital Information Security in Healthcare Act ("**DISHA**") and Personal Data Protection Bill, 2019 ("**Data Protection Bill**")*: The proposed DISHA and Data Protection Bill are major proposed changes to digital health legislation in India. DISHA would establish the NeHA as detailed above and would enact provisions for the exchange of patient information which currently exists in data-silos. The Data Protection Bill, modelled on the EU's GDPR, would overhaul India's data protection regime.

5. Please provide a brief regulatory regime for digital health in your jurisdiction.

- Digital health technology is governed under a patchwork of legislation in India. Therefore – while there is some overlap – the applicable legislation would be model specific.
- **Regulation of Medical Devices**: Broadly, digital health software is required to be registered under the MDR read with the DC Act. Under new amendments, India's medical device regulations have been expanded significantly. Effective April 1, 2020, devices that were not previously considered as 'medical devices' will now come within the scope of medical devices. As an immediate matter, they shall have the option to be registered with the Central Drugs Standard Control Organisation ("**CDSCO**") – i.e., India's primary drugs and medical devices regulator – and avail an exemption from other requirements under the rules for some time going forward. Given the broad nature of the new definition for 'medical devices', several commonly used healthcare software, including applications, either sold with a physical device, or used as standalone software would be considered medical devices and subject to the MDR. They would therefore have to register themselves and, going forward, comply with all the requirements of the MDR (such as clinical trials, licensing etc.).

- **Price Control**: Since the Government has notified all medical devices as drugs, price control by the NPPA would now be possible for all medical devices effective 31 March 2020. Broadly, under the DPCO 2013, the Government may specify / fix the ceiling price of notified drugs (and now medical devices) that are included within the list of medicines specified in the National List of Essential Medicines ("**NLEM**") which are included in the First Schedule to the DPCO 2013 ("**Scheduled Formulations**"). For those drugs and medical devices notified, but not included in the First Schedule ("**Non-Scheduled Formulations**") the DPCO 2013 empowers the Government to monitor their maximum retail price, and prohibits manufacturers and importers from increasing their price by more than 10% in any 12 month period.
- **Regulation of e-Pharmacies**: The online sale of medicines remains a grey area under Indian law. The primary legislation (the DC Act) is geared towards the sale of medicines through brick and mortar pharmacies, and requires that that all drugs be sold under a license. These licenses are granted to the premises from which such drugs are sold (either by wholesale or retail). Further, drugs can only be dispensed by a registered pharmacist to the patient who holds a valid prescription (except in the case of OTC drugs). This makes doorstep delivery of drugs via an online platform a challenge, given that a physical prescription is required to be brought to the pharmacist. Be that as it may, several companies have attempted to work around these requirements by operating as an intermediary between already licensed pharmacies and patients, rather than storing inventory. There have also been a number of court orders banning the functioning of e-pharmacies, although these have been stayed. Currently the government is contemplating amendments that would grant e-pharmacies legal recognition under a separate licensing system under the DC Rules.
- **Regulation of Healthcare Professionals**: As set out above, the MoHFW recently issued the Telemedicine Practice Guidelines. These guidelines are annexed to the Ethics Code and broadly set out the requirements to be followed during tele-consultations.
- **Data Protection/Privacy**: While we have covered broad data protection requirements under Indian law below, briefly – several digital health offerings such as Telemedicine, m-Health applications, among others collect the SPDI of users on a real-time basis, which makes protection of such data critical. While there is no uniform law on data protection digital health offerings (including doctors) dealing with personal information or SPDI would need to comply with data protection requirements under the IT Act read with the Data Protection Rules.
- **Consumer Law**: Healthcare service providers may face civil liability under the CPA in case of an unfair trade practice, deficiency in service, false advertising, faulty product(s), etc. before a dedicated consumer dispute redressal forum. This liability is uncapped and depends on the amount claimed and the specific facts of the case.

6. What are the regulations governing the transfer of technology, both domestically and cross-border?

Typically, in a cross-border transfer of technology, no regulatory approvals or statutory clearances would be required. However, the Indian counterparty would have to submit necessary declarations to their banker in accordance with Indian exchange control laws, and also pay appropriate Indian taxes (including, withholding tax on royalty payment and applicable Goods and Services tax). One notable exception is when the licensed technology under the technology transfer relates or is linked to Indian biodiversity. In such a case it would trigger the requirement of approvals under the Biological Diversity Act, 2002 and the Biological Diversity Rules, 2004.

7. What are the licencing requirements for personal and clinical use?

For more information regarding licensing requirements for the use of digital health technology, please refer to our responses to Q5 above and to Q1 of the Application Section. Broadly, digital health software is considered as a medical device under the MDR. Such devices would need to obtain a provisional registration with the CDSCO. This provisional registration, which is not a full technical submission, allows such devices

to avail an exemption from the clinical trial and other requirements of the rules for some time going forward. However, once this period is exhausted, they would need to comply with all of the requirements of the MDR.

Data Protection Overview

1. Can any types of data be shared with companies for the development of digital health technologies? Which kinds of data are permitted or prohibited?

- **Background**: While India does not have dedicated data protection legislation that regulates the collection and use of personal data, the IT Act read with the Data Protection Rules, Intermediary Guidelines, and in some cases the Indian Penal Code, 1860 prohibit the sharing of certain kinds of data. Additionally, proposed data protection legislation i.e., the Data Protection Bill, 2019 – modelled on the EU's GDPR that would significantly change the law in India – is currently in the works.
- **Types of Data**: Currently, Indian law classifies data into various types with varying degrees of protection afforded that would have an impact on the ability to share such data. The first is personal information which is defined as "any information that relates to a natural person which, either directly or indirectly, may identify that person". The second is sensitive personal data or information ("**SPDI**") which is a subset of personal information which relates to:
  a. passwords;
  b. financial information, including information relating to bank accounts, credit cards, debit cards, and other payment instrument details;
  c. physical, physiological, and mental health conditions;
  d. sexual orientation;
  e. medical records and medical history;
  f. biometric information;
  g. any detail relating to the above, as provided to the body corporate for providing service; and
  h. any such information received by body corporate for processing, or that is stored or processed under lawful contract or otherwise.
- **Restrictions:** Broadly, the Data Protection Rules regulate the collection, processing, storage, sharing, and transfer of SPDI. It also requires body corporates to draft a privacy policy that provides certain information to data subjects in instances where it handles personal information including SPDI. Furthermore, body corporates are required to appoint a grievance officer to address data subject grievances/complaints.
- In the case of SPDI, companies would need to adhere to the following:
  a. Obtaining the data subject's prior written consent for collection, disclosure, and/or transfer of SPDI.
  b. Ensuring the collection is necessary for or directly related to a lawful purpose.
  c. Disclosing SPDI to third parties is only under limited circumstances.
  d. Retaining SPDI for only as long as necessary to fulfil the organisation's purpose for collecting it.
- The data principal's consent must be free, clear, informed, capable of being withdrawn and for a specific purpose. and must be taken only after giving proper notice to the data principal regarding data collection and its subsequent sharing. Such notice must contain the purpose for processing the personal data, nature of data being collected, safeguards available to them as a right, and any other information provided in the statute or regulations formed for this purpose. It should be used only for the purpose for which notice was given or any other person which is incidental and connected to it.

- However, provisions regarding requirement of consent can be removed if the purpose falls under the exceptions granted under the IT Act and Data Protection Rules. Such purposes include undertaking safety measures or providing medical treatment during an epidemic and responding to medical emergencies involving threat to life or severe threat to health of one or more individuals. These purposes may be relevant to digital health companies.
- **Applicability:** These requirements would apply to individuals and organisations in and outside of India that process personal data either within India or outside of India if they use a computer, computer system, or computer network located in India.
- Typically, health data or any other data collected in the course of providing digital health services would be classified as SPDI under Indian law. Thus, companies dealing with such information would need to adhere to the requirements set out above. Contravention of any provisions governing the processing of sensitive personal data and other regulatory measures may attract damages - this liability is uncapped.

2. Are there any regulations or restrictions on use of data collecting or sharing digital health technologies by or in collaboration with medical institutions or doctors?

- As set out above, the Telemedicine Practice Guidelines make the data protection and privacy laws binding on registered medical practitioners who would need to be mindful of protecting patient privacy and confidentiality during the handling and transfer of such personal patient information. These guidelines are annexed to the Ethics Code that is binding on doctors. Therefore, doctors are obliged to protect the confidentiality of patients during all stages of the procedure and with regard to all aspects of the information provided by the patient to the doctor, unless there is a serious and identifiable risk to a specific person or community of a notifiable disease.
- Consequently, any technology collaborating with doctors for collecting or sharing data wherein the doctor, through itself or its medical institution, shares information gathered from the patient could be considered a violation of doctors' ethics code. Therefore, healthcare professionals using digital health technology that shares or collects patient data would need to be mindful of the Ethics Code and adopt procedural safeguards provided therein, as well as under the Data Protection Rules.

Intellectual Property Overview

1. What types of digital health technology can be patented and describe the general patent registration, if any, structure of your jurisdiction

- **Overview** – India is a signatory to the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"). The Patents Act, 1970 ("**Patents Act**") governs the grant and other matters relating to patents in India and has been modified over time through a number of amendments to be TRIPS compliant.
- **Registration** – The application for registration of a patent can be made offline at the Indian Patents office or online at its website. The application must be made at the regional patent office of the jurisdiction in which the applicant is domiciled or where the invention occurred. An applicant which does not have a domicile in India can apply to the registration office in which its service address falls.
- Patents may be filed through three routes before the Indian Patent Office. The first is a regular application. The second, convention applications under the Paris Convention which grants certain protections to foreign nationals applying for patents in its member states. As India is a member state, foreign nationals of all other member states of the Convention will receive the same protections as enjoyed by an Indian national while applying for the patent. Such foreign nationals will also get the right of priority for their application, if filed in India within twelve months of first filing in other member state, to be considered as filed on the same date as it was filed in the other member country. Lastly, applicants

may file a National Phase Application in India because India is a Patent Co-operation Treaty ("**PCT**") contracting member country.

- The statute extends the protection to a patent for a period of twenty (20) years from the date of filing. For a patent granted under priority route, the protection is available for twenty (20) years from the date of filing in the first member state. No further extensions are granted after the completion of such twenty (20) years. Additionally, this protection granted under patent laws also ceases if there is a delay of more than six (6) months in the payment of annual renewal fees.
- **Qualifications** – For a process or product to be granted patent in India, it must be novel/new, involve an inventive state/is non-obvious, and have utility/industrial application. However, the statute has carved some exceptions to this general rule. These exceptions include:
  a. invention which is obvious or obviously contrary to natural laws;
  b. any invention whose primary/commercial use is contrary to public order or morality or prejudicial to life/health of living beings or the environment;
  c. any discovery of a scientific principle or anything which is otherwise naturally occurring in nature;
  d. any discovery of a new form of known substance which does not enhance the efficacy of the substance;
  e. any product, or the process through which it is made, which is a mixture that merely reflects the properties of its constituents;
  f. any re-arrangement of devices whose individual functioning is known;
  g. any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic, or other treatment of human beings or animals;
  h. any mathematical or business method or a computer programme per se or algorithms;
  i. any aesthetic creation including literary, dramatic, musical or artistic work;
  j. any scheme, rule, method of performing mental act or playing game;
  k. any form of presentation of information;
  l. any invention which is in effect a duplication or aggregation of known properties of traditionally known component(s); and/or
  m. any invention relating to atomic energy as defined by Indian laws.
- **Patentability of Digital Health Products** – As set out above, under Indian patent law, computer programs per se cannot be patented. In other words, standalone software or computer programs are not patentable unless attached to an invention as a component of such invention. Applicants must demonstrate that the hardware is an essential part of the invention along with the software or computer program. Additionally, patent protection would not be granted for 'a process for the medicinal or other treatment of human beings and animals'.
- Therefore, digital health offerings such as standalone software, for instance wellness applications etc. would not receive patent protection under Indian law. However, wearables such as fitness trackers and smartwatches that contain both a hardware device as well as embedded software would be allowed to receive a patent under Indian law.

2. What types of digital health technology can be copyrighted and describe the general copyright registration, if any, structure of your jurisdiction?

- **Overview** – India is a signatory to the TRIPS Agreement, 1995, Berne Convention for Protection of Literary and Artistic Works, 1886, and Universal Copyrights Convention, 1952. Therefore the Copyright Act, 1957 – which governs copyright protection - is at par with global standards. Furthermore, India has

also passed the International Copyright Order, 1999 that affords copyright protection in any "works" of foreign nationals whose countries are members to the Universal Copyrights Convention.

- **Registration** – Registration of copyright is not mandatory in India, however it is recommended since it serves as prima facie evidence of the right. A copyright can be registered by making an application with the Registrar of Copyrights. After such filing, a mandatory waiting period of thirty (30) days is provided to receive possible objections. If an objection is received, the registrar will grant both parties a hearing after which the authority decides on the application. This process takes anywhere between a few months to a few years depending on the objections raised. Once granted, copyright protection is available for sixty (60) years from the beginning of the calendar year which follows the year in which the author dies.
- **Qualifications** – Copyright protection is granted for an original expression of idea and not the idea itself. Under Indian law, digital health technology would enjoy copyright protection under the following categories of literary work covered by the statute:
  a. computer programme (specifically, the source code);
  b. tables, compilations and databases (though freely available data might not be copyrightable, copyright can be granted when an individual expends effort to make an independent collection of information); and
  c. any artistic works, including the display interface of the technology.
- However, copyright shall only subsist when any such work is "original" and not when the work is infringing upon prior copyrighted work.

3. What are the main intellectual property issues arising in digital health technology development?

Computer programs and per se processes for the "medicinal or other treatment of human beings and animals" do not enjoy patent protection under Indian law, thus posing challenges to companies involved in digital health. Per the Indian Patent Office's Guidelines for Examination of Computer Related Inventions, 2017, a patent may be granted to a computer program only if it is applied for along with a novel hardware. This results in a lack of protection for entities dealing in digital health technologies if their products only have a software-component. Though they may resort to other measures, the protection would not be as effective as ensured by a patent.

The Future of Digital Health

1. Have there been any recent updates to the regulatory regime governing digital health in your jurisdiction?

The most recent updates to the digital health regulatory regime have been the inclusion of health software as a medical device. While Indian regulations are currently in a transition state, increased clarity on how software is to be classified and consequent licensing requirements is expected. Additionally, price controls have been newly introduced for medical devices. In summary, importers or manufacturers would now not only need to assess whether they are covered by the new catch-all definition of medical devices and begin compliance with the registration and other requirements under the MDR, but also be mindful of price control norms. Lastly, the government has also recently released regulations covering Telemedicine, internet diagnosis and internet hospitals. For more information please refer to our response is Q5 of the Regulatory Overview section above.

2. Are we likely to see any reforms or new regulations relating to digital health?

Yes, Indian digital health regulations are currently in a state of flux. Apart from the initiatives being undertaken by the Indian government, such as the implementation of the National Digital Health Blueprint and National Digital Health Mission, there are several pieces of legislation in the works, namely:

a. standalone medical device regulation that would create a separate regulator for medical devices;

b. the Data Privacy Bill, 2019 which would bring Indian data protection laws in like with Europe's GDPR; and

c. draft amendments to the Drugs and Cosmetics Rules, 1945 that would grant legal recognition to e-pharmacies.

In addition to this, clarifications on recent amendments that have broadened the scope of the existing MDR are to be expected in the coming months.

Application

Medical Devices

1. What types of digital health technologies need to be registered as medical devices?

Historically, India has not had regulations on all "medical devices" – certain categories of devices were regulated under the Drugs and Cosmetics Act, 1940 like "drugs". Through recent amendments the scope of "medical devices" has been expanded significantly. These amendments have become effective on 1 April 2020. As an immediate matter, devices that were not hitherto considered "medical devices" and will now be considered as "medical devices" have been given the option to provisionally register their devices with the CDSCO and avail an exemption from other requirements under the rules for some time going forward. As such, any medical device falling within the catch-all definition below is covered by the MDR –

"All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of —

(i) *diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;*

(ii) *diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;*

(iii) *investigation, replacement or modification or support of the anatomy or of a physiological process;*

(iv) *supporting or sustaining life;*

(v) *disinfection of medical devices; and*

(vi) *control of conception."*

The new definition is quite broad, covering software that is used 'alone or in combination'. Thereforeon plain reading , this definition includes software as a medical device to the extent the software has an 'intended function' linked to one or more of the 'specific purposes'. Given that the CDSCO has not provided any exceptions for apps such as health trackers etc. all wellness and other health related applications would be covered. For instance, an app that allows users to check symptoms, learn about conditions and drugs, and provide treatments and diagnoses, would fall within the new definition and would accordingly need to apply for registration with the CDSCO in the short term.

2. What types of digital health medical devices can be used and how do they work in practice?

India has several digital health medical devices currently in use such as wearables, symptom checking software, doctor finders, diagnostic software embedded in physical devices such as MRIs, among others. Companies would need to evaluate whether their product falls within the definition of "medical device" set out above.

3. What are the main legal issues surrounding digital health medical devices?

Given that Indian medical device regulations have recently been broadened significantly, there are a number of transitional issues currently being faced by importers. For instance, digital health medical devices, including software that is independent of a physical device would need to obtain provisional registration with the CDSCO. Once registered with the CDSCO, medical devices (other than the 36 notified categories) enjoy a thirty (30) – forty-two (42) month exemption period from compliance with the MDR, during which they may be marketed and sold. After such period, the manufacturer or importer (as the case may be) would need to apply for a license for such medical device. The CDSCO has released draft classifications for medical devices (which include certain kinds of widely used digital health software such as menstrual trackers) in September 2020, but these are pending stakeholder/public comments. Given that these classifications have not been formally issued, the CDSCO is yet to classify such digital medical devices from Class A to B, provide the online portal for provisional registration, or provide any other guidance/principles that would allow companies to evaluate whether they fall under the new definition (as of 23 February 2021).

For more information on other issues relating to data protection, consumer law, and others please refer to our response to Q5 of the Regulatory Overview section above.

4. What kinds of marketing activities are permitted or prohibited?

The Indian legal system does not specify any detailed rules specifically pertaining to the advertising of digital health products. However, there are a number of legislations that regulate marketing activities for drugs, as set out below:

- **The Ethics Code:**
  a. it is applicable to healthcare professionals in India;
  b. doctors are required to prescribe drugs with generic names, and ensure that there is a rational prescription and use of drugs;
  c. soliciting of patients by physicians is considered unethical; and
  d. doctors may not accept cash and/or personal gifts from drug companies.
- **The Drugs and Magical Remedies (Objectionable Advertisements) Act, 1954:**
  a. this statute prohibits the advertisement of prescription drugs. Advertising is allowed for OTC products; and
  b. no advertisement may be published in respect of any drug suggesting that it may enhance sexual performance, prevent conception or cause miscarriage, correct menstrual disorder in women, and cure, mitigate, treat or prevent any of the diseases specified in the Schedule appended to the act.
- **The Government of India has also released the (voluntary) Uniform Code for Pharmaceutical Marketing Practices:**
  a. while voluntary for the time being, it relates to marketing practices for Indian pharmaceutical companies as well as the medical devices industry;
  b. it prohibits gifts, pecuniary advantages or benefits (personal or otherwise) from being supplied, offered or promised to healthcare professionals or their family members;
  c. it sets out the parameters of what claims can be made in respect of drugs; and

d. it prohibits companies from paying any cash or monetary grants to any healthcare professional under any pretext and imposes conditions on companies who wish to appoint medical practitioners as affiliates.

m-Health

1. What types of m-Health can be used and how do they work in practice?

Several m-Health applications are currently in use in India such as symptom checkers, healthcare professional finders, clinical records software, condition education and management, and self-monitoring apps. The Government has also put in active efforts towards developing the m-Health applications, such as *Aarogya Setu* as covered Q4 of the Regulatory Overview above. Other examples of m-Health in India include:

- National Health Portal India: This app acts as a mobile extension to the National Health Portal of the Government and provides healthcare related information to the citizens across the country.
- AIIMS-WHO CC ENBC: This app, released through collaboration between the WHO and the All India Institute Of Medical Science, provides current evidence-based practices relating to infant care.
- Practo: Practo is a mobile doctor finder app with numerous doctor profiles from across the country. Patients can book confirmed appointments with doctors listed on the app or on the website.

