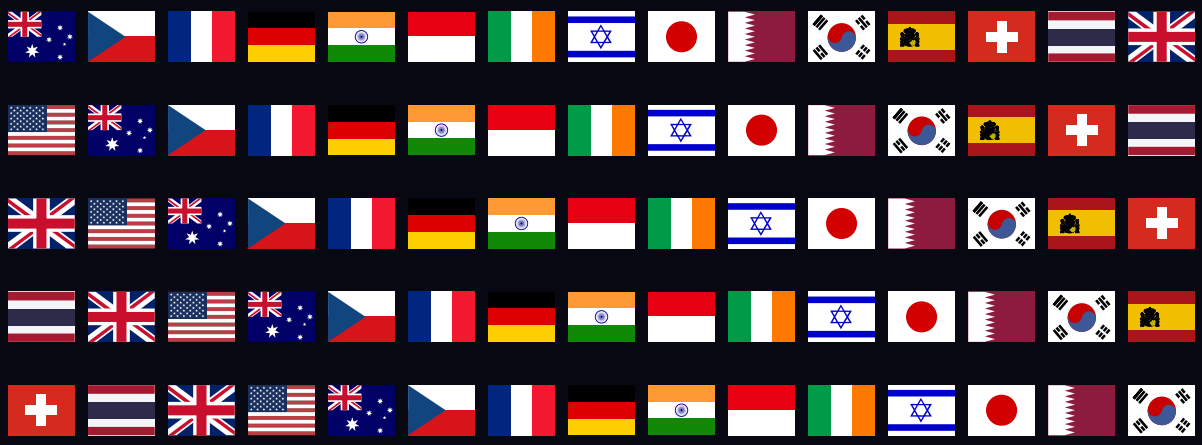
DIGITAL HEALTH

Indonesia



LEXOLOGY
Getting The Deal Through

Consulting editor
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Digital Health

Consulting editors

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Latham & Watkins LLP

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

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Table of contents

UPDATES AND TRENDS

Recent developments

Contributors

Indonesia

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MARKET OVERVIEW AND TRANSACTIONAL ISSUES

Key market players and innovations

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

The key players active in the digital health market in Indonesia are:

- healthcare providers: healthcare providers are nowadays engaged in facilitating healthcare-related services to their consumers through digital, which includes telemedicine services;
- pharmaceutical industry: currently, the sale of pharmaceutical products can be carried out through electronic trading, including websites, software and mobile apps and digital platforms. Pharmaceutical products include medicines, traditional medicines and quasi-medicines;
- pharmaceutical electronic system provider: the pharmaceutical electronic system provider provides, manages or operates an e-pharmacy (an electronic system used in the operation of a pharma undertaking) for its own needs or the needs of other parties;
- investors: the development of digital health (including the invention and creation of apps and software) needs financing, which depends partly on investor funding; and
- government: legislation enacted by the government is anticipating the development of digital health as well as information technology, although this still needs more improvement to give certainty to the investors and to build harmony with related regulations in Indonesia.

Further, the government is actively cooperating with some digital health companies, especially during the covid-19 pandemic in Indonesia. Indonesia's Ministry of Health (MoH) also incorporated a task force in 2021, the Digital Transformation Office (DTO), with a mission to transform health services in Indonesia. Its main mission is to establish within Indonesia electronic patient medical records (with patient consent), simplify health service applications, and strengthen the health technology ecosystem based on public policy innovation.

The invention of apps, websites and platforms was a game-changer in digital health in Indonesia and has provided a range of services from the provision of telemedicine, sales of medicine through electronic media, health information, health checks as well as facilitating appointments with healthcare providers and healthcare practitioners, etc.

Law stated - 03 November 2022

Investment climate

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

The investment climate for digital health technology in Indonesia is favourable, with good potential following a rapid growth in internet penetration and usage (the fastest growing in Southeast Asia). Indonesia is the fourth-largest country in the world by population, with a very young demographic, poised to become the largest market for technology-driven products, including digital apps. Being an island archipelago, access to medicine is poor in remote regions, which opens an opportunity for digital health, including telemedicine. To date, Indonesia has home-grown digital health apps, such as AloDokter, HaloDoc (the market leader in digital health technology, with the most extensive funding), KlikDokter, YesDok, KlinikGo and Good Doctor, to name a few.