2. What are the main legal issues surrounding m-Health?

- The primary legal considerations involved in m-Health applications in India are centred around data protection. Given that these apps rely on the collection and exchange of health information (in other words – SPDI under the IT Act), m-Health companies would need to be mindful of data protection requirements. Additionally, the accuracy of predictions and treatments would be of paramount importance given the reliance on these apps for monitoring various aspects of health such as hydration, sleep, and the like. Per Indian data protection requirements, such companies would need to draft a privacy policy and need robust disclaimers in place to obtain user consent for the use of such information. Lastly, cybersecurity issues such as weak or non-existent access controls, inadequate software protection, encryption, and improper or unsafe operation would need to be addressed. For more information please refer to the Data Protection Overview section above.
- Another issue surrounding m-Health are the new amendments to Indian medical device regulations and the inclusion of price control. While one would expect the CDSCO to release clarifications and exceptions to health monitoring apps and other personal wellness software, for the time being, companies would need to adhere to the new requirements.

3. Are there any regulations or restrictions on use of m-Health by or in collaboration with medical institutions or doctors?

As clarified in Q3 of the Regulatory Overview section above, India recently introduced the Telemedicine Practice Guidelines, in order to encourage the use of Telemedicine by registered medical practitioners during the period of the Covid-19 pandemic. Other licensing requirements for personal use of m-Health products have been covered in the Regulatory Overview section above as well.

4. What kinds of marketing activities are permitted or prohibited?

The rules on marketing mentioned under Q4 of the Medical Devices section above would also apply to m-Health.

Artificial Intelligence

1. What are the main legal issues surrounding artificial intelligence and digital health?

Given that AI technology also utilizes and relies on personal health data, cybersecurity and data privacy would be the primary issue for companies developing/using AI.

Second, in the case of death or injury to a patient on whom AI assisted treatment is used, it is unclear who would be liable i.e., the doctor or manufacturer.

2. What types of artificial intelligence digital health technology can be used and how do they work in practice?

The use of artificial intelligence in digital health technology has increased in recent years. AI is currently being used to:

- Assist in diagnoses. This represents the primary use of AI, which analyses chest X-rays and other radiology images, read ECGs, spot abnormal patterns etc.
- Provide hospital management services. In this case, hospitals use AI to monitor the health of critical care patients and help free up ICU beds faster.
- Process ERP transactions and medical records. It aims at developing products which assist patients and doctors in making informed decisions.

3. Can artificial intelligence digital health diagnostic services provide medical advice?

Currently, there is no law governing the use of artificial intelligence in the medical sector. However, the Telemedicine Practice Guidelines issued in March 2020 prohibit any artificial intelligence from counselling or prescribing medicines to a patient. However, they could assist and support a registered medical practitioner on patient evaluation, diagnosis or management. Further, recent amendments to Indian medical device regulations would mean that such technology would be regulated as a medical device under the MDR.

Indonesia

Regulatory Overview

1. What is the main legislation for digital health technology in your jurisdiction?

There is no single comprehensive law or regulation that specifically governs digital health technology in Indonesia. Instead, this subject matter is governed under several laws and regulations described below.

Health Law

Law No. 36 of 2009 on Health ("**Health Law**") regulates the provision, research, distribution, development and usage of health technology for public health. Health technology is defined as any method and device used to diagnose, prevent and treat human health-related Issues. The Health Law further stipulates that health technology and health technology product include any method or device used to prevent illness, detect illness, alleviate pain, cure, minimise complication and restore health.

The Health Law requires any health technology that are developed to observe the standards as required by the applicable laws and regulations. Further, the Health Law mandates that a body be established to monitor the use of health technology. However, to date, there has not been any regulations being issued by the Indonesian government to further regulate the abovementioned standards and establishment of the supervisory body.

Electronic Information and Transactions Law

As digital health technology is related to the use of electronic systems, Law No. 11 of 2008 as amended by Law No. 19 of 2016 on Electronic Information and Transactions ("**EIT Law**") also applies. Under the EIT Law, an electronic system is defined as a set of electronic devices and procedures used to prepare, collect, process, analyse, store, display, announce, send, and/or disseminate electronic information. Given the broad definition, any health-related technology, such as a software or hardware may be deemed as an electronic system and therefore subject to the EIT Law and its implementing regulations.

Under the EIT Law, a business providing health-related technology is subject to certain obligations and/or requirements, including, among others, to ensure the reliability and security of the electronic system, protect any personal data processed by it and register the electronic system to the Ministry of Communications and Information Technology ("**MOCIT**").

In addition to the above obligations, providers of the health technology must also observe personal data protection rules as set out under the EIT Law and its implementing regulations, including Government Regulation No. 71 of 2019 on the Provision of Electronic Systems and Transactions ("**GR 71**").

However, GR 71 only regulates personal data that are processed using electronic systems. This means non-digital personal data will not be subject to the personal data protection rules under GR 71.

- GR 71 requires any electronic systems providers (including providers of health technology) to observe the following principles in processing personal data:
- That the personal data collection is conducted in a limited and specific manner, legally valid, fair and with the consent and agreement of the personal data owner;
- That the personal data processing is conducted in accordance with its purpose;
- That the personal data processing is conducted by ensuring the rights of the personal data owner;
- That the personal data processing is conducted accurately and fully, is not misleading, up-to-date, accountable, and considers the intention of such personal data processing;
- That the personal data processing is conducted by protecting the personal data from any loss, misappropriation, access and illegal disclosure, as well as alteration or destruction of personal data;
- That the personal data processing is conducted by notifying the purpose of collection, processing activities, and failure in protecting personal data; and
- That the personal data processed is destroyed and/or deleted unless subject to a retention period based on laws and regulations.

Medical Records Regulation

If the use of health technology involves the processing of health data, the provider must also adheres to Minister of Health Regulation No. 269/MENKES/PER/III/2008 on Medical Records ("**Medical Records Regulation**"). The Medical Records Regulation defines a medical record as a file containing notes and documents on the identity of the patient, examination, medication, action and other services that have been provided to the patient, either in a physical or electronic form. Given this broad definition, any health data will also be deemed as a medical record. Therefore, anyone dealing with health data must also comply with the Medical Records Regulation.

The Medical Records Regulation provides that for the medical records of inpatients in hospitals must be stored for at least 5 years starting from the date when the relevant patient was lastly treated or went home from the hospital. After 5 years, the medical records concerned may be destroyed except for the discharge summary and medical treatment approvals. The discharge summary and medical treatment approvals must be stored for at least 10 years starting from the date when such summary is prepared. Meanwhile, medical records for health service facilities given outside of hospitals must be stored for at least 2 years starting from the date when the patient was lastly treated.

The confidentiality of medical records must be maintained by doctors, dentists, some health workers, management officers and head of the health services facilities. Such information may only be disclosed:

in the interest of the health of the patient;

- To fulfil any requests made by law enforcers for law enforcement purposes based upon a court order;
- Based on a request and/or consent of the patient;
- Based on the request of an institution pursuant to the laws and regulations; and
- For research, education and medical audit purposes.

Consumer Protection Law

Law No. 8 of 1999 on Consumer Protection is also relevant for providers of digital health technology, especially for users of such technology, which may be considered as consumers. Under this law, businesses are prohibited from producing and/or providing goods and/or services (including digital health goods/services) that:

- Do not fulfil or conform to the standard requirement, laws and regulations;
- Do not conform to the net weight, net volume and the quantity as specified in its label;
- Do not conform to the size, measurement, weight and quantity based on its real measurement;
- Do not conform to the condition, guarantee, superiority or efficacy as stated in its label or description;
- Do not conform to certain quality, level, composition, processing, style, model or utilisation as stated in its label or description;
- Do not conform to the promise stated in its label, description, advertisement or sales promotion;
- Do not mention any expiration date or best utilisation period;
- Do not comply with the provision on halal production based on the "halal" statement stated on its label;
- Do not have any label or provide any explanation that states the name of the goods, size, net weight/volume, composition, direction for use, manufacturing date, any side effects, name and address of the business actor and any other information related to utilisation that must be provided/made; and
- Do not provide any information and/or direction for utilisation in the Indonesian language.

Further, if the business actor produces and/or provides a product that can be utilised for more than a year, then such business actor must provide spare parts and/or after sales facility and is obliged to fulfil the given warranty or guarantee.

2. What are the main regulatory bodies for digital health in your jurisdiction and what is their corresponding regulatory scope?

There is currently no single regulatory body for digital health in Indonesia. The relevant bodies involved in matters related to digital health are summarised below.

Ministry of Health

The Ministry of Health ("**MOH**") has a regulatory function, including the formulation of national policy, implementation policy and technical policy in relation to public health, prevention and disease control, health services, pharmacy, as well as health technology and medical devices.

Ministry of Communications and Information Technology

MOCIT has a regulatory function in relation to the management of resources and equipment of post and information technology, administration of post and informatics, management of informatics applications, management of public information and communication.

3. Are there specific rules relating to digital health and compliance/dealing with HCPs in your jurisdiction?

Health care professionals are subject to the standards set in various regulations governing digital health in Indonesia. For example, the Minister of Health Regulation No. 1198/MENKES/PER/VIII/2010 stipulates that health care professionals producing medical devices must at least be educated in the type of device produced by him/her and must be working full time.

4. Are there any current government initiatives promoting digital health technology?

In 2017, the MOH issued a regulation relating to national e-health strategy, which promotes the development of e-health to improve accessibility to health services, especially by improving governance and leadership, strategy and investment, services and application, standards and interoperability,

infrastructure, legislation, policy and compliance, as well as manpower. The MOH has also issued the aforementioned regulation on the provision of telemedicine as a way to improve specialist and general health care in rural areas.

5. Please provide a brief regulatory regime for digital health in your jurisdiction

Please refer to our responses to questions 1 and 2 above.

6. What are the regulations governing the transfer of technology, both domestically and cross-border?

There is no legislation that exclusively governs the transfer of technology. The general rules on transfer of intellectual property rights will apply. Generally, for any transfer of intellectual property rights, there must be an agreement concluded by the parties and the transfer must be recorded with the Directorate General of Intellectual Property (DGIP).

7. What are the licencing requirements for personal and clinical use?

As mentioned in our answer to question 1 above, the Indonesian government has not issued any implementing regulation to the Health Law which specifically pertain to health technology.

Data Protection Overview

1. Can any types of data be shared with companies for the development of digital health technologies? Which kinds of data are permitted or prohibited?

The prevailing laws and regulations do not define data that is categorised as health data. Therefore, all health data that fulfils the criteria as a personal data will be subject to stipulations regarding personal data. As a general rule, the processing of personal data requires consent from the data subject upon disclosure of the purpose for the processing of their personal data. Therefore, a company that collects personal data must ensure that the consent of the data subjects have been obtained and that they have been informed about the use of their personal data, including the fact that their personal data will be shared for the development of certain digital health technologies.

However, under the Medical Records Regulation, an individual's identity, diagnosis, illness history, medical history and treatment history may be disclosed for research, education and medical audit purposes as long as the identity of the data subject is not disclosed.

2. Are there any regulations or restrictions on use of data collecting or sharing digital health technologies by or in collaboration with medical institutions or doctors?

While there is no specific legislation that governs digital health technologies, the use and disclosure of health data by medical institutions or doctors would be subject to:

- The obligation to keep the confidentiality of the health data;
- Limited disclosure of the health data, such as for the data subject's medical interest, law enforcement purposes or upon request of the data subject him/herself; and
- Consent of the data subject for disclosure of his/her health data for his/her medical interest.

Intellectual Property Overview

1. What types of digital health technology can be patented and describe the general patent registration, if any, structure of your jurisdiction?

General Patent Registration Structure

Pursuant to Law No. 13 of 2016 on Patents, a patent is defined as an exclusive right granted by the state to an inventor for an invention in the field of technology, for a certain time, to exploit the invention or to authorise another person to exploit it. A patent can only be granted for an invention that is novel, involves an inventive element and is susceptible of industrial application. An invention is further defined to include any idea of an inventor relating to any activity to solve a specific problem in the field of technology, either in the form of a product or a process, or an improvement to and development of a product or a process. Any novel invention that possesses an improvement of a product or a process and susceptible of industrial application can receive

The patent registration process at the Directorate General of Intellectual Property ("**DGIP**") would usually take about 55 months from the filing date, while a simple patent would usually be granted about 12 months from the filing date. A registered patent is protected for 20 years, commencing from the filing date, and upon expiry, it cannot be extended. A simple patent, on the other hand, is protected for 10 years commencing from the filing date, and upon expiry, it cannot be extended.

Indonesia also recognises the concept of priority right. An application with a priority right should be filed within 12 months commencing from the date on which the first application was received by a country that is a party to the Paris Convention or is a member country of the World Trade Organization.

Patentable digital health technology

A patentable invention can only be submitted for a novel invention, which involves an inventive step and is susceptible of industrial application.

An invention would be considered to involve an inventive step if such invention does not constitute something that is obvious to a person skilled in the art.

Hence, a digital health technology that is novel, inventive and susceptible of industrial application can be patented. Further, a computer program can be protected as long as it comprises of character (instructions) that possess technical effect and function for the purpose of tangible and intangible problem solving. In the context of digital health technology, the invention is likely to relate to the hardware, software and computer programme used for the technology.

2. What types of digital health technology can be copyrighted and describe the general copyright registration, if any, structure of your jurisdiction

General Copyright Registration Structure

Copyright is regulated under Law No. 28 of 2014 on Copyrights ("**Copyright Law**"). A copyright is defined as an exclusive right of a creator that arises automatically based on a declarative principle after a creation is reflected in a concrete form. Indonesia adopts the declarative system where the exclusive rights of a creator arise automatically after a work is produced. Registration of a creation by its creator is therefore voluntary, not mandatory.

Copyright protection for a creation covers 3 different rights, namely:

- Moral rights, which are the rights attached to the author that cannot be removed for any reason, such as the right to publish or not to publish the author's name, use a fictitious name, modify the creation, or change the title and subtitle of the creation, and to uphold the author's right in case of a distortion of the creation, modification or other occurrences that may harm the author's dignity or reputation;

- Economic rights, which are the rights of the author to gain commercial benefit from his/her work; and
- Related rights, which are rights that are related to the copyright, that is, the exclusive rights of a performer, producer of phonograms, and a broadcasting organisation.

The copyright registration process at the DGIP would take about 9 months from the filing date. The protection of moral rights and related rights are valid indefinitely, whilst the protection of economic rights will be valid during the life of the creator, with an additional protection of 70 years after the creator's death.

Protected Copyrights in Digital Health Technology

A creation protected by copyright under the Copyright Law must be a creation in the field of science, arts and literature, which includes, among other things:

- Books, pamphlets, typographical arrangement of published works, and all other written works;
- Sermons, lecturers, addresses and other works of utterance;
- Vsual aids made for educational and scientific purposes;
- Songs or music with or without lyrics;
- Dramas, musical dramas, dances, choreographic works, puppet shows, pantomimes;
- All forms of art, such as paintings, drawings, engravings, calligraphy, carvings, sculptures,
- Applied arts;
- Architecture;
- Maps;
- Batik art or other ornamental art;
- Photography;
- Cinematographic works;
- Translations, interpretations, adaptations, anthologies, database, adaptations, arrangements, modifications and other creations as a result of transformation;
- Translations, adaptations, transformations or modifications of traditional cultural expressions;
- Compilation of creations or data, both in computer program readable formats or any other devices;
- Compilation of traditional cultural expressions as long as such compilation features original creations;
- Video games; and
- Computer programs.

In the context of digital health technology, the creation that is likely to be protected by copyrights include the programming code in a computer program, artistic work and literary work.

3. What are the main intellectual property issues arising in digital health technology development?

There are no specific intellectual property issues arising in the context of digital health technology. In general, the main intellectual property issues in technology are infringement of copyrights related to programming code, infringement of designs and infringement of trade names.

The Future of Digital Health

1. Have there been any recent updates to the regulatory regime governing digital health in your jurisdiction?

Recently, MOH issued a regulation on telemedicine, which allows long distance consultation to be conducted. However, the scope of this regulation is limited only to telemedicine provided between health services facilities.

In 2018, the MOH issued a regulation on e-pharmacies as an effort to prevent sales and distribution of unlicensed medicines. Under this regulation, only businesses with an apothecary licence can establish an e-pharmacy business. The e-pharmacy business must also have a co-operation with licensed pharmacies, drug wholesalers and drugstores.

2. Are we likely to see any reforms or new regulations relating to digital health?

The rapid development of e-health in Indonesia warrants a specific regulation on digital health. However, this may take a long time due to the traditional legislative process, which is known to be lengthy.

Application

Medical Devices

1. What types of digital health technologies need to be registered as medical devices?

Any digital health technology that meets the definition of medical devices under the Health Law must be registered as a medical device if such medical device is to be distributed in Indonesia. The elements of a medical device are as follows:

- Must be in the form of an instrument, apparatus, machine and/or implant;
- Does not contain any medicine;
- Is used to prevent, diagnose, heal and relieve illness, nurse the patient, restore human's health and/or form structures and improve bodily functions.

Given the broad-ranging definition, it is likely that any innovation in the health sector would be categorised as a medical device and therefore be subject to the relevant regulations on the subject matter.

2. What types of digital health medical devices can be used and how do they work in practice?

Please refer our response to question 1 above.

3. What are the main legal issues surrounding digital health medical devices?

As digital health medical devices would be considered the same as conventional medical devices, the applicable regulations apply, including:

- Each medical device must be registered to obtain a distribution permit prior to distribution in Indonesia;
- Only medical device distributors and medical device stores are allowed to distribute medical devices;

- Manufactures and distributors are obliged to obtain the proper medical device manufacturing/distributing certificate;
- The container, wrapping, marking and advertisement of medical devices must comply with the requirements stipulated in Minister of Health Regulation No. 96/MENKES/PER/V/1977 on Containers, Packaging, Marking as well as Advertising of Cosmetics and Medical Devices and Minister of Health Regulation No. 76 of 2013 on Advertisement of Medical Devices and Household Medical Supply.

4. What kinds of marketing activities are permitted or prohibited?

Medical devices may be marketed through printed media, electronic media, information technology media, and/or digital signage. However, if the usage of a medical device requires professional assistance, then such medical device may only be advertised through scientific medicine and pharmacy printed media and/or scientific forum for the health professionals.

m-Health

1. What types of m-Health can be used and how do they work in practice?

There is no definitive definition of m-Health in Indonesia and there is no specific regulation dealing with m-Health. The World Health Organisation describes m-Health as "*medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices.*"

In Indonesia, m-Health has been used in telemedicine, where health services facilities use information and communication technologies to facilitate research, evaluation, education and exchange of information related to diagnosis, treatment, prevention of illness and injury amongst themselves.

There are apps developed for online consultation by doctors in Indonesia, however, up to this day, there is no legislation that specifically regulates online consultation. Nevertheless, doctors are required by their professional code of conduct to provide consultation, diagnosis and treatment only if a physical examination has been conducted. Hence, the activities of online medical consultation may only be conducted if it is general and non-conclusive in nature.

Further, medicine order apps have also been developed where customers can order medicines from pharmacies online.

2. What are the main legal issues surrounding m-Health?

The prevailing regulations provide a restriction on online health consultation by doctors. Doctors may only provide online consultation if it is general and non-conclusive, meaning that if the consultation is specifically directed to a certain person with conclusive diagnosis and treatment, then the doctor would be required by its code of ethical conduct to conduct a physical examination. Otherwise, the doctor would be in breach of its code of ethical conduct and may be subject to disciplinary actions.

3. Are there any regulations or restrictions on use of m-Health by or in collaboration with medical institutions or doctors?

There are no specific regulations dealing with m-Health. However, as elaborated above, doctors are prohibited from providing a specific and conclusive consultation, diagnosis and/or treatment to their patients if such consultation is provided without a physical examination.

4. What kinds of marketing activities are permitted or prohibited?

The marketing activities of m-Health is regulated under Minister of Health Regulation No. 1787/MENKES/PER/XII/2010 on Advertisement and Publication of Health Services, which stipulates that health practice may be advertised through the media in accordance to advertising ethics and professional code of ethics applicable to each health practitioner and institution.

Artificial Intelligence

1. What are the main legal issues surrounding artificial intelligence and digital health?

The adaptation of artificial intelligence in digital health is not specifically regulated in Indonesia. As such, artificial intelligence remains attributable to its inventor or owner. In respect of liability, such inventor or owner would be held accountable for the consequence of any decisions made by the artificial intelligence.

2. What types of artificial intelligence digital health technology can be used and how do they work in practice?

The types of artificial intelligence digital health technology that can be used remain unclear as there is no regulation relating to artificial intelligence in Indonesia.

3. Can artificial intelligence digital health diagnostic services provide medical advice?

Indonesia does not expressly prohibit independent diagnosis through artificial intelligence. But the recent development of digital products with diagnostic capabilities suggest that this may be an area for future regulation. At this stage, however, health diagnostic services can only be provided by health professionals through physical examination.

Japan

Regulatory Overview

1. What is the main legislation for digital health technology in your jurisdiction?

There is no specific legislation for digital health technology in Japan.

The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Pharmaceuticals and Medical Devices Act) refers to medical appliances or instruments, dental materials, medical supplies, sanitary goods, and programs (referring to instructions given to a computer and built so as to obtain a certain result) as medical appliances or instruments, and certain kinds of medical appliances or instruments are deemed as medical devices.

The Medical Practitioners' Act and the Medical Care Act regulate telemedicine.

Several guidelines on the Act on Protection of Personal Information (APPI) regulate data in relation to digital health.

2. What are the main regulatory bodies for digital health in your jurisdiction and what is their corresponding regulatory scope?

The Ministry of Health, Labour and Welfare (MHLW) is the main regulatory body for digital health in Japan. MHLW regulates (i) digital medical devices, (ii) telemedicine and (iii) data related to medical data and data of patients.

Pharmaceuticals and Medical Devices Agency (PMDA), which is working with MHLW, conducts scientific reviews of marketing authorization application of medical devices, monitoring of their post-marketing safety.

The Ministry of Economy, Trade, and Industry (METI) encourages improvements in digital health in relation to invention of medical devices and services[48].

3. Are there specific rules relating to digital health and compliance/dealing with HCPs in your jurisdiction?

[48] https://www.meti.go.jp/policy/mono_info_service/healthcare/01metihealthcarepolicy.pdf

The MHLW has published "Basic Approach to Programmed Medical Devices (November 14, 2014)"[49] and "Guidelines for the Proper Conduct of Online Practice (March 2018, partially revised July 2019)"[50].

In addition, the following guidelines have been published for medical data:

- Guidelines for the Safety Management of Medical Information Systems (issued by MHLW, March 31, 2005, latest update on May 17, 2019);
- Guidelines for Safety Management when Handling Medical Information by Cloud Service Providers (issued by Ministry of Internal Affairs and Communication (MIC), July 31, 2018);
- Safety Management Guidelines for Information Processing Business Operators Engaged in Contract Management of Medical Information (issued by METI, March 2008 and revised on October 15, 2012);
- Strengthening of security measures for basic systems concerning the appropriate handling of personal information (Request) (issued by MHLW on June 17, 2015); and
- Guidance for the appropriate handling of personal information by medical and long-term care providers (jointly issued by the Secretary-General of the Personal Information Protection Committee and MHLW, b on April 14, 2017).

4. Are there any current government initiatives promoting digital health technology?

On 24 October 2019, the Cabinet Office announced the "Advanced Diagnosis and Treatment System Research and Development Plan by Artificial Intelligence (artificial intelligence) Hospital" (Plan) as part of the Strategic Innovation Cpreation Program (SIP)[51].

According to the Plan, the development, construction, and implementation of "AI hospital system" using AI analysis technology will be promoted to aid diagnosis, education and communication support in the medical field as well as the comprehensive collection of patient information and the development of big data using medical devices and IoT devices. This makes it possible to effectively utilize a large amount of medical information for medical treatment and to establish a system for providing highly advanced and optimized medical services. In addition, these technologies will be used to reduce the burden on doctors, nurses, and other medical professionals in hospitals and to improve the efficiency of medical expenses, thereby contributing to overcoming various issues and economic development in Japan's aging society.

The Plan is divided into Parts A to E as follows:

- Construction of a highly secure medical information database and development of technologies for extracting and analysing useful medical information using the database;
- Automatic documentation of medical records using AI and development of a two-way communication system using AI at the time of informed consent;
- Development of a support system (including the development and utilization of sensors, inspection equipment, etc.) for diagnosis, monitoring and treatment (including therapeutic agents) selection, etc., using AI technology based on patient biological information, etc., focusing on ultra-precision blood and other tests using AI technology that reduces the burden on patients and leads to ultra-early diagnosis of cancer recurrence, etc.;
- Research evaluation by demonstrative tests based on implementation of AI hospital functions in the medical field; and

[49] https://www.mhlw.go.jp/file/06-Seisakujouhou-11120000-Iyakushokuhinkyoku/261114.pdf
[50] https://www.mhlw.go.jp/content/000534254.pdf
[51] https://www8.cao.go.jp/cstp/gaiyo/sip/keikaku2/10_aihospital.pdf

- Measures related to intellectual property management related to research and development of AI hospitals, technical standardization and the Open/Close strategy for the general dissemination of systems, and matching for public-private partnerships.

5. Please provide a brief regulatory regime for digital health in your jurisdiction

Digital health issues in Japan are mainly recognized as (1) remote and online medical care, (2) digital medical devices, and (3) the use of medical information. There are no specific regulations for digital health, and they are regulated by individual laws such as the Medical Practitioners Act and the Pharmaceuticals and Medical Devices Act.

Remote and online medical care

The Medical Practitioners' Act (Act No. 201 of 1948) regulates that physicians shall not treat patients or issue medical certificates or prescriptions without performing their own medical examinations. The Medical Care Act (Act No. 205 of 1948) regulates that medical care must be provided in hospitals, clinics, long-term care health facilities, dispensing pharmacies, and other facilities that provide medical care ("health-care provider"), and in the homes of the patients, etc., efficiently according to the functions of the medical institutions, while seeking effective coordination with welfare services and other related services. This raises questions as to whether remote medical care or online medical care is possible.

The "Guidelines for the proper conduct of online medical care" defines remote medical care as the practice of health promotion and medical care using information and communications devices, and online medical care as certain remote medical care, in which medical care and examination of patients are performed between doctors and patients through information and communications devices, and medical practices such as transmission of diagnosis results and prescriptions are performed in real time.

These Guidelines require that online medical care should be provided with the following objectives: (1) to further improve the quality of medical care by obtaining information on patients' daily lives; (2) to ensure accessibility to medical care (Ease of Access) and to increase opportunities for patients who need medical care to obtain better medical care; and (3) to maximize the effects of treatment by patients' active participation in treatment.

Physicians should provide online medical care in accordance with the following principles:

Confidentiality between doctors and patients

In the relationship between doctors and patients, mutual trust is required when doctors ask patients to provide necessary information or when patients agree on a doctor's treatment plan.

For this reason, online medical care is basically used only when there is already a direct relationship between the physician and the patient, such as through daily face-to-face medical care. In principle, the first medical examination should be conducted face-to-face, and then face-to-face medical care by the same physician should be conducted in an appropriate combination with online medical care.

Responsibilities of the Physician

In principle, the physician/doctor is responsible for the medical treatment performed by the physician through online medical treatment. Therefore, physicians are required to make a careful judgment as to whether they are able to obtain sufficient information through online medical care and whether they can make an appropriate diagnosis based on this information; if online medical care is not appropriate, they are required to immediately stop online medical care and switch to face-to-face medical care.

Physicians must also ensure that adequate information security measures are in place for information and communications and the storage of patient medical information to prevent leakage or alteration of patient medical information.

Confirmation of the quality of medical care and ensuring patient safety

Physicians must regularly evaluate the effectiveness of their online practice, including the results of treatment, to ensure that it is safe and optimal. In addition, in the event of an emergency, such as a sudden change in the patient, that is not appropriate for online medical care, the physician must ensure the necessary systems to ensure the safety of the patient.

Provision of accurate information

In online medical care, the information on the patient's mental and physical condition is limited when compared to the face-to-face medical care. Physicians must correctly understand the limitations of online medical care and explain to patients and their families the benefits of online medical care and the possible disadvantages that may arise from it.

Medical care based on evidence of safety and efficacy

In order to promote appropriate online medical care, it is necessary to ensure the safety, necessity, and effectiveness of medical care, and physicians are required to provide medical care based on evidence on safety and effectiveness. In addition, since online medical care provides less information than face-to-face medical care, medical care that has not undergone clinical trials and clinical trials whose safety has not been established should not be provided online.

Provision at the request of the patient

Online medical care should be provided when a patient requests it after understanding the benefits and possible disadvantages, and should not be provided primarily for research purposes or solely for the convenience of the physician.

Only medical practitioners licensed in Japan can provide online medical examinations/consultations in Japan. However, it is permissible for non-medical practitioners to give consultations which provide general medical information or recommendations to see a doctor for treatment.

Generic telehealth (i.e. distribution of general health information through electronic or telecommunication means) is permissible under the conditions that:

- The advisor (including doctor) does not tell of possible medical conditions to the advisee (patient) that the may be suffering; and
- If the advisor is not qualified as a doctor, the advisor may not give the advisee any medical advice on the physical and/or mental condition of advisee.

Digital medical devices

Digital medical devices are regulated under the Pharmaceuticals and Medical Devices Act if they are designed to be used for the diagnosis, treatment, or prevention of human diseases or to affect the structure or function of the human body in the state of tangible devices installed in general-purpose computers or personal digital assistants unless they have little risk of affecting human life and health.

Specifically, the following should be considered: (1) to what extent the device contributes to the treatment and diagnosis of illness in light of the importance of the results obtained, and (2) whether the device is used for the diagnosis, treatment, and prevention of illness, or whether it is intended to affect for the body, keeping in mind the probability of a total risk including the risk of affecting human life and health in the event of a functional disorder, etc.

Medical data

Medical data is protected as personal information and sensitive personal information under the APPI, and as medical information under the Act on Anonymously Processed Medical Information for Contributing to Research and Development in the Medical Field (May 12, 2017； "Next Generation Medical Infrastructure Act"). Various types of protection are also regulated in the aforementioned guidelines.

The Next Generation Medical Infrastructure Act defines medical information as information concerning a specific individual's medical history and other information concerning the individual's mental and physical condition, which requires special consideration for the handling of such information so as not to cause unfair discrimination, prejudice or other disadvantage against the individual or his/her descendants on the basis of the individual's mental and physical condition, and which (1) can identify the specific individual by name, date of birth or other description contained in such information (including information that can be easily collated with other information and thereby identify a particular individual) or (2) contains an individual identification code.

The APPI limits personal information to information concerning living individuals, but medical information under the Next Generation Medical Infrastructure Act includes information concerning deceased individuals.

6. What are the regulations governing the transfer of technology, both domestically and cross-border?

Technology transfer and IP sharing may be done through licensing and/or assignment. If IP exists as a patent, design rights and/or utility model rights, a transfer of it may be registered under the Patent Act, the Design Rights Act of the Utility Right Act. With respect to the cross-border transfer of technology, IP rights are territorial. As such, the registration or grant of a patent in Japan does not provide protection overseas. Generally, in order to enforce IP rights in digital health technology in jurisdictions outside Japan, the IP rights need to be registered in the relevant overseas jurisdictions.

However, this is not the case for copyright in digital health technology (such as copyright subsisting in software code), because copyright works in Japan automatically vests in the creator and does not require registration although registration is possible. Copyright is recognised internationally by jurisdictions (including Japan) that are a contracting party to the Berne Convention.

7. What are the licencing requirements for personal and clinical use?

Irrespective of personal or clinical use, it is required to obtain licences for each of the manufacturing company, manufacturing plant and product respectively in Japan.

Company

License for Marketing Authorization Holder (MAH) is required under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices ("PMD Act"). The term "marketing" as used in this Act refers to manufacturing (including cases of manufacturing outsourcing to others, but excluding manufacturing entrusted by others) or importing pharmaceuticals (excluding pharmaceuticals that are active ingredients), quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products, and then selling, leasing or providing them to others, or to offering medical device programs (medical devices which are programs) via telecommunication lines.

Plant

It is necessary to obtain (i) Registration for Manufacturing Business and/or (ii) Registration of Foreign Manufacturers of Medical Devices.

Product

The necessary procedures vary depending on the classification of medical devices

Specially Controlled (Class III IV)	Approval by MHLW (+ Reviewed by PMDA)
Designated Specially Controlled or Controlled (Class II, III)	Certification by Registered Certification Body

General (Class I)	Self Declaration (Submit Marketing Notification to PMDA)

Other Licenses for Company

Retail/Rental Service License/Notification

When selling and leasing Specially Controlled Medical Devices or Controlled Medical Devices, a license for selling and leasing or a notification for selling and leasing is required. However, this does not apply to cases where MAH sells or leases them to holders of a marketing authorization for, or to manufacturers, sellers or leasers of them.

Repairs License

Only a person authorized for repairing medical devices may engage in the business of repairing medical devices. These licenses are either Specially Controlled or Non-controlled depending on the scope of the repairs. Each of these categories has 9 product classifications, and organizations are required to hold the necessary licenses for the specific classification of the product handled.

Data Protection Overview

1. Can any types of data be shared with companies for the development of digital health technologies? Which kinds of data are permitted or prohibited?

Personal Information

The scope of what constitutes personal information now includes “Personal Identifier Codes” and “Sensitive Personal Information”.

A “Personal Identifier Code” includes:

- Characters, numbers, symbols and/or other codes for computer use which represent certain specified physical characteristics (such as DNA sequences, facial appearance, iris patterns, vocalizations, posture and walking movements, finger and palm prints, and vein patterns) and which are sufficient to identify a specific individual;
- Certain identifier numbers, such as those on passports, driver’s licenses and resident’s cards, and the ‘My Number’ individual ID number; and
- Unique characters, numbers, symbols and other codes designated by the Enforcement Ordinance that are assigned to and specified on health and care insurance cards; and
- Any characters, numbers, symbols and other codes designated by the Enforcement Rules of the Personal Information Protection Commission as being equivalent to any of (1) through (3) above.

Data holders which hold personal information must not provide a third party with personal data (i.e. personal information compiled in a personal information database etc.) without obtaining the data subject’s consent to do so in advance, except in the following cases:

- The data holder provides the third party with personal data based on laws and regulations;
- It is necessary for the data holder to provide the third party with the personal data in order to protect the life, body, or property of an individual, and it is difficult to obtain the consent of the data subject;
- There is a special need for the data holder to provide the third party with the personal data in order to improve public health or promote healthy child development, and it is difficult to obtain the consent of the data subject;

- It is necessary for the data holder to provide the third party with the personal data in order to cooperate with a national government organ, local government, or an individual or a business operator entrusted thereby with performing the affairs prescribed by laws and regulations, and obtaining the consent of the data subject is likely to interfere with the performance of those affairs.

Guidelines clarify that the following cases are deemed as transfer to a third party:

- Exchange/transfer of personal data between subsidiaries, jointly controlled companies and group companies;
- Exchange/transfer of personal data between a franchisor and its franchisees; and
- Exchange/transfer of certain personal data between the same professions/industry.

However, in the following cases, a person being provided with personal data is not deemed to be a third party for the purpose of transfer of the data:

- A person who the data holder entrusts all or part of the handling of personal data within the scope necessary for achieving the Purpose of Use;
- If the personal data is provided to the person when it succeeds to the business of the original data holder due to a merger or similar circumstances;
- If personal data is used jointly with data holders provided that they either notify the person (data subject) in advance of (a) this joint use, (b) the items of the personal data used jointly, (c) the extent of the joint users, (d) the purposes of joint use, and (e) the name of the individual or business operator who is responsible for managing the personal data, or make the foregoing information readily accessible to the person in advance.

Sensitive Personal Information

"Sensitive Personal Information" means any personal information relating to matters such as physical or mental disabilities, medical records, medical and pharmacological treatment, and arrest, detention or criminal proceedings (whether as an adult or a juvenile). It is necessary to obtain the consent from the data subject in order to obtain or transfer the Sensitive Personal Information, and the opt-out system (deemed consent given where the data subject has been given the chance to refuse consent but has not done so) cannot be used for a transfer of the Sensitive Personal Information.

Anonymously processed medical information

For research and development in the medical field, the Next Generation Medical Infrastructure Act has established a system to certify those who are engaged in the business of creating anonymously processed medical information; i.e. medical information that is processed so as not to be able to identify a specific individual, and regulates the handling of anonymously processed medical information. A business operator handling medical information may provide medical information to a business operator authorized to anonymously processed medical information without obtaining the consent of the data subject.

Most medical information falls under the category of care-required personal information (sensitive personal information) under the APPI, but under the Next Generation Medical Infrastructure Act, when a data subject is notified of certain matters concerning medical information in advance and the competent minister is notified, a business operator handling medical information may provide the medical information to a business accredited anonymously processed medical information producer without obtaining the consent of the data subject. A business authorized to anonymously process medical information may, in response to a request from another such business, provide medical information provided by a medical information handling business operator to the extent necessary for the production of anonymously processed.

2. Are there any regulations or restrictions on use of data collecting or sharing digital health technologies by or in collaboration with medical institutions or doctors?

Please see No. 1 ((3) Anonymously processed medical information) above.

Intellectual Property Overview

1. What types of digital health technology can be patented and describe the general patent registration, if any, structure of your jurisdiction

The Patent Act protects inventions, which it defines as a 'highly advanced creation of technical ideas utilizing the laws of nature'. Patents are granted to the inventor of an invention with industrial applications after examination, provided the invention is not, prior to the filing of the patent application: (i) publicly known in Japan or a foreign country; (ii) publicly used in Japan or a foreign country; or (iii) described in a distributed publication, or made publicly available electronically in Japan or a foreign country. Patentability also requires novelty, and so patents are not granted where a person ordinarily skilled in the art of the invention would have been able to easily make the invention based on an invention prescribed in any of items (i) through (iii) above prior to the filing of the patent application. Japan is a member of the Patent Cooperation Treaty (PCT), which is intended to simplify the process for applicants seeking patent protection internationally for their inventions, helps patent offices with decisions on patents, and facilitates public access to a wealth of technical information relating to inventions going back to 1978.

Digital health technology can be patented if the technology is novel and not publicly known, used or described in Japan or a foreign country. There is no specific provision on non-patentable matters in relation to digital health technology under the Patent Act.

The procedure for obtaining a patent right is as follows; (i) Application to Japan Patent Office (JPO); (ii) Formality Examination (to be checked whether the necessary procedural and formal requirements are fulfilled); (iii) Publication (the contents of an application is published in the official gazette after 18 months have passed from the application date), (iv) Request for Examination (an examination will be carried out only when a request for examination is filed and the examination fees are paid; if there is no request within three years from filing date, the application will be regarded as withdrawn); (v) Substantive Examination (whether the claimed invention should be patented is examined); (vi) Decision to Grant a Patent/ Decision of Refusal (in the case of refusal, there are the processes of notification of reasons, appeal against the decision of refusal, an examination of the appeal and decision to grant/ decision of refusal); (vii) Registration (if a decision to grant a patent is made, the registration will be made if the patent fee for the registration is paid) and (viii) Publication (the contents of the patent right will be published in the Patent Gazette).

2. What types of digital health technology can be copyrighted and describe the general copyright registration, if any, structure of your jurisdiction

Under the Copyright Act (Act No. 48 of 1970), copyrightable works are those in which thoughts or sentiments are expressed creatively, and which fall within the literary, scientific, artistic or musical domain. Copyrightable works include novels, plays or films, scripts, dissertations, lectures and other literary works; musical works, choreographic works and pantomimes; paintings, engravings, sculptures and other artistic works; architectural works; maps and diagrammatical works of a scientific nature, such as drawings, charts and models; cinematographic works; photographic works; and computer programs. However, works categorised as 'applied works', usually meaning those for sale as utility goods or souvenirs, cannot be protected by copyright. Works on digital health in which thoughts or sentiments are expressed creatively, and which fall within the "scientific category" can be copyrighted.

Registration is not mandatory and a work may be protected by copyright without copyright registration. However, registration is necessary to assert against third parties the transfer (other than by inheritance or

other succession) of the copyright, restrictions on the disposal of the copyright, the establishment, transfer, modification or termination of a pledge on the copyright, or restrictions on the disposal of a pledge established on the copyright. Registration is made with the Agency of Cultural Affairs (ACA) or, in the case of software programs, with the Software Information Centre (SOFTIC). The author of a work that is made public anonymously or pseudonymously may have his or her true name registered with ACA and SOFTIC based on the moral right of the author with respect to work, regardless of whether he or she actually owns the copyright. In addition, the copyright holder of any work, or the publisher of an anonymous or pseudonymous work, may register the work's date of first publication or the date when the work was first made public. In the case of computer programs, the author may have the date of the creation of the work registered with SOFTIC provided this is done within six months of the work's creation.

The protection period begins at the time the work is created and subsists for 70 years after the death of the author or, in the case of a jointly authored work, for 70 years after the death of the last surviving co-author. The copyright protection period for a work that bears the name of a juridical person, or other corporate body as its author, is 70 years either from the date the work was first made public, or, if the work was not made public within 70 years of its creation, 70 years from the date of its creation.

3. What are the main intellectual property issues arising in digital health technology development?

In the field of digital health technology, research and development using AI is expected, but it is not clear who should be granted intellectual property rights in relation to new discoveries made by AI and system works. Although inventions are the subject of patent rights and works are the subject of copyright rights, all of them are primarily human, and there are no provisions in the current Intellectual Property Law concerning the results achieved by AI.