Improvement is needed on the regulatory side as the government has yet to prepare an extensive regulatory framework

specifically on digital health business as well as clarity on how the existing regulations would apply – creating uncertainties for investors as to what is allowed and restricted in carrying out the business.

To date, the prevailing regulations in Indonesia on digital health are currently limited to:

- telemedicine, which is used at health service facilities (eg, hospitals, clinics), under MoH Regulation No. 20 of 2019 on Telemedicine Services as part of Health Services Facilities Regulation No. 20 of 2019; and
- online distribution of medicine, under Food and Drug Authority (BPOM) Regulation No. 8 of 2020 on the Supervision of Online Distribution of Medicine and Food, as amended under BPOM Regulation No. 32 of 2020 on the Amendment of BPOM Regulation No. 8 of 2020.

There is also a need for regulations on digital health apps that would allow health practitioners to communicate directly with patients. At present, the regulations neither govern nor restrict the utilisation of these apps, so they operate within a somewhat grey area.

Nonetheless, during the covid-19 pandemic, the government issued several regulations to highlight the authority of health practitioners in providing services through telemedicine to slow the spread of the coronavirus. The regulations provide more clarity on the dos and don'ts of the digital health business. However, investors must anticipate the re-emergence of uncertainty in the telemedicine business, post-pandemic.

Other challenges include:

- a lack of data integration and records, in which data is currently fragmented between many health service providers (as a unified health data system in Indonesia does not yet exist), and a real-time health database is not accessible to health service providers; and
- a lack of adequate data security for users of digital health platforms.

For example, security was breached on the data of 279 million National Health Insurance participants and 1.3 million Electronic Health Alert Card participants managed by the MoH. However, no information on resultant enforcement action has yet been publicly disclosed.

Law stated - 03 November 2022

Recent deals

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

Some recent notable deals include Seri A funding of US$5.15 billion for Smarter Health in January 2022, led by East Ventures (with other strategic investors such as Orbit Malaysia, Citrine Capital, HMI Group and EMTEK), focused on product development and market expansion in Southeast Asia. A new development is S Second Medical Opinion, which allows patients to review their medical assessment prepared by curated health services in Singapore.

Another notable deal occurred in August 2022, in which Diri Care, a consumer health technology startup, focused on aesthetic and health digital clinic services. It announced a deal on initial seed funding of US$4.3 billion, which was oversubscribed, and led by East Ventures, Sequoia Capital India, Surge (from Southeast Asia) and Henry Hendrawan.

Although not specifically related to digital health, East Venture, which has been investing in health-tech startups, including Nalagenetics, Nusantics, FitHappy, Riliv, etc, also supported the launch of the Biomedical and Genome Science Initiative by the MoH to provide medical services to the public. The aim is to develop more targeted treatment for the public through the collection of genetic information (genomes) from humans, and pathogens. (Further detail on

the value of East Ventures' funding is still awaited.)

Law stated - 03 November 2022

Due diligence

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

Digital health ventures in Indonesia are not comprehensively regulated. Hence, there is currently no definitive guidance for investors engaging in the business. Existing digital health ventures might also be affected by a ruling on the operation of the business when it is eventually issued.

Today, digital health ventures (such as digital health app companies) are classified as 'web platform' providers (that fall under the scope of the information technology sector, and not the health sector). Thus, their operations generally do not extend to the provision of health services, as this is done in cooperation with health practitioners.

There is no restriction on foreign investment in a digital platform company. Foreign investors in a digital platform company are required to invest more than 10 billion rupiahs (excluding land and building value) and inject at least 10 billion rupiahs capital into the company, for doing business in Indonesia.

Typical Indonesian mergers and acquisitions diligence points would still be applicable, including the checking of capitalisation and share ownership in a digital health company, licensing and coverage of the business scope of digital health. From a contractual perspective, the due diligence on a digital health company should also cover a review of negative covenants that prohibit a digital health company from entering into a particular transaction.

Law stated - 03 November 2022

Financing and government support

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

The most common financing structures used by digital health ventures are equity funding and credit or loan arrangements by financial institutions. For startup companies, venture capital is also a notable funding option as it allows a digital health venture to expand its business in cooperation with a venture capital firm. This type of funding is often seen as suitable for a startup business, as its operation will be under valuable guidance and supervision from professionals of the venture capital firm.

For example, the funding stage of a startup company involves the following:

- seed funding (preliminary funding for a startup company when the product is already built);
- Series-A funding (financed by a venture capital firm, usually allotting preferred stocks);
- Series-A financing is usually for working capital, additional market research or the finalisation of products and services;
- Series-B funding (financed by a venture capital firm when the products and services are sold in the market. The capital is used to scale up and obtain profit);
- Series-C funding (financed by a venture capital firm when the company is already successful in the market. Series-C is usually for greater market share, acquisitions or developing products or services); and
- initial public offering (meaning the company becomes a publicly listed company at the stock exchange. The

finance is funded by the public from the shares offered at the stock exchange).

The government has also not provided specific financing procedures for digital health ventures. However, the legislation allows central and regional governments to finance telemedicine services, sourced from state and regional budgets and other non-binding sources, in accordance with the prevailing regulations. Nevertheless, the financing of telemedicine funded by the government is limited to telemedicine by health services facilities (and not between healthcare facilities and patients).

Support to promote the development of digital health by the government is achieved through collaboration with digital health provider companies for health education through apps.

Law stated - 03 November 2022

LEGAL AND REGULATORY FRAMEWORK

Legislation

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

The principal legislation governing the digital health sector is:

Legislation	Governing body	Highlights
Ministry of Health (MoH) Regulation No. 21 of 2020 on the MoH Strategic Plan for 2020–2024	MoH	As part of its strategic plan, the government is preparing a new regulation on the utilisation of technology through telemedicine for direct health services between doctors and patients; and such regulation was expected to be issued in 2021. However, to date, such regulation has not been issued.
MoH Regulation No. 90 of 2015 on the Implementation of Health Services in Health Services Facilities in Remote Areas and Very Remote Areas	MoH	Under the regulation, telemedicine is used as part of the development of health services facilities located within remote and very remote areas. The regulation defines 'telemedicine' as the use of technology in combination with medical expertise to provide health services, from consultations, diagnoses and medical procedures performed remotely.
Regulation 20 No. of 2019	MoH	Regulation No. 20 of 2019 specifically stipulates the use of telemedicine by health services facilities and covers telemedicine with patients. The term 'telemedicine' is defined as the provision of remote health services by health professionals using technology (eg, exchange of information on diagnosis, treatment, prevention of disease and injury, research and evaluation). Under Regulation No. 20 of 2019, only health services facilities in a hospital may provide telemedicine services to other facilities (eg, hospitals, clinics and public health centres), which includes teleradiology, tele-electrocardiography, tele-ultrasonography, clinical teleconsultation and other services. In these examples, both facilities must be registered with the MoH.

Regulation No. 8 of 2020	The Food and Drug Authority	Regulation No. 8 of 2020 allows the pharmaceutical industry, wholesalers and pharmacies to distribute medicine through an electronic system. Only a pharmacy may engage a third party to provide the system while the pharmaceutical industry and wholesalers may only use their own electronic system. In delivering medicine to patients, Regulation No. 8 of 2020 allows pharmacies to deliver independently or engage a third-party legal entity to do it (the pharmaceutical electronic system provider). Regulation No. 8 of 2020 covers the distribution of over-the-counter, quasi medicines and prescribed medicines. The regulation also stipulates certain requirements and limitations on pharmacies or platform providers when distributing drugs and cosmetics online. For example, prescription-only medicines, medicines containing pharmaceutical precursors, medicines for erection dysfunction, injection preparations (except for insulin), implant preparations, narcotics and psychotropics, and cosmetics with certain substances.