The Future of Digital Health

1. Have there been any recent updates to the regulatory regime governing digital health in your jurisdiction?

Continuous improvements are characteristics of medical devices and such improvements are handled by partial change approvals that require clinical studies, partial change approvals that can be evaluated in non-clinical studies, and minor change notices, depending on the effect of the change on the product. An approval review system has been introduced to enable continuous improvement of medical devices that are being developed sequentially in specific disease areas and that are expected to be improved due to technological innovations such as AI, for which programs with constantly changing performance have been developed since the initial approval.

A person who has received approval for manufacturing of medical devices may obtain confirmation from the MHLW with regard to plans for changes in performance and manufacturing methods, etc., among matters to be approved, and a person who has obtained confirmation is not required to obtain approval for changes in accordance with the plan if he/she has notified the change in advance.

2. Are we likely to see any reforms or new regulations relating to digital health?

Three Guidelines provided by Three Ministries

With regard to the handling of medical information, there are three guidelines provided by three ministries: (i) the "Guidelines for Safety Management when Handling Medical Information by Cloud Service Providers" (July 31, 2018) by MIC for cloud service providers handling medical information, (ii) the "Safety Management Guidelines for Information Processing Business Operators Engaged in Contract Management of Medical Information" (5th edition published in May 17, 2019) by METI, and (iii) the

"Guidelines for Safety Management of Medical Information Systems" by MHLW. MIC and METI plan to discuss integration of the guidelines. They will also consider ensuring consistency with MHLW's guidelines in the future.

Electronic Prescriptions

In March 2016, MHLW published a ministerial ordinance to enable the preparation, delivery, and preservation of electronic prescriptions in the form of electromagnetic records, and formulated the "Operational Guidelines for Electronic Prescriptions" to contribute to the smooth operation of electronic prescriptions. However, electronic prescriptions are hardly ever used in accordance with these guidelines due to strict requirements. Under the current ordinance, the use of paper electronic prescription exchange certificates, which may be converted to ordinary prescriptions, has been provided. MHLW will organize a new operation method of fully computerized electronic prescriptions, and consider necessary measures such as reviewing said operational guidelines.

Application

Medical Devices

1. What types of digital health technologies need to be registered as medical devices?

Under the Pharmaceuticals and Medical Devices Act, digital health technology such as programs that fall under the following categories are subject to regulation.

(a) A program that processes data (including images) obtained from medical devices, and creates indicators, images, graphs, and the like for use in diagnosis or treatment. For example:

- (i) A program (excluding storage and display as medical records) that displays images taken by diagnostic imaging equipment on a general-purpose computer or the like for use in diagnosis.
- (ii) A program that processes and processes images taken with diagnostic imaging equipment and test data obtained with testing equipment to support the display of candidate locations where lesions exist and the detection of lesions or abnormal values (CADe (Computer-Aided Detection)).
- (iii) A program to provide diagnostic support by providing quantitative data such as classification of lesions as benign or malignant, disease progression, etc., and information on candidate diagnosis results and risk assessment in addition to the CADs function (CADx (Computer-Aided Diagnosis)).
- (iv) A program that processes data on changes over time in the concentrations of radiopharmaceuticals, etc. on images taken with nuclear medicine diagnostic equipment, etc. using radiopharmaceuticals, etc., calculates physiological parameters (tissue blood flow, load response, substrate metabolism, receptor binding capacity, etc.), and performs statistical comparisons with healthy groups, etc.
- (v) A program that presents new indicators such as the severity of diabetes by processing and processing data obtained from medical devices such as simple blood glucose meters.
- (vi) A program (for example, a program that processes and processes images and examination data obtained from a fundus camera, an ophthalmoscope, and other ophthalmic examination equipment, displays shapes, areas, thicknesses, volumes, concentrations, colors, and the like, and compares the shapes, areas, thicknesses, volumes, concentrations, and colors of the tissues, cells, and layer structures of the eyeball with the shape information.) that processes examination data and images obtained from one or more examination devices and presents information for diagnosis.

(b) Programs to help determine treatment plans and methods (including simulation). For example:

(i) A program that processes image data obtained from imaging diagnostic equipment such as CT, presents, evaluates and diagnoses treatment candidates by displaying image images of the positions of teeth and implants, and simulating surgical procedures for orthodontic treatment or implant treatment, creates treatment plans, and predicts expected treatment results.

(ii) A program (RTPS (radiation treatment planning system)) that simulates the delivery of radiation to a patient during radiation therapy and calculates estimates of absorbed dose distributions in human tissue.

(iii) A program for navigating operations such as neurosurgery, plastic surgery, otolaryngology and spinal surgery using images.

(iv) A program for creating preoperative plan of orthopaedic surgery by processing and processing images photographed by diagnostic imaging equipment such as CT

(v) A program that processes data obtained with diagnostic imaging and testing equipment, simulates surgical results, supports the selection of surgical procedures and approaches by the surgeon, and calculates parameters used with the surgical equipment at the time of surgery (for example, a program (refraction correction surgery laser irradiation data preparation program) for creating laser irradiation data by performing a simulation of an operation result in consideration of a corneal irregularity component in refractive surgery on the basis of corneal shape data acquired by a refract keratometer having a corneal topography function.).

(vi) A program to support administration of an anesthetic by calculating the dose of the anesthetic from data such as the patient's body weight using a method that cannot be easily verified.

2. What types of digital health medical devices can be used and how do they work in practice?

Digital medical devices used for the diagnosis, treatment, or prevention of human diseases or to affect the structure or function of the human body would be classified as a medical device. However, digital health devices that have little risk of affecting human life and health are excluded from the scope of medical devices.

Many digital health wearable device are classified as "General Medical Device" which require notification to marketing notification to the PMDA or non-medical device.

(Please see Overview 5. (2))

3. What are the main legal issues surrounding digital health medical devices?

There is no clear distinction between medical devices that require marketing approval and those that do not, and approval is determined through consultation with the government. When a medical device is marketed without approval, it is often overlooked by the authorities if the device does not cause any problems.

4. What kinds of marketing activities are permitted or prohibited?

In regards to medical devices, the Pharmaceuticals and Medical Devices Act prohibits: (i) advertising false or exaggerated statements, whether explicit or implicit, relating to the name, manufacturing process, efficacy, effect or performance of a medical device; (ii) advertising statements that could be misinterpreted as endorsing the efficacy, efficacy or performance of a medical device by a physician or other person; and (iii) using documents or drawings that imply abortion or that are obscene with respect to a medical device the same as the case of pharmaceuticals.

The following advertisements are prohibited by the "Appropriate Advertising Guide for Medical Devices", a voluntary standard established by the Japan Federation of Medical Device Industries:

- An expression that indicates the specific efficacy and safety of a medical device and guarantees that it is safe;
- Advertisements of medical devices that may promote excessive consumption or excessive use beyond the approved or notified method of use;
- In relation to diseases for which a cure is generally not expected unless diagnosed by a physician or a dentist or treated by a medical treatment, to make an expression in an advertisement for the general public as to whether a cure is possible without a physician's or a dentist's diagnosis or treatment; and
- Advertisements offering medical equipment as a prize.

m-Health

What types of m-Health can be used and how do they work in practice?

1. What are the main legal issues surrounding m-Health?

It is not clear whether the application or mobile health device is a medical device or not. In addition, whether the application's or device's advice violates the Medical Practitioners Act, which prohibits diagnosis by anyone other than a doctor, is an issue.

Programs that display, transfer, and store measurements (weight, blood pressure, heart rate, and blood sugar) that indicate an individual's health status for daily health management, and programs that detect individual health information using sensors built in portable information terminals (mobile devices) and present life improvement menus for the purpose of improving health and physical fitness are not considered medical devices. Many companies manufacture and sell health devices in a form that does not fall under "medical devices."

2. Are there any regulations or restrictions on use of m-Health by or in collaboration with medical institutions or doctors?

There is no specific regulations or restrictions on use of m-Health.

3. What kinds of marketing activities are permitted or prohibited?

If a device falls under the category of "medical device," the same regulations for medical devices apply to the device.

Artificial Intelligence

1. What are the main legal issues surrounding artificial intelligence and digital health?

The use of AI in healthcare has the potential to dramatically improve the quality and accuracy of health care.

Based on the analysis of AI information using big data, it may be possible to make more accurate diagnosis and treatment decisions than doctors, and to detect diseases that were thought to be difficult for

doctors to detect by reading a large amount of image data and having in-depth learning with advanced analysis predictions by AI. Health care programs are also being developed to help patients develop an appropriate treatment plan and to assist guide drug administration.

Medical products and services using AI technology, such as medical robots, may fall under the category of “medical device”. If a product falls under such category, the Pharmaceuticals and Medical Devices Act requires the technology to ensure strict safety.

2. What types of artificial intelligence digital health technology can be used and how do they work in practice?

AI is used in programs that process and process data from medical devices to create indicators, images and graphs for diagnosis and treatment.

3. Can artificial intelligence digital health diagnostic services provide medical advice?

The Medical Practitioners Law prohibits medical treatment by unlicensed persons from providing services and permit only doctors to do so, so there are certain restrictions on the use of AI for diagnostic services.

On the other hand, it is possible for doctors to refer to the information provided by AI when performing diagnostic and therapeutic activities. Under current law, AI can provide a decision in a diagnostic treatment as long as the physician makes a final decision about the diagnostic treatment.

Singapore

Regulatory Overview

1. What is the main legislation for digital health technology in your jurisdiction?

There is currently no specific legislation governing digital health technology in Singapore. Health and medical products are generally governed by the Health Products Act (Cap. 122D, 2008 Rev Ed) and its subsidiary legislation, including Health Products (Medical Devices) Regulations 2010, Health Products (Clinical Trials) Regulations 2016, and Health Products (Therapeutic Products as Clinical Research Materials) Regulations 2016.

In recent years, digital health technologies such as telehealth has emerged. Telehealth refers to the use of infocomm technology in providing healthcare services over physically separate environments. Currently, the regulatory regime for telehealth comprises an accretion of various codes and guidelines issued by regulatory bodies, including the National Telemedicine Guidelines ("**NTG**") issued by the Ministry of Health in 2015 setting out best practices, the 2016 Ethical Code and Ethical Guidelines ("**ECEG**") and Handbook on Medical Ethics ("**Handbook**") issued by the Singapore Medical Council, and the Regulatory Guideline For Telehealth Products last updated by the Health Sciences Authority in April 2019.

2. What are the main regulatory bodies for digital health in your jurisdiction and what is their corresponding regulatory scope?

At present, the main regulatory bodies in Singapore for digital health, are the Ministry of Health ("**MOH**"), Singapore Medical Council ("**SMC**") and the Health Sciences Authority ("**HSA**").

The MOH, as a ministry of the Government of Singapore, oversees and manages the healthcare system in Singapore, and is responsible for providing information, raising health awareness and education, ensuring the accessibility of health services, and monitoring and regulating the quality of health services provided to citizens and visitors in Singapore including efforts in developing digital health technology.

The SMC is a statutory board under the MOH, and is responsible for maintaining the Register of Medical Practitioners in Singapore, administering compulsory continuing medical education (CME) programme as well as governing and regulating the professional conduct and ethics of registered medical practitioners.

The HSA is also statutory board under the MOH, and is responsible for regulating health products, managing the national blood bank, and promoting the development of health sciences.

3. Are there specific rules relating to digital health and compliance/dealing with HCPs in your jurisdiction?

Yes, doctors providing telemedicine services in Singapore are required to comply with the ECEG. Among other things under the ECEG, doctors offering telemedicine must endeavour to provide the same quality and standard of care as in-person medical care, or state the limitations of their opinions. Failure to meet the standards required under the ECEG may lead to disciplinary proceedings by the Singapore Medical Council. The Handbook supplements the ECEG, providing the rationale behind the ethical standards in the ECEG and explaining how doctors can achieve such standards.

Apart from this, the Regulatory Guidelines for Telehealth Products ("RGTP") issued by HSA provides clarity on the types of telehealth products regulated as medical devices, and the risk classification of such telehealth medical devices. Under the RGTP, the classification of a telehealth product hinges on the intended use of the device by the product owner.

4. Are there any current government initiatives promoting digital health technology?

In Singapore, the Smart-Health Assist ("**SHA**") programme was conceived in 2015 as part of the Government's broader Infocomm Media 2025 Masterplan. The SHA programme explores the use of technology to support new models of healthcare, in both home as well as community settings. One key area of focus is Telehealth, which is the long-distance delivery of clinical care through the means of electronic communications.

Another such initiative is the Licensing Experimentation and Adaptation Programme ("**LEAP**") launched by MOH in April 2018. LEAP is a regulatory sandbox initiative to support the development of new and innovative telemedicine healthcare models in a controlled and safe environment. Various telemedicine providers have joined the LEAP sandbox, allowing them to offer services to patients in Singapore while staying within specified patient safety and welfare parameters.

5. Please provide a brief regulatory regime for digital health in your jurisdiction

While there is no overarching regulatory regime for digital health, the regulation of telehealth comprises an accretion of various codes and guidelines issued by regulatory bodies, including the National Telemedicine Guidelines ("NTG") issued by the Ministry of Health ("MOH") in 2015, the Ethical Code and Ethical Guidelines ("ECEG") and Handbook on Medical Ethics ("Handbook") issued by the Singapore Medical Council ("SMC") in 2017, and the Telehealth Product Guidelines ("TP Guidelines") issued by the Health Sciences Authority ("HSA") in 2017.

6. What are the regulations governing the transfer of technology, both domestically and cross-border?

The Strategic Goods (Control) Act (SGCA) regulates the export, transhipment, transit, intangible transfer of technology and brokering of strategic goods and strategic goods technology. The Act regulates military as well as dual-use goods and technology, and prescribes a "catch-all" provision where all goods or technology intended or likely to be used for weapons of mass destruction purposes will be subject to controls.

Under the laws in Singapore, intellectual property may be assigned or transferred in the same way as personal or movable property. The Patents Act (Cap. 221, 2005 Rev. Ed.) additionally imposes restrictions on patent applications abroad by Singapore residents. Section 34 of the Patents Act prescribes that a person resident in Singapore shall not file or cause to be filed outside Singapore a patent application without written authority granted by the Registrar unless a patent application for the same invention has been filed in Singapore not less than 2 months before the application outside Singapore.

7. What are the licencing requirements for personal and clinical use?

There is currently no specific licencing regime for the personal and clinical use of digital health technology. Telehealth products may need to be registered with HSA depending on its classification as a medical device.

Data Protection Overview

1. Can any types of data be shared with companies for the development of digital health technologies? Which kinds of data are permitted or prohibited?

No. The Personal Data Protection Act 2012 (Act 26 of 2012) ("**PDPA**") governs the collection, use and disclosure of individuals' personal data by organisations in a manner that recognises both the right of individuals to protect their personal data and the need of organisations to collect, use and disclose personal data for purposes that a reasonable person would consider appropriate in the circumstances. The healthcare and medical data of an individual is highly sensitive and is likely to constitute personal data under the PDPA insofar as the individual may be identified from that data, or from that data and other information that a company has access to.

To the extent that personal data of individuals are contained in data shared with companies for the development of digital health technologies, organisations must ensure that they comply with their obligations under the PDPA when collecting, using and disclosing the personal data of individuals. Generally, consent is a valid basis for collecting personal data, and an organisation may collect, use and/or disclose an individual's personal data if the individual validly gives, or is deemed to have validly given, his consent to the collection, use or disclosure, as the case may be, and subject to such standard of consent required under the PDPA.

Nonetheless, organisations are generally **not** allowed to collect, use or disclose National IDs (this includes NRICs, Birth Certificate numbers, Foreign Identification Numbers and Work Permit numbers) in Singapore, regardless of whether an organisation has obtained express consent from the relevant individuals to collect, use and/or disclose such National IDs relating to them. This general prohibition under the Advisory Guidelines on the Personal Data Protection Act for NRIC and Other National Identification Numbers which came into effect on 1 September 2019 is subject to two exceptions.

As a way to reduce obligations under the PDPA, organisations should aggregate and anonymise the collected data at the earliest opportunity, and where necessary, take steps to assess the risks of re-identification and the robustness of the anonymisation. Anonymisation refers to the process of converting personal data into data that cannot be used to identify any particular individual. Data which has been anonymised is not personal data and would not be governed by the PDPA.

2. Are there any regulations or restrictions on use of data collecting or sharing digital health technologies by or in collaboration with medical institutions or doctors?

To the extent that such use of data collecting or sharing contains the personal data of individuals, the obligations under the PDPA must be met.

The Singapore Personal Data Protection Commission ("**PDPC**") has released an Advisory Guidelines for the Healthcare Sector which provides guidance to healthcare providers on complying with their obligations under the PDPA in a variety of scenarios where personal data of individuals may be collected, used or disclosed.

It should however be noted that the obligations under the PDPA do not apply to any public agency in Singapore or an organisation in the course of acting on behalf of a public agency in relation to the collection, use or disclosure of the personal data.

Intellectual Property Overview

1. What types of digital health technology can be patented and describe the general patent registration, if any, structure of your jurisdiction

Whether a type of digital health technology is patentable is assessed in the same way as all other subject matters. A patentable invention must satisfy the following conditions:

- The invention is new;
- It involves an inventive step; and
- It is capable of industrial application.

It should be noted that under Section 16(2) of the Patents Act (Cap. 221, 2005 Rev. Ed.), methods of treatment (whether by surgery or therapy or of diagnosis) practised on the human or animal body are expressly stated as not capable of industrial application and as such are not patentable.

Patent registration structure in Singapore

Once a patent application is filed, it will undergo preliminary examination by the Intellectual Property Office of Singapore to ensure that filing and formality requirements are met. Details of the patent application will be published in the Patents Journal as soon as possible after 18 months. At this stage, the application is required to undergo search and examination whereby patent examiners will search for similar earlier inventions in the same field as the patent application (known as "prior art"). The examiner will examine and compare the prior art to the patent application and determine if the prior art destroys the novelty of the application. The patent examiner will also determine if the other patentability criteria (such as inventive step and industrial application) are met. If a positive examination report is issued and there are no unresolved objections, a Notice of Eligibility to Proceed to Grant will be issued and the applicant can file a request for the issuance of the Certificate of Grant, following which the Certificate of Grant will be issued to the applicant.

2. What types of digital health technology can be copyrighted and describe the general copyright registration, if any, structure of your jurisdiction

There are no restrictions on the copyrighting of digital health technology, so long as it falls under subject matter which copyright can subsist in. Digital health technology may be protected as literary works, which includes compilation and computer programs. Copyright automatically subsists in original works and there is no copyright registration system in Singapore.

3. What are the main intellectual property issues arising in digital health technology development?

The main intellectual property issues arising in digital health technology development include the protection of industrial design and patent rights, as well as the protection of know-how and confidential information from theft.

The Future of Digital Health

1. Have there been any recent updates to the regulatory regime governing digital health in your jurisdiction?

Please refer to our answers to Q3 of Regulatory Overview above.

2. Are we likely to see any reforms or new regulations relating to digital health?

Yes, reforms and new regulations relating to digital health are underway and are expected to take effect in Singapore in the near future. Notably, the Healthcare Services Bill ("HCS Bill") was read in Parliament for the first time on 4 November 2019, and will replace the existing Private Hospitals and Medical Clinics Act ("**PHMCA**"). The HCS Bill was introduced by MOH to address key changes in the healthcare industry and accommodate rapid developments in digital health technology, such as the growing range of medical services available in the market and the increasing use of digital health and related platforms in the provision of such services.

Under the HCS Bill, healthcare providers will be licensed based on the type of services they provide, and a notable addition is the inclusion of non-premised based services such as telemedicine. This is a significant change from the current PHMCA where providers are licensed based on physical premises, such as hospitals, laboratories, general practitioners' clinic etc.

Application

Medical Devices

1. What types of digital health technologies need to be registered as medical devices?

In Singapore, medical devices are governed by the Health Products (Medical Devices) Regulations 2010 (the "**Regulations**") and are classified into Classes A, B, C or D in ascending order of the health risk posed to an end-user. The intended use of a digital health technology product (whether hardware devices, software and mobile applications) will determine whether it will be regulated as a medical device. If such a product is intended by the Product owner to be used for investigation, detection, diagnosis, monitoring, treatment or management of any medical condition, disease, anatomy or physiological process, it will be considered as a medical device and is subject to Health and Sciences Authority ("**HSA**") regulatory control.

Class A medical devices include simple, low risk tools such as wheelchairs and tongue depressors while Class D medical devices include complex, high risk objects such as heart valves and implantable defibrillators. While Class A medical devices are exempted from product registration, medical devices classified into Classes B, C and D must be registered with the HSA in view of their higher risks.