In addition to the above, the government issued the following regulation on the use of telemedicine during the coronavirus pandemic:

Legislation	Governing body	Highlights
MoH Decree No. HK.01.07/ MENKES/413/2020 on Guidelines for Prevention and Control of Coronavirus Disease, as amended by MoH Decree No. HK.01.07/MENKES/4834/2021 on Covid-19 Funeral Management Protocol and MoH Decree No. HK.01.07/ MENKES/4641/2021 on Guidelines for Implementation of Checking, Tracing, Quarantine and Isolation for Covid-19 Prevention and Control	MoH	As a preventive measure to limit the spread of covid-19, the MoH acknowledges the need for the provision of health services through telemedicine.

MoH Decree No. HK.01.07/ MENKES/4829/2021 on Guidelines of Health Services through Telemedicine on Corona Virus Disease 2019 Pandemic	MoH	The regulation provides guidelines for central government, regional government, doctors and other health workers, health services facility, persons in charge of telemedicine apps and other relevant stakeholders in providing health services via telemedicine (namely, remote health services using information and communication technology) during the covid-19 pandemic, which includes the provision of health information, diagnosis, treatment, prevention of deterioration, evaluation of the patient's health condition, and pharma services, including for monitoring covid-19 patients who are self-isolating. Pursuant to the regulation, health services facilities via telemedicine can be performed by hospitals, public health centres (known as pusat kesehatan masyarakat), clinics, medical laboratories, pharmacies, and independent practice medical doctors, dentists or physicians, using an app developed by them or another app owned by the government or private entity. The regulation also stipulates the clinical guidance of covid-19 patients, depending on the conditions, eg, non-symptomatic or symptomatic, which consist of certain vitamins and medications such as antivirus and antibiotics and recommended dosage. The regulation also provides guidelines for self-isolation.

Regulation of the Indonesian Medical Council No. 74 of 2020 on Clinical and Practical Medical Authority through Telemedicine during the Coronavirus Pandemic in Indonesia (Regulation 74/2020)	Indonesian Medical Council	Regulation No. 74 of 2020 is aimed at providing additional authority for doctors to engage in medical practice during the pandemic in Indonesia. It is stipulated that during the pandemic, medical practice for patients can also be done using a telemedicine app or an electronic system, which can be online writing, voice or video. Doctors providing services through telemedicine must have a Registration Certificate and Medical Practice Certificate in the relevant health services facility. Further, they are required to refer the patient to a health services facility if the patient is in critical condition or requires diagnostic action or therapy. This provision seems to restrict doctors from carrying out a diagnosis on patients using telemedicine. There are also specific limitations on the authority of doctors in carrying out medical practice through telemedicine under the regulation. For instance, doctors are prohibited from performing teleconsultations directly with patients without a health service facility, or diagnosis beyond their competence. When using a telemedicine service, patients must provide general or informed consent in accordance with the prevailing laws. A medical practice using telemedicine must maintain medical records that may be manual or electronic, in accordance with the prevailing laws.

Law stated - 03 November 2022

Regulatory and enforcement bodies

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

The implementation of the digital health sector in Indonesia is primarily under the jurisdiction of the following ministries or institutions:

- the MoH, on telemedicine and health services in general, integration of health data, and development and improvement of a digital health ecosystem in Indonesia;
- the Food and Drug Authority for the distribution of medicines (online and offline);
- the Ministry of Communications and Information Technology, on electronic systems used for telemedicine; and
- the Ministry of Industry and the Ministry of Trade, on business licensing of electronic systems providers.

Law stated - 03 November 2022

Licensing and authorisation

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

There is still no specific licensing requirement for telemedicine platforms in Indonesia. However, if a platform provides online distribution of medicine, the provider must obtain Pharma Electronic System Operator Registration from the MoH as required under MoH Regulation No. 14 of 2021 on Standards for Business Activities and Products in the Implementation of Risk Based Assessment Business Licensing of Health Sector, as amended under MoH Regulation No. 8 of 2022. If a digital health provider provides telemedicine in cooperation with other health providers (meaning that the digital health provider is an intermediary in telemedicine services), the digital health provider must be licensed as a digital platform company and electronic system provider.

As a general concept, aside from a specific licence or registration that may need to be obtained in relation to the healthcare services, the platform provider is required to obtain certain general permits to carry out its business activity within Indonesian territory, including the relevant business licensing issued through the Online Single Submission system and Electronic System Provider Registration from the Ministry of Communication and Information Technology.

The implementation of digital health services is also subject to licensing and authorisation that are applicable to the business via conventional methods. A party involved in an online business (eg, doctors, pharmacies, pharmaceutical industry or wholesalers) must obtain the relevant permits to carry out their normal businesses. Likewise, any medicine distributed online must also be registered and obtain the necessary permit as if distributed offline, including marketing authorisation.

Law stated - 03 November 2022

Soft law and guidance

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

There is no notable ‘soft’ law or guidance governing digital health in Indonesia. However, the MoH has issued several technical guidelines between 2020 to 2021 that must be implemented by the government-mandated community health clinics (locally known as Puskesmas), clinics and hospitals during the covid-19 pandemic. All of these guidelines allow healthcare facilities to provide telemedicine services to their patient.

Nevertheless, in performing their services, doctors are still subject to the regulations under the Indonesian Medical Council, as an autonomous and independent body responsible to the Indonesian President for providing certain arrangements and guidance to medical practices. This includes limitations on doctors to provide diagnosis via telemedicine under Regulation No. 74 of 2020.

Law stated - 03 November 2022

Liability regimes

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

The key liability regimes that are applicable specifically to digital health products and services in Indonesia are as follows:

Sector	Key liability	Legal basis
Online distribution of medicine	Pharma industry, wholesalers and pharmacies must guarantee the medicine being distributed online.	Regulation No. 8 of 2020
Electronic prescriptions	Doctors who write electronic prescriptions for medicines and (or) medical devices must take responsibility for the content and impact that may arise from the medicine stated in electronic prescriptions. Note that the electronic prescription cannot be used for prescript medicines that fall under narcotics and psychotropics, injection (except for self-use insulin), and family planning implants. The copy of the electronic prescription shall be kept as a printed or electronic copy as part of medical records. Responsibility for the health services provided through telemedicine, which were initially the responsibility of the doctors under MoH Circular Letter No. HK.02.01.07/MENKES/303/2020 is no longer stated under MoH Decree No. HK.01.07/MENKES/4829/2021. The responsibility of doctors with regard to telemedicine is limited to online prescriptions.	MoH Decree No. HK.01.07/MENKES/4829/2021
Delivery of medicine and (or) medical devices	In delivering medicine or medical devices for e-pharmacy services, the pharma service facility or the delivery service provider must guarantee the safety and quality of the medicine and medical devices being delivered.	MoH Decree No. HK.01.07/MENKES/4829/2021

In addition, as regulated in conventional doctors' practice, the Health Law also stipulates the right of a party to claim against healthcare personnel or a health services facility in the event of loss due to fault or negligence in the health services received by that party.

Other than the above civil liabilities, the management of the company, as individuals, may also be exposed to liabilities that involve criminal sanctions. The Health Law also stipulates that criminal sanction is also applicable for some violations that involve:

- trading of pharmaceutical products without proper marketing authorisation;
- medical practice without expertise and authorisation; and
- the procurement, storage, processing, promotion and distribution of pharmaceutical preparations and medical equipment that do not fulfil the quality standard for pharmaceutical services.

Under the Consumer Protection Law, entrepreneurs (eg, health services providers) are responsible for paying compensation for damages, contamination or losses suffered by a consumer as a result of consuming or using the goods or services produced or traded. The compensation referred to above can be a cash refund or replacement of goods or services that are of a similar type or comparable value, or medical treatment or provision of sympathetic care in accordance with the prevailing regulation. The provision of compensation will not preclude criminal sanction on the basis of further verification of a fault.

As to the application of the liability regime in the cross-border provision, it is to be noted that the prevailing regulations governing digital health business in Indonesia only cover the provision of digital health products and services within Indonesia territory; hence the liability should not extend to cross-border provision.