2. What types of digital health medical devices can be used and how do they work in practice?

At present, there is no exhaustive list of the types of digital health medical devices that can be used. Digital health medical devices may be used as long as they comply with the Regulations and requirements set out by HSA.

Digital health products that are intended for use as a wellness device (e.g. for fitness tracking), but are able to perform such medical function/purpose (e.g. monitoring heart rate), are not medical devices. Product owners must however include a clarification statement on the product label to avoid misleading users regarding intended use.

3. What are the main legal issues surrounding digital health medical devices?

The main legal issues surrounding digital health medical devices concern the health and safety of the public, and must meet quality, safety, and performance requirements prescribed by the HSA.

4. What kinds of marketing activities are permitted or prohibited?

Advertisements of medical devices have to comply with the requirements set out in Part V of the Health Products Act (Cap. 122D, 2008 Rev Ed) and the further requirements in Part V of the Regulations. Generally, false and misleading advertisements of medical devices are prohibited. Moreover, a registered medical device must not be advertised in such a way as to represent the registered medical device as being usable for any purpose other than that for which it has been registered.

In respect of medical devices intended for direct delivery to the general public or for direct use by the general public, advertisements of such medical devices must not contain any statement regarding the intended use and efficacy of the medical device unless such statement has been verified by objective evidence, and, where the medical device is a registered medical device, the objective evidence must be furnished to the Health Sciences Authority at the time the application was made to register the medical device.

Advertisements of medical devices that contain any statement, assertion, certification, award or feature of uniqueness or prominence differentiating the medical device from competing devices, the statement assertion, certification, award or feature of uniqueness must be substantiated by facts or evidence.

Moreover, "Professional use only" medical devices (i.e. medical devices that are to be used on an individual solely by, or under the supervision of, a qualified practitioner) cannot be advertised unless the advertisement is distributed only to, or is contained in a publication intended for mainly among qualified practitioners.

Moreover, advertisements relating to a medical device shall not expressly or implicitly claim, indicate or suggest that the medical device will prevent, alleviate or cure certain diseases or conditions as specified in the Regulations, including blindness, cancer, and diabetes, unless the advertisement is distributed only to, or is contained in a publication intended for circulation among qualified practitioners, registered pharmacists, registered nurses and midwives, and persons undergoing training to be considered as these following classes of persons.

m-Health

1. What types of m-Health can be used and how do they work in practice?

At present, there is no exhaustive list of the types of m-Health that can be used. Where applicable, m-Health products must comply with regulations and guidelines issued by regulatory bodies. For example, doctors providing advice through apps or mobile health devices must comply with the Ethical Code and Ethical Guidelines ("**ECEG**") and Handbook on Medical Ethics ("**Handbook**") issued by the Singapore Medical Council. Moreover, mobile applications used in the delivery of telehealth services may need to be registered with HSA if they are classified as medical devices.

2. What are the main legal issues surrounding m-Health?

The main legal issues surrounding m-Health relate to the protection of personal data as well as the health and safety of the public.

3. Are there any regulations or restrictions on use of m-Health by or in collaboration with medical institutions or doctors?

Yes. For example, doctors providing advice through apps or mobile health devices must comply with the Ethical Code and Ethical Guidelines ("**ECEG**") and Handbook on Medical Ethics ("**Handbook**") issued by

the Singapore Medical Council. To the extent that such m-Health products are classified as medical devices, they must comply with the Regulations and may need to be registered with the HSA.

4. What kinds of marketing activities are permitted or prohibited?

This may depend on whether the m-Health product is classified as a medical device. Medical devices are subject to advertising and labelling requirements under the Regulations. Moreover, the SMC in regulating the conduct and ethics of doctors in Singapore, has also set down guidelines in the ECEG for the social media conduct of doctors.

Artificial Intelligence

1. What are the main legal issues surrounding artificial intelligence and digital health?

The main legal issues surrounding artificial intelligence and digital health relate to the protection of personal data as well as the health and safety of the public.

2. What types of artificial intelligence digital health technology can be used and how do they work in practice?

There is no exhaustive list of artificial intelligence digital health technology that can be used. To the extent that artificial intelligence digital health technology is incorporated in medical devices, these medical devices must comply with the Regulations and may need to be registered with the HSA.

3. Can artificial intelligence digital health diagnostic services provide medical advice?

It is unlikely that artificial intelligence digital health diagnostic services will be allowed to provide medical advice independently. Such devices incorporating artificial intelligence digital health diagnostic services will be classified as medical devices requiring registration with the HSA, possibly as “professional use only” medical devices. Such “professional use only” medical devices may only be used on an individual solely by, or under the supervision of, a registered medical practitioner under the Medical Registration Act (Cap. 174) or a registered dentist under the Dental Registration Act (Cap. 76). Thus, it is likely that medical advice provided by such artificial intelligence digital health diagnostic services may only be used by or under the supervision of a qualified practitioner.

South Korea

Regulatory Overview

1. What is the main legislation for digital health technology in your jurisdiction?

In Korea, there are no separate laws regulating digital health. Instead, existing laws including the Medical Services Act, Pharmaceutical Affairs Act, Medical Devices Act, and Personal Data Protection Act (for cases involving data) are applied to digital health.

2. What are the main regulatory bodies for digital health in your jurisdiction and what is their corresponding regulatory scope?

As mentioned previously, because there are no separate laws regulating digital health, the Ministry responsible for relevant existing laws becomes the pertinent regulatory body. As a result, regarding the Medical Services Act, the Ministry of Health and Welfare (MOHW) acts as the regulatory body. Likewise, the Ministry of Food and Drug Safety (MFDS) acts as the regulatory body regarding the Medical Devices Act and the Pharmaceutical Affairs Act. Additionally, for cases involving data and the Personal Data Protection Act, the Ministry of Public Administration and Security acts as the regulatory body.

3. Are there specific rules relating to digital health and compliance/dealing with HCPs in your jurisdiction?

As mentioned in the answer to No. 1, no separate law has been enacted to specifically regulate the digital health sector. Thus, existing laws including the Medical Services Act, the Pharmaceutical Affairs Act, the Medical Devices Act, and the Personal Data Protection Act (for cases involving data) are applied. However, for some specific cases within the field of digital health, relevant guidelines may have been published (e.g., licensing and auditing guidelines for medical devices with virtual and augmented reality (VR, AR) technology, published by the Ministry of Food and Drug Safety).

4. Are there any current government initiatives promoting digital health technology?

The ‘Healthcare Special Committee’ was established in December 2017 and was placed under the Presidential Committee on the Fourth Industrial Revolution. The Healthcare Special Committee is comprised of members from the Ministry of Health and Welfare, the Ministry of Science, Technology,

Information and Communication, the Ministry of Trade, Industry and Energy, and the Ministry of Food and Drug Safety. Additionally, the Healthcare Special Committee has selected six key projects, some of which are the development of new artificial intelligence-based drugs and the development of smart fusion medical equipment.

5. Please provide a brief regulatory regime for digital health in your jurisdiction

See answers to No. 1 and No. 2 above.

6. What are the regulations governing the transfer of technology, both domestically and cross-border?

There are no regulations specific to restricting the transfer of digital health technology. In order to promote technology transfers in general, the Technology Transfer and Commercialization Promotion Act was enacted. The aforementioned law mainly stipulates matters for promoting technology transfers by public institutions. Korean law generally protects technology through patent and utility rights. The Patent Act and the Utility Model Act stipulate relevant matters, including the registration of each right.

7. What are the licencing requirements for personal and clinical use?

Licensing requirements must be met in accordance with different laws, depending on the use of the digital health technology. If the digital health technology is used as a medical device, the Medical Devices Act applies, if used for telemedicine, the Medical Services Act applies, and if used as a drug, the Pharmaceutical Affairs Act applies. For some cases, licensing requirements may need to be met under multiple laws.

Data Protection Overview

1. Can any types of data be shared with companies for the development of digital health technologies? Which kinds of data are permitted or prohibited?

Digital health cases involving personal information sharing is regulated by the Personal Data Protection Act. More specifically, medical information falls under the 'sensitive information' category that is more strictly regulated in comparison to other categories of personal information under the Personal Data Protection Act. Furthermore, a patient's medical information is even more strictly protected under the Medical Services Act and so in order for a medical institution to use such information for other purposes than the patient's treatment or to share such information to a third party, the patient's explicit consent must be obtained and specific procedures and requirements in using or sharing such information must be followed. Therefore, in order to collect, use, and provide such information, the requirements and procedures under the Act must be complied with thoroughly. Although the government has published 'Guidelines for De-identification of Personal Information,' there are limitations in that specific criteria for the utilization of medical data that are not provided in the guidelines.

2. Are there any regulations or restrictions on use of data collecting or sharing digital health technologies by or in collaboration with medical institutions or doctors?

Personal information including medical information is regulated under the Personal Data Protection Act and other privacy laws and statutes related to information protection. In addition, as mentioned in the answer to No. 1 above, the Medical Services Act also applies. Furthermore, the Bioethics and Safety Act applies to genetic information.

Intellectual Property Overview

1. What types of digital health technology can be patented and describe the general patent registration, if any, structure of your jurisdiction

Digital health technology can be registered as a patent in the form of a thing, process, or process of manufacturing a thing. The request for review must be made within three years of the initial patent application. Once the patent requirements, which include a showing of novelty and inventiveness to the examiner, are met, the technology can be patented. Lastly, once the registration fee is paid, the patent is registered.

2. What types of digital health technology can be copyrighted and describe the general copyright registration, if any, structure of your jurisdiction

Computer programs, images, designs, etc. can be protected under copyright laws. Copyright occurs from the time the work is created and registration is not required to create a copyright. However, registration puts on record a verifiable account of the date and content of a copyright which can be used in the event of an adverse claim. Copyright registration is handled by the Korean Copyright Commission under the Ministry of Culture, Sports and Tourism and is registered without an examination process.

3. What are the main intellectual property issues arising in digital health technology development?

We have not seen any recurring or noteworthy IP issues with regard to digital health technology recently. A noteworthy observation, however, is that we are noticing an increasing amount of patent applications by Korean companies and individuals being made in China.

The Future of Digital Health

1. Have there been any recent updates to the regulatory regime governing digital health in your jurisdiction?

The National Assembly recently passed the 'In Vitro Diagnostic Devices Act, ' which is scheduled to take effect on May 1, 2020. In the case of in vitro diagnostic medical devices, it is believed that the technology combined with the genetic analysis technology could be used in the field of personalized medical care. The In Vitro Diagnostic Devices Act regulates the manufacturing, importing, handling and managing vitro diagnostic medical devices to be used not for diagnosis but for treatment, reflecting the characteristics of it. In addition, the National Assembly also passed the 'Promotion of Medical Devices Industry and Innovative Medical Devices Support Act, ' which recognizes special cases in licensing procedures by designating high-tech medical devices as 'innovative medical devices.' The Promotion of Medical Devices Industry and Innovative Medical Devices Support Act is also scheduled to take effect on May 1, 2020.

2. Are we likely to see any reforms or new regulations relating to digital health?

The "Act on Advanced Rehabilitation Medicine and Advanced Bio-Drugs" is currently pending, which regulates matters such as advanced regenerative medicine technology that can be applied to advanced biotechnology.

Application

Medical Devices

1. What types of digital health technologies need to be registered as medical devices?

Whether a device is categorized as a medical device or not depends on whether the device fits the definition of 'Medical Device', as defined in the Medical Devices Act. In principle, digital health technology that is used for the purpose of diagnosing, treating or preventing diseases as specified in Article 2 Paragraph 1 of the Medical Devices Act, can be regulated as a medical device.

2. What types of digital health medical devices can be used and how do they work in practice?

As mentioned above, a device that fall under the definition of a 'Medical Device' under Paragraph 1 of the Medical Devices Act, can be regulated as a medical device. For instance, a digital health wearable device that serves the purpose of disease diagnosis or prevention, would satisfy the definition of a 'Medical Device' and therefore be regulated by the Medical Devices Act.

3. What are the main legal issues surrounding digital health medical devices?

In recent years, there have been an increasing number of issues with regards to whether a device should be considered a medical device or a simple personal health care product (wellness). In relation to this, the Ministry of Food and Drug Safety has published guidelines for approval and inspection of medical devices with virtual or augmented reality (VR, AR) technology. In addition, the sentiment for allowing telemedicine using digital health medical devices is getting stronger, but legislation for new laws allowing the practice of such telemedicine has been delayed due to insurance reimbursement issues and strong opposition from small clinics.

4. What kinds of marketing activities are permitted or prohibited?

Regarding marketing activities, advertising regulations within the existing Medical Services Act and the Medical Devices Act are applied accordingly. For example, the Medical Devices Act prohibits an advertisement that includes inaccurate, misleading or exaggerated performance and/or efficacy information in comparison to the performance and/or efficacy information for which a license for the medical devise was obtained. Therefore, whether certain marketing activity would be allowed requires a specific case-by-case determination.

m-Health

1. What types of m-Health can be used and how do they work in practice?

Under the Medical Services Act, medical practice by a non-medical practitioner is prohibited. Telemedicine is only allowed between medical personnels, and those who intend to perform or receive telemedicine must have certain facilities and equipment. Due to these restrictions, m-Health is not widely used, and it is utilized mainly in the form of Apps. The scope of such usage is limited to non-medical activities – so-called wellness activities – such as diet management, sleeping habits, exercise management, and blood sugar management. However, since 2016, the Ministry of Health and Welfare has been piloting a health care business to monitor patients' health abnormalities and to give health counselling by doctors.

2. What are the main legal issues surrounding m-Health?

Under the recently enacted 'Special Act on Promotion and Convergence of Information and Communications Technology, Etc.' and the 'Industrial Convergence Promotion Act,' those who intend to do business by utilizing new information and communication convergence technologies and services can apply for a temporary authorization. Additionally, legislative attempts are being made to ease regulations on m-Health, such as pursuing new legislation that would allow the Minister of Trade, Industry and Energy to give authorization for those who intend to engage in a business of verifying and testing new industrial convergence products and services. However, in order for digital health medical devices or m-Health to be more actively utilized, the Medical Services Act and other related regulations that currently prohibit telemedicine in principle must first be amended.

3. Are there any regulations or restrictions on use of m-Health by or in collaboration with medical institutions or doctors?

See our answer to No. 1 above.

4. What kinds of marketing activities are permitted or prohibited?

See our answer to No. 4 of the Medical Devices Section above.

Artificial Intelligence

1. What are the main legal issues surrounding artificial intelligence and digital health?

Similar legal issues as those relating to m-Health are being discussed, but the main issues would be the protection of patient data and where to place liability in the event of malpractice. See our answer to No. 1 of the m-Health Section above.

2. What types of artificial intelligence digital health technology can be used and how do they work in practice?

IBM Watson has been implemented in at least nine hospitals to improve diagnostic accuracy. In addition, there are hospitals that utilize AI and big data to provide patients with imaging diagnostics of bone, brain, and lungs.

3. Can artificial intelligence digital health diagnostic services provide medical advice?

Under the Medical Services Act, a medical act is an act which may cause harm to a person's life, body or the public health unless performed by a medical practitioner. Therefore, the practice of medicine by a non-medical practitioner is strictly prohibited. Diagnosis is a medical act under Korean law. Consequently, AI Diagnostic services may play a role in assisting a medical practitioner, but the final diagnosis must be performed by a medical practitioner (as in the case of China).

Taiwan

Regulatory Overview

1. What is the main legislation for digital health technology in your jurisdiction?

In Taiwan, currently there is no law specifically enacted for the regulation of digital health technology. The main legislations covering the regulation of digital health technology in Taiwan may include:

- Pharmaceutical Affairs Act, which was promulgated on 17 August 1970;
- Regulations for Governing the Management of Medical Device, which was established in accordance with Paragraph 2, Article 13 of the Pharmaceutical Affairs Act and promulgated on 30 December 2004 (the "**Management Regulations**");
- Regulation for Registration of Medical Devices, which was established in accordance with Paragraph 3, Article 40 of the Pharmaceutical Affairs Act and promulgated on 30 December 2004 (the "**Registration Regulations**");
- Medical Care Act, which was promulgated on 24 November 1986;
- Physicians Act, which was promulgated on 22 September 1943;
- Rules of Medical Diagnosis and Treatment by Telecommunications, which was established in accordance with Paragraph 2, Article 11 of the Physicians Act and promulgated on 11 May 2018 (the "**Telecommunications Rules**");
- Personal Information Protection Act, which was promulgated on 11 August 1995.

2. What are the main regulatory bodies for digital health in your jurisdiction and what is their corresponding regulatory scope?

Under the Pharmaceutical Affairs Act, Management Regulations, Registration Regulations, Medical Care Act, Physicians Act and the Telecommunications Rules, the administrative regulatory bodies are Ministry of Health and Welfare (at the central government level), municipal governments (at the municipal level) and the county/city governments (at the county/city level). The administrative regulatory bodies have the authority to conduct investigation and interdiction, revoke medicament permit license, limit the scope of practice, suspend or cancel the practice license, or impose administrative fines on any violating person or companies.

Under the Personal Information Protection Act, the administrative regulatory bodies are government authority in charge of the subject industry, municipality and the county or city government. For industries such as healthcare providers and manufacturers of drugs or medical devices, the government authority in charge is Ministry of Health and Welfare. The administrative regulatory bodies may perform inspections, examinations and impose administrative fines on any non-government agency violating the Personal Information Protection Act.

Furthermore, certain criminal liabilities may be triggered under the Pharmaceutical Affairs Act, Medical Care Act, Physicians Act and Personal Information Protection Act. Under such circumstances, the judiciary regulatory body would be the prosecutor and criminal court that have the authorities to press a charge and sentence any violating person imprisonment, custody or criminal fines.

3. Are there specific rules relating to digital health and compliance/dealing with HCPs in your jurisdiction?

According to Article 11 of the Physicians Act, a physician may not treat, issue prescription or certificate of diagnosis to patient not diagnosed by the physician himself or herself. Nevertheless, in response to medical needs in mountain areas, outlying islands, remote areas, or under special or urgent circumstances, the physician appointed by the competent authority may exceptionally use telecommunications methods to inquire about illness, set diagnosis and issue prescriptions. The Telecommunications Rules were therefore established to regulate the related treatment items, appointment of physician and the telecommunications methods under the forgoing circumstances.

4. Are there any current government initiatives promoting digital health technology?

Industrial Innovation 5+2 is a development plan proposed by Taiwan President Tsai Ing-Wen in 2015, which focused on seven main aspects: “Artificial Intelligence”, “Asia Silicon Valley”, “Green Tech”, “BioMed”, “Defence Industries”, “New Agriculture” and “Circular Economy” to promote the industrial growth for Taiwan’s next generation. For BioMed, the Bio Taiwan Committee (the “BTC”) held by the Executive Yuan in 2018 has introduced the concept of digital and regenerative health care and announced a development plan which combines industrial innovation and artificial intelligence to lead Taiwan BioMed industry into a field of digital, precision and big data. In 2018, BTC also proposed three development priorities for BioMed industry: the establishment of friendly legal environment, invitation of investments and M&A, and the cultivation of professionals. Given such, by the end of 2018, the revenue of BioMed industry has come to NTD 514.1 billion and there are over 120 BioMed companies listed in Taiwan. The government is also working on the reformation of the legal environment of BioMed industry and many key bills are under review of the Legislative Yuan, the national council of Taiwan.

5. Please provide a brief regulatory regime for digital health in your jurisdiction

The Pharmaceutical Affairs Act, Management Regulations and Registration Regulations govern the registration and market approval of medical devices. According to Article 40 of the Pharmaceutical Affairs Act, no manufacturing and importation of medical devices shall be allowed unless an application being filed with the central competent authority for registration and market approval and a medical device permit license is approved and issued by the central competent authority. Any person who manufactures or imports medical devices without proceeding with the requirements above shall be punished with imprisonment and may, in addition thereto, be imposed with a fine. Under the Management Regulations and Registration Regulations, medical devices are classified into three classes according to their level of risks and shall follow their manufacturing procedures and requirements respectively.

The Medical Care Act regulates the development and operation of medical care industry, including the establishment of medical care institutions, operation of medical practices, advertisement for medical care and the distribution of medical manpower and facilities. On the other hand, the Physicians Act governs the qualification and obligation of respective physicians, which may include the academic requirements for physician’s qualification exam, the procedure to set up medical practice and the code of conducts physicians shall follow when implementing medical practices. Any violation of the proceeding regulations shall be subject to criminal or administrative liabilities in accordance with the behavioural patterns and seriousness of the conducts.

Personal Information Protection Act governs the collection, processing and use of personal information so as to prevent harm on personality rights, and to facilitate the proper use of personal information. According to Article 2 of the Personal Information Protection Act, personal information includes the name, date of birth, I.D. Card number, passport number, characteristics, fingerprints, marital status, family, education, occupation, medical record, medical treatment, genetic information, sexual life, health examination, criminal record, contact information, financial conditions, social activities and other information which may be used to identify a natural person, both directly and indirectly. The collection, processing and use of any personal information must comply with the regulations under Personal Information Protection Act and any violation shall be subject to criminal or administrative liabilities in accordance with the behavioural patterns and seriousness of the conducts.

6. What are the regulations governing the transfer of technology, both domestically and cross-border?

There are no regulations or rules specifically governing the transfer of technology by and between private entities. Nevertheless, for scientific and technological research and development projects which are subsidized, commissioned, or funded by the government, or are conducted under scientific and technological research and development budgets prepared by public research institutes/organizations in accordance with law, the transfer of technology of which shall comply with the regulations under the Fundamental Science and Technology Act and Government Scientific and Technological Research and Development Results Ownership and Utilization Regulation (the "**Utilization Regulation**"). Under such regulations, although the research and development results from such project may be conferred, in whole or in part, to the executing research and development units for ownership or licensing for use, the transfer of such result, unless otherwise provided by law or contract, shall be approved by the funding agency. Furthermore, the transfer or licensing aforementioned must comply with the following requirements unless there are other manners that conform to the goals and intents of the Fundamental Science and Technology Act: (i) it must be done in a fair, open, and compensated manner; (ii) it must target public schools, public research agencies/organizations, government-operated enterprises, and juristic persons or organizations.

There are no regulations or rules specifically governing the transfer of technology by and between natural or juristic person of Taiwan and offshore entities. However, if the transfer of technology were to be done by and between natural or juristic person of Taiwan and People's Republic of China, including Hong Kong and Macao (the "**PRC**"), a prior permission issued by Investment Board, Ministry of Economic Affairs must be obtained in accordance with Act Governing Relations between the People of the Taiwan Area and the Mainland Area and Laws and Regulations Regarding Hong Kong & Macao Affairs.

7. What are the licencing requirements for personal and clinical use?

The licencing requirements for medical devices under Registration Regulations are categorized based on whether the medical devices are manufactured or imported.

According to Article 3 of the Registration Regulations, the applicant shall pay the application fee and submit completed application forms with all required documents to the central competent authority for approval of a valid medical device permit license. According to Article 5 of the Registration Regulations, the application of medical device permit license shall be disapproved if: (i) fees have not been paid, or attached materials are incomplete, or are inconsistent with the contents of the application; (ii) the applicant has failed to collect the permit license or to submit samples for testing by the designated deadline, or the samples submitted for testing do not meet requirements; (iii) the applicant has failed to publish, revise, or change the packaging, labelling, or instruction leaflet of the medical devices; (iv) the medical device under application is considered to be hazardous to human health, or raises safety, quality, or efficacy concerns; (v) other situations in nonconformity with this Regulation, other related laws or regulations, or proclamations of the central competent authority.

Data Protection Overview

1. Can any types of data be shared with companies for the development of digital health technologies? Which kinds of data are permitted or prohibited?

According to Article 6 of the Personal Information Protection Act, personal information of medical records, medical treatment, genetic information, sexual life, health examination and criminal records should not be collected, processed or used unless: (i) when in accordance with law; (ii) when it is necessary for a government agency to perform its legal duties or for a non-government agency to fulfil its legal obligation, and proper security measures are adopted prior or subsequent to such collection, processing or use; (iii) when the owner of the personal information has made such information public by himself, or when the information concerned has been publicized legally; (iv) where it is necessary to perform statistical or other academic research, a government agency or an academic research institution collects, processes, or uses personal information for the purpose of medical treatment, public health, or crime prevention. The information may not lead to the identification of a specific person after its processing by the provider, or from the disclosure by the collector; (v) where it is necessary to assist a government agency in performing its legal duties or a non-government agency in fulfilling its legal obligations, and proper security measures are adopted prior or subsequent to such collection, processing, or use; (vi) where the owner of the personal information has consented in writing; unless such consent exceeds the necessary scope of the specific purpose; the collection, processing or use merely with the consent of the owner of the personal information is prohibited by other statutes; or such consent is against the owner's will.

2. Are there any regulations or restrictions on use of data collecting or sharing digital health technologies by or in collaboration with medical institutions or doctors?

The government agency and non-government agency shall both comply with the regulations under Personal Information Protection Act. Medical institutions, doctors and the digital health technology developers all have the obligation to comply with the requirements stated in the preceding paragraph in collecting or sharing any digital health data.

Furthermore, according to Articles 22 and 23 of the Physicians Act, when receiving an inquiry or being asked for an appraisal by the concerned authorities, a physician may not submit a false explanation or report. Except for the previous article, a physician may not without reason reveal information about a patient's condition or health information that he or she is aware of or in possession of as a result of his or her practice. As stated in Article 316 of the Criminal Code, a medical doctor, pharmacist, druggist, midwife, mental therapist, clergyman, lawyer, defender, notary public, accountant, one of their business assistants, or one who has previously engaged in such occupation who without reason discloses the secrets of another which he knows or possesses because of his occupation shall be sentenced to imprisonment for not more than 1 year, short-term imprisonment, or a fine of not more than NTD 50,000. According to Article 72 of the Medical Care Act, medical care institutions and their staff shall not without reason disclose any information regarding a patient's illnesses or health that are acquired by virtue of practice. Any violation of the previous article shall subject to a fine from NTD 50,000 to NTD 250,000.

Intellectual Property Overview

1. What types of digital health technology can be patented and describe the general patent registration, if any, structure of your jurisdiction

According to Article 22 of the Patent Act, an “invention” which is industrially applicable may be granted a patent upon application in accordance with the Act, except that the invention is without novelty or non-obviousness. However, according to Article 24 of the Patent Act, an invention patent shall not be granted in respect of any of the following: … 2. diagnostic, therapeutic and surgical methods for the treatment of humans or animals. This restriction could relate to digital health technology. Taiwan Intellectual Property Office (TIPO) addresses the criteria of this subparagraph in Chapter 13, Article 1 of the Patent Examination Guideline. It reveals three necessary elements: 1) the object shall be living humans or animals; 2) it should be a diagnostic method for disease; and 3) the direct purpose should be for obtaining a diagnosis result of disease. As result, if there is any element missing, this subparagraph will not be trigged and digital health technology may be patented.

In addition, there are two other patent types under the Patent Act, i.e. utility model patent and design patent. According to Article 104 of the Patent Act, "utility model" means the creation of technical ideas relating to the shape or structure of an article or combination of articles, utilizing the laws of nature. And according to Article 121 of the same act, "design" means the creation made in respect of the shape, pattern, colour, or any combination thereof, of an article as a whole or in part by visual appeal. For example, the design of the icon or graphic user interface (GUI) used by certain health technology may be regarded as a design patent.

Regarding the patent registration structure of Taiwan, a patent application shall be filed with TIPO by the owner of the right to apply for a patent who is required to provide an application form, a description, claim(s), an abstract, and the necessary drawing(s). After receiving application documents and determining through examination that the application conforms to stipulated formality requirement and contains no elements that may be deemed unsuitable for lying open, TIPO will lay open the patent application for invention for eighteen (18) months since its filing. During examining the patent application for invention, TIPO may notify the applicant to amend the description, claim(s), or drawings within a specified time period. Upon completion of examination of a patent application for invention, a written decision will be rendered and served on the applicant. If the invention patent applicant dissatisfies with the decision of rejection, he may provide reason(s) to request a re-examination within two (2) months after the date on which the decision of rejection is served.

2. What types of digital health technology can be copyrighted and describe the general copyright registration, if any, structure of your jurisdiction

According to Article 3 of the Copyright Act, the definition of “work” means a creation that is within a literary, scientific, artistic, or other intellectual domain. And according to Article 5 of the Copyright Act, the types of "works" include, but not limited to, oral and literary works, musical works, dramatic and choreographic works, artistic works, photographic works, pictorial and graphical works, audiovisual works, sound recordings, architectural works, and computer programs. As a result, any digital health technology belongs to those types, e.g. a computer program, can be copyrighted.

There is no official copyright registration in Taiwan. According to Article 10 of the Copyright Act, the author of a work shall enjoy copyright upon completion of the work, and no registration is required by the act. The only exception is the plate right, which allows a plate maker, who arranges and prints a literary work or an artistic work that has no economic rights or for which the economic rights have been extinguished, to have the exclusive right to photocopy, print, or use similar methods of reproduction based on the plate. But it should be less relevant with digital health technology.

3. What are the main intellectual property issues arising in digital health technology development?

The development of digital health technology in Taiwan is still at early stage; therefore, we do not see many cases relating to intellectual property dispute of digital health technology. However, it is worthy to note that Taiwan government has strengthened its emphasis and protection of trade secret in recent

years, and therefore, the Trade Secret Act may also serve important functions for the protection of new-developed digital health technology.

The Future of Digital Health

1. Have there been any recent updates to the regulatory regime governing digital health in your jurisdiction?

With respect to the fact that the digital and innovative medical materials have been blooming in recent years and the business model of medical device industries had gradually differed from drugs, it would be difficult for the current Pharmaceutical Affairs Act to satisfy the regulatory need of medical devices. In order to implement the *Industrial Innovation* 5+2 development plan proposed by the ruling party of Taiwan and be in line with international trend and standards of the medical device industries, the Ministry of Health and Welfare planned to isolate the regulations regarding medical devices from the current Pharmaceutical Affairs Act and enacted Medical Device Management Act specifically for the management of medical devices.

Furthermore, many industry participants had reported that the rigorous regulations under the Personal Information Protection Act had formed improper restrictions for the development of digital health. Given such, it is necessary and urgent to establish a specific regulation for medical and health related personal information so as to alleviate the restriction on such information.

2. Are we likely to see any reforms or new regulations relating to digital health?

On December 14 2017, the Executive Yuan, the highest administrative agency in Taiwan, had proposed the draft of Medical Device Management Act (the "**Draft**"). Apart from the current Pharmaceutical Affairs Act, the Draft provided specific regulations on the definition, manufacturing, sales, advertisement, approval of permit license, inspections, examinations and punishment of violation of medical devices. However, the Draft is still under review of the Legislative Yuan, the national parliament of Taiwan and the exact date that the Draft would come into effect remains uncertain.

As for the reformation of medical and health related personal information, although there are many discussions on the alleviation of regulatory burden, the Ministry of Health and Welfare or the Executive Yuan has not proposed any specific draft of acts or amendments toward this issue. Thus, the Personal Information Protection Act is still the effective regulation that governs the collection, processing and usage of the medical and health related personal information.

Application

Medical Devices

1. What types of digital health technologies need to be registered as medical devices?

According to Article 13 of the Pharmaceutical Affairs Act, medical device shall refer to any instruments, machines, apparatus, materials, software, reagent for in vitro use, and other similar or related articles, which is used in diagnosing, curing, alleviating, or directly preventing human diseases, regulating fertility, or which may affect the body structure or functions of human beings, and do not achieve its primary intended function by pharmacological, immunological or metabolic means in or on the human body. If a digital health technology falls into the definitions above, it is deemed and shall be registered as a medical device under the Pharmaceutical Affairs Act and cannot be manufactured or imported without a permit license approved or issued by the central competent authority.

2. What types of digital health medical devices can be used and how do they work in practice?

According to Article 3 of the Management Regulations, in accordance to the function, intended use, instruction for use and working principle, medical devices are classified into the following categories: (i) Clinical Chemistry and Clinical Toxicology Devices; (ii) Hematology and Pathology Devices; (iii)

Immunology and Microbiology Device; (iv) Anesthesiology Devices; (v) Cardiovascular Devices; (vi) Dental Devices; (vii) Ear, Nose, and Throat Devices; (viii) Gastroenterology and Urology Devices; (ix) General and Plastic Surgery Devices; (x) General Hospital and Personal Use Devices; (xi) Neurological Devices; (xii) Obstetrical and Gynecological Devices; (xiii) Ophthalmic Devices; (xiv) Orthopedic Devices; (xv) Physical Medicine Devices; (xvi) Radiology Devices and (xvii) Other Categories Specified by the central competent authority. In practice, we do find digital health wearable devices, such as wearable temperature and multi-parameter monitors and diagnosis aid equipment, such as image capture and angiography systems are registered as medical devices in Taiwan.

3. What are the main legal issues surrounding digital health medical devices?

According to Article 84 of the Pharmaceutical Affairs Act, any person who manufactures or imports medical devices without obtaining prior approval shall be punished with imprisonment of not more than three years and may, in addition thereto, be imposed with a fine of not more than NTD 10,000,000. The forgoing punishment applies to any person who knowingly sells, supplies, transports, stores, brokers, transfers or displays with intent to sell the medical implements set forth. Furthermore, any person who commits the offence set forth by negligence shall also be punished with imprisonment of not more than six months, detention or a fine of not more than NTD 5,000,000. Since the types and forms of digital health medical devices had been grown and varied rapidly these years, it would be necessary and crucial for players in the digital health medical devices industry to note the restriction and to review carefully whether their products fall within the regulated categories under the Pharmaceutical Affairs Act so as to lower the legal risk arising therefrom.

4. What kinds of marketing activities are permitted or prohibited?

The Medical Technology Association of Australia (MTAA) also publishes a non-mandatory industry Code of Practice for medical technology companies which sets out the ethical framework within which they must work, in their relationships with healthcare professionals and also, where relevant, with the consumer. The Code is not law. It is a guide to industry best practice and all companies in the industry are encouraged to comply with it, including provisions related to advertising and marketing of medical devices.

m-Health

1. What types of m-Health can be used and how do they work in practice?

According to Article 3 of the Telecommunications Rules, the medical items (the "**tele-medicine**") allowed may encompass: (i) disease history-taking; (ii) diagnosis; (iii) issuance of prescriptions; (iv) issuance of medical advice; (v) adjustment of original prescriptions or advice and (vi) health education. However, no prescriptions shall be issued in the event that the residents of institutional residential long-term care organization holding valid chronic disease refill prescription from the medical care provider whom they have entered into a medical service agreement with and require diagnosis or treatment by the provider's physicians. As stated in Article 6 of the Telecommunications Rules, tele-medicine may be implemented by means of land-line or mobile communications, the Internet, and other communication devices or methods that enable communications.

2. What are the main legal issues surrounding m-Health?

The rule that a physician shall treat, issue prescription or certificate of diagnosis to patient by himself or herself still serves as a principle under the Physicians Act. Any violation shall be subject to administrative fines from NTD 20,000 to NTD 100,000. In other words, the development of implementing and integrating m-Health into daily life of Taiwanese people still faces rigorous legal limitations by now.

3. Are there any regulations or restrictions on use of m-Health by or in collaboration with medical institutions or doctors?

According to Article 11 of the Physicians Act, the tele-medicine could only be conducted in mountain areas, outlying islands, remote areas, or under special or urgent circumstances. As stated in Article 2 of

the Telecommunications Rules, special circumstances shall refer to the circumstances meeting any of the following criteria: (i) acute inpatients who according to the discharge service plan, requiring follow-up treatment within three months after being discharged; (ii) residents of institutional residential long-term care organization holding valid chronic disease refill prescription from the medical care provider whom they have entered into a medical service agreement with and require diagnosis or treatment by the provider's physicians; (iii) patients in need of integrated care by family physicians that are specified in the Rules and Decrees by either competent authorities or their subordinate agencies; (iv) participants requiring follow-up treatment within three months after diagnosis and treatment from the responsible medical team and having been earlier qualified by related Rules and Decrees for the tele-care programs approved by competent authorities or their subordinate agencies and (v) foreign patients without citizenship and void in the National Health Insurance intending to undergo or having undergone treatment in medical institutions in Taiwan. The urgent circumstances shall mean any life-threatening conditions or emergencies demanding immediate medical treatment. Subject to the forgoing limitations, no tele-medicine could be conducted without meeting one of the exceptional circumstances above.

4. What kinds of marketing activities are permitted or prohibited?

According to Articles 84 to 86 of the Medical Care Act, non-medical care institutions shall not make advertisements for medical care and the content of advertisements shall be restricted to the following items: (i) the name, practice license number, address, and telephone number of, and directions to, the medical care institution; (ii) the name, sex, academic background, professional experience, and physician or specialist physician certificate number of the physician; (iii) hospitals or clinics contracted or associated with the National Health Insurance or other non-commercial insurances; (iv) clinic practices and clinic hours; (v) the year, month, and date of the opening, suspension, close, resumption, or relocation of practice and (vi) other items approved and announced by the central competent authority for publication or broadcast. Nevertheless, the information provided by medical care institutions through the internet shall not be restricted by the content limitations above, as long as such contents does not involve in (i) false, exaggerated, or distorted facts, or is indecent; (ii) promotes illegal abortion and (iii) has already been penalized three times within one year.

Furthermore, the advertisements for medical care shall not be made in any of the following manners: (i) to publicize by making use of the name of other person(s); (ii) to publicize by sale or gift of medical publications; (iii) to publicize by making known family trade secrets or by public question and response; (iv) to publicize by making use of content contained in medical publications; (v) to publicize by means of releasing an interview or news report; (vi) to publicize in association or side-by-side with advertisements in violation of Article 85 of the Medical Care Act; (vii) to publicize by any other improper means.

Artificial Intelligence

1. What are the main legal issues surrounding artificial intelligence and digital health?

As aforementioned, a physician shall treat, issue prescription or certificate of diagnosis to patients by himself or herself under the Physicians Act. Even if there are exceptions that allow physicians to conduct tele-medicine, such conduct still need to be carried out by physicians. In other words, under the current legal environment, there is no medical care action that could be conducted without the involvement of physicians, which means Artificial Intelligence (the "**AI**") by now could only serve as assistance in helping physicians performing their duties.

2. What types of artificial intelligence digital health technology can be used and how do they work in practice?

There are no laws or regulations that specifically govern the AI implementation and development in digital health technology. However, if such technology falls within the regulated scope of medical devices, it shall be deemed as a medical device and shall comply with the regulations prescribed in the Pharmaceutical Affairs Act.

3. Can artificial intelligence digital health diagnostic services provide medical advice?

As mentioned in question 1 above, it is the physician who shall treat, issue prescription or certificate of diagnosis to patients under the Physicians Act and AI could not conduct medical diagnose independently but could only serve as assistance in helping physicians performing their duties.

Thailand

Regulatory Overview

1. What is the main legislation for digital health technology in your jurisdiction?

The main legislation governing digital health technology in Thailand is as follows:

- Medical Device Act B.E. 2551 (A.D. 2008), as amended in B.E. 2562 (A.D. 2019), enforced by the Medical Device Control Division of the Food and Drug Administration dated 26 April 2019 on the definition and control of a Medical Device;
- Personal Data Protection Act B.E. 2562 (A.D. 2019), enforced by the Ministry of Digital Economy and Society, allowing the Personal Data Protection Committee to monitor how a user's personal data is used by a data collector; and
- National Cyber Security Act B.E. 2562 (A.D. 2019), enforced by the Ministry of Digital Economy and Society, allowing the National Cyber Security Committee (NCSC) to regulate the Ministry of Public Health with regard to the publication and regulation of the Cyber Security System for health products.

2. What are the main regulatory bodies for digital health in your jurisdiction and what is their corresponding regulatory scope?

The main regulatory body in charge of digital health activities is the Ministry of Public Health (MoPH). In particular, the MoPH has the authority to direct, provide guidelines on, and inspect digital health activities. The Medical Device Control Division of the Food and Drug Administration is under the control of the MoPH. It has the authority to enforce any regulations relating to the Medical Device Act.

The definition of a Medical Device in Thailand is largely harmonised with international standards. In general, devices that include software and accessories used for the diagnosis, monitoring, prevention, or treatment of diseases fall within the scope of a Medical Device, provided such devices do not achieve their primary intended action by immunological, metabolic, or pharmacological mans. Therefore, it is inevitable that certain mobile medical apps and software are classified as Medical Devices in Thailand.

3. Are there specific rules relating to digital health and compliance/dealing with HCPs in your jurisdiction?

As mentioned in the answer to question 2 above, if a digital health product (i.e. software) is intended for use under the scope of Medical Devices, it must follow the Medical Device Act. In order to receive consultative advice as to whether a product is under the scope of a Medical Device, the product owner can request that the FDA determine the classification of a product. If it is a Medical Device, the notification or registration of Medical Device is required prior to its importation into Thailand. Furthermore, as it concerns digital health, the use of data provided by the product must follow the Personal Data Protection Committee's Regulations.