Law stated - 03 November 2022

DATA PROTECTION AND MANAGEMENT

Definition of 'health data'

What constitutes 'health data'? Is there a definition of 'anonymised' health data?

Health data within the context of health information system legislation in Indonesia is a type of patient health metadata used for health development. Health data in this context is collected by the health services facilities and government institutions, to be further processed by the Ministry of Health into 'health information'. The aim of collecting health data is to enhance knowledge to support health development.

In addition, the legislation also stipulates that 'health information', means health data processed to be of value and meaning for enhancing knowledge to support health development.

Indonesian legislation does not stipulate the definition of 'anonymised data' as well as 'anonymised health data'. Nevertheless, the common understanding is that 'anonymised' data means data stripped of person-identifiable information and therefore cannot be used for identifying certain individuals).

Law stated - 03 November 2022

Data protection law

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

In the health sector, the Health Law (Law No. 36 of 2009 on Health, as amended by Law No. 11 of 2020 on Job Creation) and its implementing regulation protect information on patients contained in medical records. Except in certain circumstances, information in the medical records must be kept confidential by doctors, dentists, certain health workers, management officers and heads of health service facilities (the head of the place where the medical practice is performed) and may not be shared with other parties without the approval of the patients themselves. The medical records can be accessed only in the following limited circumstances:

- in the interests of a patient's health;
- upon a government request for purposes of law enforcement;
- at a patient's request;
- if stipulated under the prevailing laws; or
- for research, education and medical audit so long it does not reveal the identity of the patient.

Any disclosure of medical records must be submitted in writing to the head of health service facilities.

Other than the above, legal protection of personal data should follow the general provisions on personal data protection under Law No. 27 of 2022 on Personal Data Protection (the PDP Law) and the Electronic Information and Transactions Law (Law No. 11 of 2008 on Electronic Information and Transactions (the EIT Law), as amended by Law No. 19 of 2016) and its implementing regulations.

An organisation that functions as an electronic services provider (eg, a digital platform company that establishes apps, websites and others) in Indonesia must:

- provide a standard protection procedure that guarantees the security or confidentiality of patient data (as

electronic information or documents);
- manage risk in the event of damage or loss arising out of the operation of an electronic system;
- provide and carry out procedures and facilities to protect an electronic system from interference and material or non-material loss;
- provide a security standard to cover procedures and systems to prevent and overcome threats or attempted interference.

Pursuant to the PDP Law and Government Regulation No. 71 of 2019 on the Provision of Electronic Systems and Transactions (GR 71/2019), personal data is defined as data on a person that is identified or identifiable, either separately or in combination with other information, either directly or indirectly, through an electronic system or via non-electronic means. Given this definition, the term 'personal data' has a broad interpretation, and would include any data attributable to an individual and could be used to identify an individual. Accordingly, the health data of an individual would constitute personal data under this definition.

The PDP Law acknowledges several lawful bases for personal data processing:

- express consent;
- contractual necessity;
- compliance with a data controller's legal obligations;
- protection of the vital interests of a data subject;
- public interest in the provision of public services or for the exercise of lawful authority; and
- legitimate interest.

Processing of personal data must be based on the above.

Further, the recently issued PDP Law classifies health data as 'specific personal data'. In this case, the PDP Law does not specify a compliance requirement for processing 'specific personal data' as compared with 'general personal data'. Nevertheless, a data controller processing 'specific personal data' is subject to the following obligations:

- preparation of data protection impact assessment; and
- appointment of a data protection officer, if the main operations of the data controller involve large-scale personal data processing of 'specific personal data'.

Further, data controllers must maintain confidentiality, completeness, authenticity, accessibility, availability and traceability of electronic information or electronic documents pursuant to the prevailing laws and regulations. A party may submit a claim against the data controller that results in a loss to that party.

Law stated - 03 November 2022

Anonymised health data

Is anonymised health data subject to specific regulations or guidelines?