With regard to the COVID-19 pandemic, on 19 May 2020, the Thai Cabinet approved the implementation of a Royal Decree providing a one-year exemption from certain provisions under the Personal Data Protection Act 2019 (PDPA), which includes complaints, liability issues, and penalties. In the current draft, the exemptions of businesses include, for example, banking, commercial, communications and telecommunications, construction, digital, education, energy, finance, insurance, medical and public health, professional practices, real estate, tourism, and transportation.

4. Are there any current government initiatives promoting digital health technology?

Yes. The MoPH has been promoting digital health technology. There have been several conferences, health software competitions, plans, and seminars on the development of digital transformation. For example, the MoPH has enacted its e-Health Strategy of the Ministry of Public Health (2017–2026), which is a ten-year plan for the development of e-government initiatives that include digital health initiatives.

Some of the official standards for governmental hospitals are as follows:

- Hospitality Service Standards
  - AI: AI Unit, CXR, Retina
  - Smart Hospital: Queue, Less Paper
- Development of Data System Standards
  - Big Data Analysis: Eyes, Kidney, Heart

This includes promoting "Telehealth", as some hospitals have their own official LINE accounts, where a doctor/pharmacist can give patient advice remotely. Another form of government initiative on digital health is the Smart Health profile, which is the sharing of patient profiles remotely between the hospitals. This will hasten the process.

In 2019, there was a collaboration between three government agencies, namely, the MoPH, the Ministry of Digital Economy and Society, and the Digital Government Development Agency (public organization). The aim of the recently introduced telemedicine project is to connect the healthcare services provided by 116 public hospitals under the MoPH via an IT system and mobile phone applications. This project would allow Thai physicians to share medical information online, e.g., by sending and receiving digital images and sound. In addition, the project would cover long-distance study in the medical sciences. Medical consultations would include TeleRadiology, TeleCardiology and TelePathology. Apart from this project, the MoPH is coordinating with the National Broadcasting Telecommunication Commission (NBTC) to utilize high-speed internet for providing certain health services, including screenings for selected diseases, e.g., non-communicable diseases (NCD), diabetes, hypertension, skin diseases, eye diseases, etc. The latter project is known as the "Telehealth" project.

In addition, the COVID-19 pandemic has acted as a catalyst for the implementation of digital health options in Thailand. The National Innovation Agency (NIA) of Thailand promotes thematic innovations in relation to healthcare solutions and devices, wherein an entrepreneur can obtain financial support for the development of a digital health platform. For example, the YMID Portal is the online platform under the campaign "Thai TeleHealth Fight Covid-10", which is an online platform providing health information in relation to COVID-19.

5. Please provide a brief regulatory regime for digital health in your jurisdiction

Please refer to our response in question 3 above.

6. What are the regulations governing the transfer of technology, both domestically and cross-border?

If the technology falls under a Medical Device classification, it must follow the Medical Device Control Regulations. For technologies that are subject to Intellectual Property (IP) rights protection, the transfer of IP rights must be carried out in accordance with the regulations of the Law on Intellectual Property.

7. What are the licencing requirements for personal and clinical use?

There is no specific license required for the provision of digital health information for personal use. However, public health care units (i.e. hospitals, clinics, etc.), doctors, or pharmacists using such products must have a Medical Facility License, Medical Professional License, or Pharmacy Professional License, respectively.

Data Protection Overview

1. Can any types of data be shared with companies for the development of digital health technologies? Which kinds of data are permitted or prohibited?

Any type of health data can be shared with third parties for the development of digital health technology and for other purposes, provided that the prior consent of the data subjects (i.e. patients) is obtained. The data is under protection of Thailand's Personal Data Protection Act (PDPA), which was enacted on 27 May 2019. The PDPA was scheduled to be implemented on 27 May 2020, but with the COVID-19 pandemic, the new enforcement date was delayed until 31 May 2021. To clarify, in general, personal data can be classified into general data and sensitive data, as mentioned in Section 26 of the PDPA. Sensitive data requires the subject's consent in order to be collected, except in certain circumstances (i.e. preventing health damage, for the use of a non-profit organization, for scientific use, etc.)

The government anticipates that the extension will give applicable business operators and organizations more flexibility in preparing themselves for compliance with the PDPA. However, it should be emphasized that, during the one-year extension period, businesses should continue to internally roll out their assessment programs and make use of the time to understand their current practices for handling and processing personal data, as well as to identify and resolve any compliance gaps.

2. Are there any regulations or restrictions on use of data collecting or sharing digital health technologies by or in collaboration with medical institutions or doctors?

Please refer to our answer provided in question 1 above in the Data Protection Overview section.

Intellectual Property Overview

1. What types of digital health technology can be patented and describe the general patent registration, if any, structure of your jurisdiction?

Generally, any technical solution in the form of a product or a process that is novel, inventive, and susceptible to industrial application can be patented, with the following exceptions:

- Naturally occurring microorganisms and their components, animals, plants, or extracts from animals or plants;
- Scientific or mathematical rules or theories;
- Computer programs;
- Methods of diagnosis, treatment, or cure of human and animal diseases; and
- Inventions contrary to public order, morality, health, or welfare.

For general patent registration, patent applications (for inventions and petty patent) can be filed directly at the Intellectual Property Office (IP Thailand), at its branches, or via paper-based or online-submission. A patent or petty patent is granted after the substantive examination. To request substantive examination, the applicant can file a request for substantive examination, which is possible once the application has been published. The deadline to file a request is within five years as from the publication date.

For invention patents, the following factors will be examined during the substantive examination: (i) novelty, (ii) inventive step, and (iii) industrial applicability. For petty patents, only (i) novelty and (ii) industrial applicability are examined.

Copies of the examination and search reports, office actions, and patents granted in a corresponding application filed in another examining country, e.g., U.S.A., U.K., E.P., etc., must be submitted to the Thai Patent Office. Examination of the Thai application will be initiated upon submission of the documents to the Patent Office. The examination of the Thai application will be based on the patent(s) and office actions, as the Examiner will verify whether the specification and claims of the Thai case conform to those of the submitted documents. If there is no conformity, the Examiner will issue an office action instructing the applicant to amend the specification and claims of the Thai application to conform to the corresponding patent. If no further amendment is required in the application, a notification to pay the registration fee will be issued, which takes approximately two years as from when the request for substantive examination has been filed.

An invention patent and a petty patent will be valid from the grant date until the end of the 20th year and from the end of the 10th year following the filing date, respectively.

2. What types of digital health technology can be copyrighted and describe the general copyright registration, if any, structure of your jurisdiction?

Computer programs and/or data compilations of digital health technology can be copyrighted.

Regarding general copyright registration, there is no copyright registration requirement. A work will have automatic protection upon fixation if it is copyrightable. In principle, to enforce copyright, copyright registration is not required. However, a certificate of copyright can be used as *prima facie* evidence of copyright ownership. Therefore, it is still recommended to obtain a certificate of copyright registration.

3. What are the main intellectual property issues arising in digital health technology development?

Some of the main issues regarding digital health technology developments might include the ability to protect the IP rights of digital health technologies or copyright, in order to remain vigilant against patent theft.

Under the current IP system, enforcement of unregistered IP is very difficult. In addition, enforcement of copyright and/or trade secrets is generally weak.

The Future of Digital Health

1. Have there been any recent updates to the regulatory regime governing digital health in your jurisdiction?

According to the e-Health Strategy of the MoPH (2017–2026), in response to question 4 of the Regulatory Overview, there is a plan for updating digital health. The status of Thailand's e-Health and the nation's direction of e-Health development consist of three parts as follows:

- Foundation Policies & Strategy – The MoPH has adopted Thailand 4.0 and the Digital Thailand regulations for enabling National e-Government policies and strategies.
- Enabling Policies & Strategy – There are IT courses for health science students and professionals. Furthermore, there are standards set for the core data of national health.
- e-Health Application – The updates in this section are those pilot programs for m-Health/Telemedicine/ e-Learning in the health sciences and the Health Information Exchange.

2. Are we likely to see any reforms or new regulations relating to digital health?

Referring to our answer above, section one of the e-Health Strategy of the MoPH (Foundation Policies and Strategy) does mention the establishment of National e-Health policies and strategies. However, these have not yet been developed.

Application

Medical Devices

1. What types of digital health technologies need to be registered as Medical Devices?

There is no clear guidance listing the types of digital health Medical Devices. In principle, digital health technology needs to be registered as a Medical Device if it is used for one or more of the following specific purposes:

- To diagnose, prevent, monitor, treat, or eliminate illness or to compensate for injury or damage;
- To examine, replace, adjust, or assist with surgical activities or physiological processes;
- To support or sustain life;
- To control conception;
- To sterilise medical equipment, including chemicals used in testing;
- To provide information for diagnosis, monitoring, and treatment through the examination of samples taken from the human body.
- To sterilize Medical Devices; and
- To use with Medical Devices mentioned in (a) through (g).

2. What types of digital health Medical Devices can be used and how do they work in practice?

There are many types of digital health Medical Devices that can be used in Thailand; for example, computerized tomography scanners, electrocardiograms, digital blood pressure monitors, endoscopes, and blood glucose meters. Some of the devices are limited for use in hospitals, while others are allowed for personal use.

3. What are the main legal issues surrounding digital health medical devices?

So far, we have not seen any outstanding legal issues surrounding digital health Medical Devices. Digital health Medical Devices are still being treated as low-risk medical devices (General Medical Devices).

4. What kinds of marketing activities are permitted or prohibited?

The MoPH has not provided any specific bans/guidance on marketing activities for digital health Medical Devices. Thus, digital health Medical Devices are marketed as normal Medical Devices. However, the applicant must ensure that the marketing activity complies well with the advertisement regulation.

m-Health

1. What types of m-Health can be used and how do they work in practice?

m-Health (i.e. advice provided by doctors through apps or mobile health advice) is permissible in Thailand. All m-Health service providers must be healthcare facilities responsible for disease prevention or practitioners with licenses for medical examination and treatment, which comply with the regulatory requirements on IT infrastructure and measures, as discussed in question 3 of the "Overview" section above. Please refer to our responses under the "Overview" section above for further details on the regulatory requirements.

2. What are the main legal issues surrounding m-Health?

Please refer to our responses under the "Overview" section above.

3. Are there any regulations or restrictions on use of m-Health by or in collaboration with medical institutions or doctors?

Please refer to our responses under the "Overview" section above.

4. What kinds of marketing activities are permitted or prohibited?

If the device has an intended use within the scope of Medical Devices, it must follow advertisement notification of a Medical Device. The summary of such notification is to prevent over-claims of the product's effectiveness.

Artificial Intelligence

1. What are the main legal issues surrounding artificial intelligence and digital health?

- Artificial intelligence for medical indications requires evidence of effectiveness, namely, the results from a clinical trial. A technology assessment may need to be evaluated by the FDA prior to product registration. Both are required for registering Medical Devices in Thailand.
- The FDA has announced certain conditions for artificial intelligence software registration, whereby the applicant must specify their software and whether it is general software or AI software. Additionally, an applicant has to specify further whether such software is stand-alone or embedded. However, an applicant can ask for the authority's advice at the Division of Medical Devices or www.fda.moph.go.th.

  Ref: https://oryor.com/%E0%B8%AD%E0%B8%A2/detail/media_news/1685

2. What types of artificial intelligence digital health technology can be used and how do they work in practice?

Artificial intelligence digital health technology may include data processing of EMR systems, obtaining health data from wearable devices, recording patient/health data from big data analysis, auto-analysing/making decisions on customers' health conditions, and using virtual reality.

3. Can artificial intelligence digital health diagnostic services provide medical advice?

We are not aware of any information as to whether digital health diagnostic services are allowed.

Vietnam

Regulatory Overview

1. What is the main legislation for digital health technology in your jurisdiction?

The main legislation governing digital health technology in Vietnam is as follows:

- Law on Network Information Security No. 86/2015/QH13 adopted by the National Assembly of Vietnam on 19 November 2015 ("Law on Network Information Security");
- Circular No. 46/2018/TT-BYT of the Ministry of Health dated 28 December 2018 on electronic medical records ("Circular 46");
- Circular No. 49/2017/TT-BYT of the Ministry of Health dated 28 December 2017 on telemedicine ("Circular 49");
- Circular No. 53/2014/TT-BYT of the Ministry of Health dated 29 December 2014 on provision of online healthcare services ("Circular 53"); and
- Circular No. 54/2017/TT-BYT of the Ministry of Health dated 29 December 2017 on criteria for information technology applications at healthcare facilities ("**Circular 54**").

2. What are the main regulatory bodies for digital health in your jurisdiction and what is their corresponding regulatory scope?

The main regulatory body in charge of digital health activities is the Information Technology Department of the Ministry of Health ("**MOH**") (Article 14 of Circular 49; Article 10.1 of Circular 53; Article 23 of Circular 46; and Article 7 of Circular 54). In particular, the MOH has the following authorities:

- To direct, provide guidelines on, and inspect digital health activities; and
- To cooperate with other state agencies (at both central and provincial levels) to implement state management of digital health activities.

3. Are there specific rules relating to digital health and compliance/dealing with HCPs in your jurisdiction?

Vietnam allows and encourages healthcare facilities to use technology to provide and improve their services. In particular, commencing from February 2018, telemedicine activities (including provision of remote consultation on medical examination and treatment via technology applications, tele-radiology, remote anatomy consultation, remote surgery consultation, and training in telemedicine technology transfer) are permissible and regulated under Vietnamese law. Medical records can also be prepared and stored in digital form. Some salient rules relating to digital health will be discussed in Question 5 of this section.

4. Are there any current government initiatives promoting digital health technology?

Yes, the Vietnam government is currently promoting digital health technology. There have been several decisions, plans and seminars on the development of smart healthcare that have been issued/organized

by government agencies. For example, the City of Hanoi and the Ministry of Health have approved plans for the development of e-government that include digital health initiatives.

5. Please provide a brief regulatory regime for digital health in your jurisdiction

Telemedicine (including provision of remote consultation on medical examination and treatment via technology applications, tele-radiology, remote anatomy consultation, remote surgery consultation, and training in telemedicine technology transfer) is permissible under Vietnamese law, provided that such activities are performed in healthcare facilities responsible for disease prevention or those with licenses for medical examination and treatment in accordance with regulations of the Law on Medical Examination and Treatment and other relevant legislative documents (Articles 1.1 and 5 of Circular 49). IT infrastructure and measures of telemedicine service providers must ensure confidentiality of information, satisfy technical requirements, and be operated by qualified IT operators set out under Circular 53 (Article 4 of Circular 49).

Some salient IT infrastructure and measures set out under Circular 53 include:

- Design of the IT infrastructure must comply with national and international standards, including HL7 standard, DICOM, ISO/IEEE 11073, SDMX-HD, and other standards set out by law;
- There must be a backup plan to ensure continued operation of the network system; Electronic Medical Records ("EMRs") must be backed up on a weekly basis;
- Policies on information security must be formulated in accordance with regulations on ensuring the security of the State and the provider's own information technology system;
- There must be measures for intrusion detection and prevention, malicious code prevention, database attack prevention, and technology risk and disaster prevention;
- There must be procedures for incident management, specifying the responsibilities of relevant departments and steps and informing users and operators of information technology systems. If the IT infrastructure is outsourced, the service provider must offer procedures for handling incidents;
- There must be regulations on protecting and granting privileges to access database resources;
- Patient data and EMRs must be made, retained and used in a manner that ensures patient privacy and in accordance with provisions of the Law on Medical Examination and Treatment, Circular 46, Circular 54 and the Law on Network Information Security;
- EMR data must be encrypted in the course of connecting to and sharing with third parties; and
- If outsourcing IT application services, there must be a contract containing each party's commitment to legally use information and responsibilities for incident occurrence.

6. What are the regulations governing the transfer of technology, both domestically and cross-border?

In Vietnam, technology transfer activities, which includes both domestic and cross-border technology transfers, are governed by the Law on Technology Transfer 2017 and other subordinate legislation. For technologies that are subject to intellectual property (IP) rights protection, the transfer of the IP rights must be carried out in accordance with regulations of the Law on Intellectual Property

7. What are the licencing requirements for personal and clinical use?

There is no specific license required for provision of telemedicine services. However, telemedicine service providers must be healthcare facilities responsible for disease prevention or those that have licenses for medical examination and treatment and comply with the regulatory requirements on IT infrastructure and measure as discussed in Question 5 of this section.

Data Protection Overview

1. Can any types of data be shared with companies for the development of digital health technologies? Which kinds of data are permitted or prohibited?

Any type of health data can be shared with third parties for development of digital health technology and other purposes, provided that the prior consent of the data subjects (i.e., patients) is obtained.

To clarify, in general, Vietnam does not separate personal data into general data and sensitive data, except in specifically controlled sectors such as financial services. According to Vietnamese data protection and privacy laws/regulations, generally, all types of personal data are treated the same. The key principles for the collection, processing and use of personal data ("**Data Processing**") in Vietnam are that the Data Processing must be notified and consented to by the data subject, and the use of such data must be in line with the purposes as notified and consented to. Personal data can only be transferred to a third party if the data subject consents to the transfer, it is at the request of a relevant authority, or the law provides otherwise. Personal data can be transferred across borders to and from Vietnam if prior consent of the data subject is obtained.

2. Are there any regulations or restrictions on use of data collecting or sharing digital health technologies by or in collaboration with medical institutions or doctors?

Yes. Please see our response to Question 1 of this section.

Moreover, in respect of sharing patient data with a third-party IT service provider, the law further provides that there must be a contract containing each party's commitment to legally use information and responsibilities in the event of an incident, and the service provider must offer incident handling procedures (Articles 4.5(a) and 6.8 of Circular 53). EMR data must be encrypted in the course of connection and sharing (Article 10.3 of Circular 46).

The representative of the supervisory authority of a health facility, investigation authorities, People's Procuracies, courts, healthcare inspectors, insurance offices, providers of forensic examination and forensic psychiatric assessment, and lawyers may be allowed to access EMRs on the premises of healthcare facilities or make hard copies of EMRs with the approval of the head of that healthcare facility for the purpose of fulfilling their assigned duties (Article 7.1(b) of Circular 46).

Intellectual Property Overview

1. What types of digital health technology can be patented and describe the general patent registration, if any, structure of your jurisdiction

Generally, any technical solution in the form of a product or a process that is novel, inventive and susceptible to industrial application can be patented in Vietnam, with the following exceptions (emphasis added):

- Discoveries, scientific theories and mathematical methods;
- Schemes, plans, rules or methods for performing mental activities, training domestic animals, playing games, doing business; computer programs;
- Presentations of information;
- Solutions of aesthetic characteristics only;
- Plant varieties or animal varieties;
- Processes of an essentially biological nature for the production of plants and animals other than microbiological processes;
- Disease prevention, diagnostics and treatment methods for humans or animals; and
- Claims of all formats are accepted, excluding: use claims, omnibus claims, claims written as an improvement, etc.

For general patent registration, patent applications (for inventions and utility solutions) can be filed (paper based) directly at the Vietnam Intellectual Property Office (IP Vietnam), at its branches, or via post. Vietnam's patent system allows substantive examination. To request substantive examination, an examination request must be made within 42 months from the priority date. An examination request can be filed within six months after the 42-month deadline if legitimate reasons can be provided.

For invention patents, the following factors will be examined during the substantive examination: (i) novelty, (ii) inventive step, and (iii) industrial applicability. For utility solutions, only (i) novelty and (ii) industrial applicability are examined.

Substantive examination results will be available within 18 months from either (i) the date of receipt of the request for substantive examination, if the request is submitted after the publication date, or (ii) the publication date, if the request is lodged before the publication date.

An invention patent and a utility solution patent will be valid from the grant date until the end of the 20th year and 10th year following the filing date, respectively.

2. What types of digital health technology can be copyrighted and describe the general copyright registration, if any, structure of your jurisdiction

Computer programs and/or data compilations of digital health technology can be copyrighted.

Regarding general copyright registration: Under Vietnam's IP Law, there is no copyright registration requirement. A work will have automatic protection upon fixation if it is copyrightable. In principle, to enforce copyright, copyright registration is not required. However, a certificate of copyright can be used as *prima facie* evidence of copyright ownership. Therefore, it is still recommended to obtain a certificate of copyright registration. Copyright holders can register their copyrighted works with the Copyright Office of Vietnam. It normally takes from three to five weeks to complete a copyright registration in Vietnam.

3. What are the main intellectual property issues arising in digital health technology development?

Some of the main issues regarding digital health technology development might include the protectability of IP rights in digital health technologies, copyright and patent stealing.

Under the current IP system in Vietnam, the enforcement of unregistered IP would be very difficult. In addition, the enforcement of copyright and/or trade secrets is generally weak.

The Future of Digital Health

1. Have there been any recent updates to the regulatory regime governing digital health in your jurisdiction?

Yes. In particular, Vietnam has recently promulgated Circular 54/2017/TT-BYT on criteria for information technology applications at healthcare facilities; Circular No. 46/2018/TT-BYT on EMRs; and Circular No. 49/2017/TT-BYT on provision of telemedicine services.

2. Are we likely to see any reforms or new regulations relating to digital health?

The implementation of EMR processing and electronic payment for healthcare facilities is anticipated to occur at most public hospitals in Vietnam relatively soon.

Application

Medical Devices

1. What types of digital health technologies need to be registered as medical devices?

There is no clear guidance listing the types of digital health medical devices in Vietnam. In principle, digital health technology needs to be registered as a medical device if it is used for one or more of the following specific purposes:

- To diagnose, prevent, monitor, treat, or eliminate illness or to compensate for injury or damage;
- To examine, replace, adjust, or assist with surgical activities or physiological processes;
- To support or sustain life;
- To control conception;
- To sterilise medical equipment, including chemicals used in testing; and
- To provide information for diagnosis, monitoring, and treatment through the examination of samples taken from the human body.

2. What types of digital health medical devices can be used and how do they work in practice?

There are many types of digital health medical devices which can be used in Vietnam, for example, LED visual charts, digital refractors, digital blood pressure monitors, digital thermometers, and patient rings.

3. What are the main legal issues surrounding digital health medical devices?

So far, we have not seen any outstanding legal issues surrounding digital health medical devices in Vietnam. Digital health medical devices are still being treated as normal medical devices.

4. What kinds of marketing activities are permitted or prohibited?

The MOH has not provided any specific bans/guidance on marketing activities for digital health medical devices. Thus, digital health medical devices are marketed as normal medical devices.

m-Health

1. What types of m-Health can be used and how do they work in practice?

m-Health (i.e., advice being provided by doctors through apps or mobile health advice) is permissible in Vietnam. According to Vietnamese laws, m-Health service providers must be healthcare facilities responsible for disease prevention or those with licenses for medical examination and treatment and which comply with regulatory requirements on IT infrastructure and measures as discussed in Question 5 of the “Overview” section above. Please refer to our responses under the “Overview” section above for more details on the regulatory requirements.

2. What are the main legal issues surrounding m-Health?

Please refer to our responses under the “Overview” section above.

3. Are there any regulations or restrictions on use of m-Health by or in collaboration with medical institutions or doctors?

Please refer to our responses under the “Overview” section above.

4. What kinds of marketing activities are permitted or prohibited?

We have seen some healthcare applications marketed in Vietnam. However, the MOH has not provided any specific prohibitions or guidance on marketing activities of such applications.

Artificial Intelligence

1. What are the main legal issues surrounding artificial intelligence and digital health?

Vietnam has recently issued some legal documents on digital health. However, the application of artificial intelligence and digital health is still new in Vietnam and is in the first stage of development. Thus, it is too early to know what the main issues are.

2. What types of artificial intelligence digital health technology can be used and how do they work in practice?

According to an MOH official, artificial intelligence digital health technology may include processing of EMR systems, obtaining health data from wearable devices, recording patient/health data from big data analysis, auto-analysing / making decision on customers' health conditions, and using virtual reality.

3. Can artificial intelligence digital health diagnostic services provide medical advice?

We are not aware of any information on whether digital health diagnostic services are allowed in Vietnam.

How can LAN help?

Together, we can provide you with the best industry focused legal advice available in the APAC region. This is because we have:

Depth: more Lifesciences focused experts across key jurisdictions than any one firm.

Coverage: >2000 lawyers operating from 23 offices in Australia, China, Hong Kong, India, Indonesia, Japan, Korea, Singapore, Thailand and Vietnam who understand the local culture and can provide local knowledge.

Technical experts: supported by numerous scientists, pharmacists and food technicians to provide specialist understanding.

Value for money: an ability to deliver expert and commercially focused advice at local and competitive rates.

Cross-border coordination: providing a one-stop shop for all your legal needs.

Powered by major international law firms: the network comprises some of the leading international law firms from the key 'pharmerging markets' in Asia-Pacific including Assegaf Hamzah & Partners, Atsumi & Sakai, Chen & Lin, CMS, Corrs Chambers Westgarth, Rajah & Tann Singapore LLP, Tilleke & Gibbins and Yulchon LLC.

Pan-regional services

Contact Us

Australia

Kate Hay
Partner
Corrs Chambers Westgarth
T +61 3 9672 3155
E kate.hay@corrs.com.au

Kate is the head of Corrs' intellectual property group. She has worked on a number of high profile patent cases including the Australian case that clarified the law relating to patentability of methods of medical treatment. In addition to acting for pharmaceutical companies, Kate has acted for many international clients in relation to medical devices including drug-eluting stents, catheters, braces and increasingly advises in relation to med tech innovation and protection.

Kate has particular expertise in multi-jurisdictional litigation and currently acts for Lundbeck in its long running escitalopram patent litigation and for Cargill in its bovine genome patent litigation.

Although Kate is foremost a litigator, she also has extensive experience in advertising and regulatory approvals and trade mark and contractual disputes in the pharmaceutical sector.

Kate is consistently listed as a leading lawyer by legal directories and publications including Chambers and Partners, Best Lawyers, World Trade Mark Review, IAM Patent 1000 and was named one of the top 250 Women in IP globally in the 2019 by Managing Intellectual Property's IP Stars. In Chambers she is noted for 'her ability to translate highly technical detail into plain language' and 'sector insight, understanding and knowledge both locally in Australia and across the Asia-Pacific region.' She is described as 'a patent, trade mark and copyright maven, well known for her work in life sciences and technology fields' in World Trade Mark Review 2019 and as a 'a versatile contentious wiz who adeptly advises and litigates across the group's technical theatres of operation' in IAM Patent 1000, 2019.

Kate is an Australian committee member of the International Association for the Protection of Intellectual Property (AIPPI) and a member of the Intellectual Property Society of Australia and New Zealand.

Nick Beckett
Managing Partner, Beijing Office
Managing Director, Hong Kong Office
Global Co-Head CMS Life Sciences & Healthcare Sector Group
T +86 10 8527 0287/+852 2533 7818
E nick.beckett@cms-cmno.com

Nick is the Managing Partner of the Beijing Office, Managing Director of Lau, Horton & Wise LLP in Association with CMS Hasche Sigle, Hong Kong LLP, Global Co-Head of CMS Life Sciences & Healthcare Sector Group and Head of Asia-Pacific IP. Nick is also a registered foreign lawyer in Hong Kong. Nick has extensive experience in advising on all aspects of intellectual property, regulatory and commercial matters affecting Life Sciences & Healthcare clients internationally and his practice spans both contentious and non-contentious issues.

Nick has substantial experience in coordinating complex multi-jurisdictional matters, regularly working with colleagues throughout CMS and around the world. His work in the areas of commercial and corporate transactions and disputes, parallel trade, anti-counterfeiting, trade mark and patent opinions and IP infringement particularly spans international borders.

Nick is recommended as a prominent practitioner in his field in Chambers & Partners, Legal 500, Euromoney's Expert Legal Guide – Life Sciences, Who's Who Legal Life Sciences (Patent Litigation, Regulatory, Transactional), IAM 1000 and Who's Who Legal: *Thought Leaders – Global Elite for Life Sciences*. Nick is also recommended in Who's Who Legal 'China – Patents and Life Sciences'. Nick was awarded '*Life Sciences Lawyer of the Year in China'* in Leaders in Law - 2020 Global Awards, The Best Lawyers in China 2020 for Intellectual Property Law (International Firms).

Nick has also been recognised as a *'Top 15 IP Lawyer in China'* by Asian Legal Business 2017, *IP (Expertise Based Abroad) - UK* in Chambers Global.

Nick led the team on Takeda's €9.6 billion acquisition of Swiss drug company, Nycomed A/S, which won the FT & Mergermarket Private Equity's Deal of the Year. In China, Nick's team has been ranked in the Asian Legal Business Asia's Top 50 Largest Law Firms (2014-2020) and been highly commended at the FT Innovative Lawyers for Asia-Pacific (2014-2020). In addition, the IP team in Asia is recognised in the Asian Legal Business IP Rankings.

Nick is a Solicitor-Advocate of the English Courts and a listed Arbitrator at the Beijing International Arbitration Centre (BIAC) and Beijing Arbitration Commission (BAC) and an 'Advisory Expert of the National Advisory Center for Overseas Intellectual Property Dispute Settlement' in China. He is an Honorary Lecturer at the China Pharmaceutical University in Nanjing and lectures also at Peking University, University of International Business and Economics (UIBE) and China-EU School of Law at China University of Political Science and Law.

Indonesia

Eko Basyuni
Partner
Assegaf Hamzah & Partners
T +62 21 2555 7802
E eko.basyuni@ahp.co.id

ASSEGAF HAMZAH & PARTNERS

Eko holds an LL.M. in banking and financial law from Boston University and has more than 15 years' experience as a legal practitioner. His focus extends across the corporate, banking & finance, and FDI practices, and he has amassed extensive experience in a range of rapidly expanding sectors, including Lifesciences, the creative industries and TMT.

He has advised a number of multinational companies on their FDI ventures in Indonesia, and is an Asialaw Profiles 'Recommended Lawyer.' His expertise was one of the contributing factors to Assegaf Hamzah being named an Asian-Mena Counsel 2014 'In-house Community Firm of the Year' in Indonesia for Lifesciences.

Prior to joining Assegaf Hamzah, Eko served as legal counsel with the Indonesian Bank Restructuring Agency (IBRA) during a tumultuous period that saw the agency rebuild the country's decimated financial services sector from the ruins of the 1997/98 Asian financial crisis. Eko speaks Indonesian and English.

Japan

Chie Kasahara
Partner
Atsumi & Sakai
T +81 3-5501-2438
E chie.kasahara@aplaw.jp

渥美坂井法律事務所・外国法共同事業
Atsumi & Sakai

Chie, a Japanese-qualified attorney (Bengoshi) of some 15 years' standing, leads the IP/IT & Healthcare team. She is an IP/IT & Healthcare practitioner with deep knowledge of legal issues relevant to the lifesciences field, and highly experienced in patent and regulatory/compliance matters. She represents biotechnology, medical device and other pharmaceutical companies in patent protection and litigation both domestic and cross-border. She also advises her clients on licensing, transfer, development and collaboration agreements.

Korea

Ki Young Kim
Partner
Yulchon LLC
T +82 2 528 5222
E kykim@yulchon.com

Ki Young is a co-chair of Yulchon's Healthcare Practice Team and a partner in the Corporate & Finance Group. After joining Yulchon in 1998, he successfully advised a number of international and Korean pharma/medical device companies on general corporate matters, including mergers and acquisitions, joint ventures and other strategic alliances, drug/medical device sales and distribution agreements, R&D related matters, and licensing and related disputes. Ki Young also specializes in government regulation and policy issues, including issues related to product approvals, market access, pricing, labeling, advertisement, healthcare insurance and regulation by the MOHW and the MFDS. Ki Young also provides extensive compliance and anti-corruption advice related to marketing activities to numerous international and Korean pharma/ medical device companies.

Ki Young's experience includes a secondment with Allen & Overy, Hong Kong from 2003 to 2004 and service as an outside director of Ildong Pharmaceutical Co., Ltd. from 2010 to 2014. Currently, he serves as a legal adviser to the Korean Cosmetics Association, Korea Pharmaceutical Traders Association and Korea Medical Devices Industry Association, and he is an IRB member of St. Mary Hospital in Seoul.

Ki Young speaks English and Korean.

Singapore/Malaysia/Philippines

Wee Hann Lim
Partner
Rajah & Tann Singapore LLP
T +65 6232 0606
E wee.hann.lim@rajahtann.com

Wee Hann has over 23 years of experience in advising companies on cross-border investments, private mergers & acquisitions, sale & purchase of companies and businesses and other corporate transactions. Wee Hann also specialises in labour law and employee benefits.

Wee Hann's expertise includes advising numerous biotechnology, health and pharmaceutical global leaders on cross-border acquisitions and divestments. He is a recommended lawyer in the PLC Lifesciences Handbook for his work in the Lifesciences industry and is also listed by the International Who's Who of Lifesciences Lawyers as one of the world's leading practitioners in the field of Lifesciences.

Wee Hann speaks English, Bahasa Malaysia, Mandarin, Vietnamese and is learning Japanese.

Taiwan

Jennifer Wang
Partner
Chen & Lin Attorneys-at-Law
T +886 2 2715 0270
E jenniferwang@chenandlin.com

Jennifer is the partner of Chen & Lin Attorneys-at-Law since 2008. Jennifer and Chen & Lin team have extensive experiences in serving clients in the sector of pharmaceuticals, biotech, medical device, nutritious food as well as cosmetics, including both domestic and international companies, hospitals, laboratories, associations and individuals.

Jennifer's specialised legal areas include foreign (PRC) investment, legal compliance, corporate, M&A, securities and anti-trust related issues. Jennifer, together with the team, provides holistic legal services to Lifesciences clients, ranging from administrative application, local legal compliance, fundraising, M&A, IPO, licensing, daily operation related agreements, patent litigation, maltreatment litigation and criminal procedures about health insurance fraud.

Jennifer is one of the ranked lawyers in Taiwan in Chambers & Partners Asia-Pacific 2018 in the fields of corporate/M&A and capital market.

Jennifer speaks Mandarin and English.

Thailand/Cambodia/Laos/Myanmar

Alan Adcock
Partner
Tilleke & Gibbins
T +66 2056 5871
E alan.a@tilleke.com

Alan is a partner and the deputy director of Tilleke & Gibbins' intellectual property and regulatory affairs groups, helping to oversee the firm's client work in these areas across ASEAN. He also co-heads the firm's regional lifesciences practice with Thomas Treutler.

Alan has over 20 years' experience in Asia, during which time he has devoted much of his work to IP acquisitions, strategic structuring, technology transfer, and IP licensing and securitisation agreements, mainly in the pharmaceutical, agrochemical, and material science sectors. He handles various IP infringement and regulatory infraction cases involving labelling, advertising, clinical trials, product handling/warehousing, product registration, taxation, and import/ export violations in the Asia-Pacific region. He also deals with local pre- litigation strategy and litigation management for infringement and invalidation matters in the region.

Since 2005, Alan has been recognized by *Asialaw Leading Lawyers* as one of Asia's leading business lawyers in the area of intellectual property, and he has been named a top IP lawyer in Thailand by *The Legal 500 Asia Pacific* and *WTR 1000*. Alan is also recognized as a leading IP strategist by *IAM Strategy 300*, an expert on patents in *IAM Patent 1000*, one of the world's foremost lifesciences practitioners by *IAM Lifesciences 250*, and a leading lifesciences regulatory lawyer by *Who's Who Legal*.

Alan is licensed to practice in New York and New Jersey and is admitted in the U.S. District Courts of Southern and Eastern New York. He speaks English and Mandarin.

Vietnam

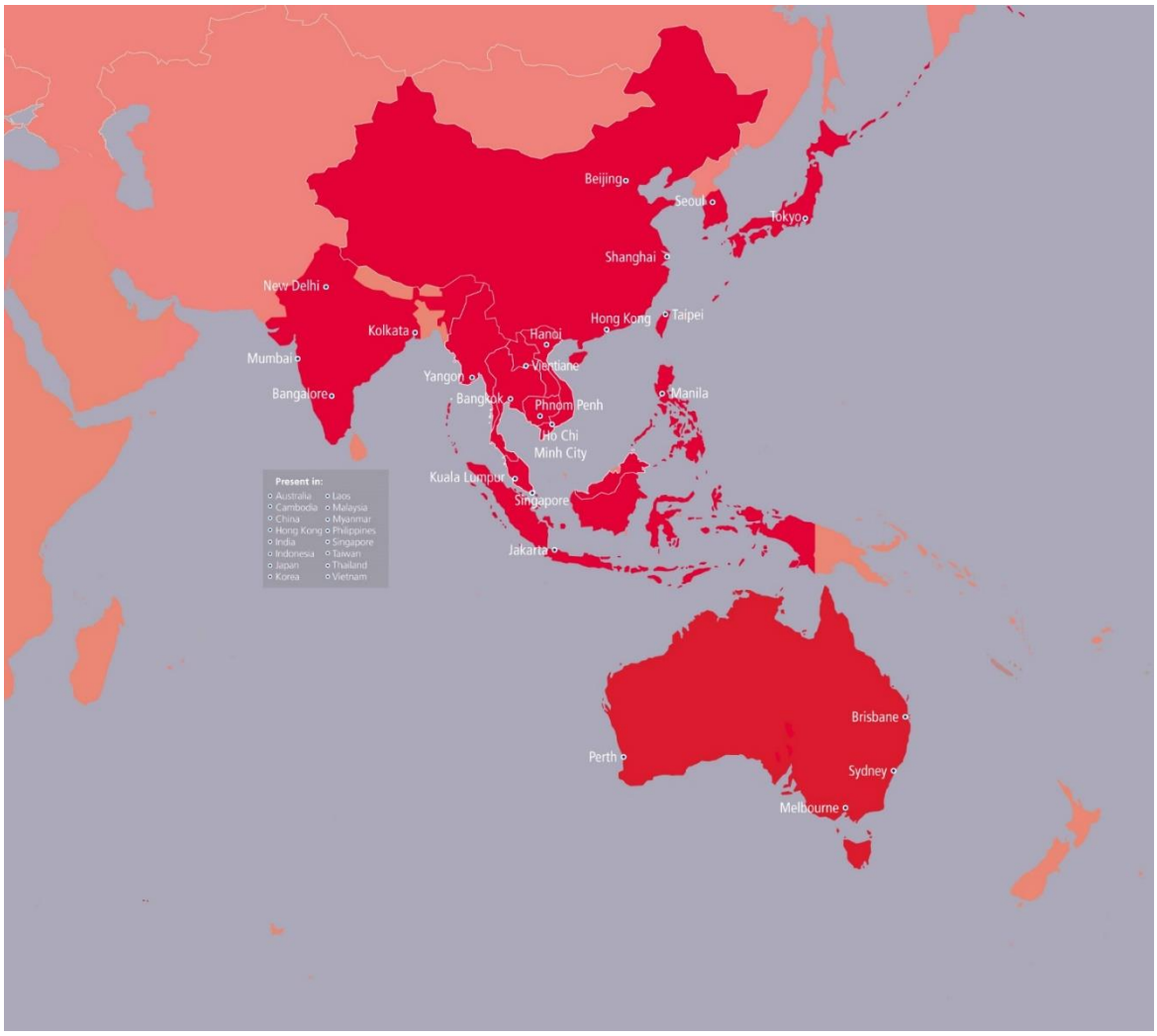
Thomas J. Treutler
Partner
Tilleke & Gibbins
T +84 8 3936 2068
E thomas.t@tilleke.com

Tom is the Managing Director of Tilleke & Gibbins' Vietnam offices. He is an attorney licensed by the State Bar of California and is registered to practice as a foreign lawyer in Vietnam and before the USPTO and the U.S. Court of International Trade.

Tom has worked in the legal services field in Vietnam since 1994, specializing in corporate and commercial law as well as IP. He co-heads Tilleke & Gibbins' regional lifesciences practice with Alan Adcock. Recognized as a leading lawyer by *Chambers*, *The Legal 500*, and *Managing IP*, Tom has extensive experience in IP enforcement and has secured a number of landmark victories for foreign investors operating in the lifesciences and technology sectors.

Tom is a former Chair of the East Asia and Pacific Subcommittee of INTA's Famous and Well-Known Marks Committee, is a member of the INTA Asia-Pacific Global Advisory Council, and currently sits on the INTA Copyright Committee. He has advised EuroCham Vietnam's Pharma Group (an industry group of major pharmaceutical innovators), and has assisted with drafting position papers on compulsory licensing and a roadmap for Vietnam's compliance with the EU-Vietnam Free Trade Agreement and TRIPS. Tom also serves as a local expert for Vietnam for the European Commission's ASEAN IPR SME Helpdesk.

Tom earned his JD, *magna cum laude*, from Indiana University Bloomington's Maurer School of Law, where he now serves as a member of the Dean's Global Advisory Board. He speaks English and Vietnamese.



The collaboration presented in this publication is limited to Lifesciences. The information held in this publication is for general purposes and guidance only and does not purport to constitute legal or professional advice.

Assegaf Hamzah & Partners, Atsumi & Sakai, Chen & Lin, CMS, China, Corrs Chambers Westgarth, Rajah & Tann Singapore LLP, Tilleke & Gibbins and Yulchon LLC are all independent law firms.

Further information about each firm can be found respectively at www.ahp.co.id, www.aplaw.jp/en/, www.chenandlin.com, cms.law, www.corrs.com.au, www.rajahtann.com, www.tilleke.com, www.yulchon.com