Indonesian legislation does not stipulate the definition of 'anonymised' data or 'anonymised' health data. Nevertheless, in general, as long as the 'anonymised' data is stripped of any-identifiable information and therefore such data cannot be used to identify a certain individual either on its own or in combination with other data using any means whatsoever, it is our understanding that 'anonymised' data or 'anonymised' health data would not constitute personal data. Thus,

the collection, use, storage, dissemination and deletion thereof is not subject to personal data protection requirements under the law and regulations.

Law stated - 03 November 2022

Enforcement

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

Currently, Indonesia does not have rules or regulations for digital healthcare systems. Regulations on patient confidentiality and safety have not yet been issued. Apart from medical records, data protection in the health sector should be enforced in accordance with general data protection for electronic systems. There is no specific regulation on data protection for digital healthcare technologies.

Within the context of personal data, upon the occurrence of a data breach, a data controller is required to notify the regulator and the affected data subjects within 72 hours.

Further, failure to comply with the obligation to comply with the personal data protection requirements is subject to the following sanctions:

- criminal sanction of imprisonment up to six years and (or) fine of up to 6 billion rupiahs (multiplied by a factor of up to 10, if committed by a corporation), as well as:
  - the seizure of assets obtained or generated from the crime;
  - the freezing of all or part of the corporation's business;
  - the permanent prohibition on carrying out certain actions;
  - the closure of all or part of the corporation's business premises and activities;
  - an order to carry out an obligation that has been neglected;
  - the payment of compensation;
  - the revocation of licence; and (or)
  - the dissolution of the corporation;
- administrative sanction in the form of (stipulated in GR 71/2019 and Ministry of Communication and Information Technology (MCIT) Regulation No. 20 of 2016 on Personal Data Protection in Electronic Systems (MR 20/2016):
  - a verbal warning;
  - a written warning;
  - an administrative fine;
  - a temporary suspension of business activities;
  - termination of access;
  - exclusion from the registry maintained by the MCIT; or
  - an announcement on MCIT's online website that the electronic system's operator had not implemented proper personal data protection measures;
- administrative sanction (stipulated in the PDP Law) of:
  - a written warning,
  - a temporary ban on personal data processing,
  - the deletion or destruction of personal data; and (or)
  - an administrative fine of up to 2 per cent of an organisation's total annual income or revenue.

A data controller may be held accountable or sued by the affected data subject in the event of a loss arising suffered by

the data subject from a failure to comply with the personal data protection requirements.

Nevertheless, to this date, we are not aware of any enforcement of criminal sanction, administrative sanction, or a civil claim for damages with regard to digital healthcare technologies in the private sector. In the public sector, a data breach involved health data maintained by the Social Security Agency. However, the enforcement action following this incident has not been disclosed to the public.

Law stated - 03 November 2022

Cybersecurity

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

In general, GR 71/2019 requires electronic systems operators to maintain and implement procedures and facilities to secure their electronic systems to mitigate any interference, failure, and damages.

The Indonesia cybersecurity regulatory framework is currently still under development. The National Cyber Encryption Agency (BSSN) has set out a general requirement for information security management under BSSN Regulation No. 8 of 2020 on Security Systems in the Operation of Electronic Systems. Under this regulation, subject to the risk level of an electronic system, certain security standards must be implemented by the electronic system's operator, including SNI ISO/IEC 27001 and other security standards implemented by the BSSN or other ministries or institutions.

Although there is no standalone cybersecurity law in Indonesia, the EIT has included general provisions touching on cybersecurity issues.

The EIT Law includes restrictions on the following:

- the distribution or transmission or making accessible electronic information or electronic documents that violate decency including gambling content, insults or defamation, extortion or threats;
- access to computer or electronic systems by any means to obtain electronic information or electronic documents;
- access to a computer or electronic system by any means, by violating, breaching, trespassing or penetrating a security system.
- interception of transmission of private electronic information or electronic documents, on a computer or electronic system owned by another party;
- any act that causes interference to an electronic system or causes electronic system malfunction; and
- production, sale, procurement for use purposes, importing, distributing, providing or possessing the following items for facilitating certain prohibited actions under the EIT Law:
  - computer hardware or software designed or specifically developed to facilitate an act as mentioned under the Information Technology Law; or
  - computer password, access code or similar login.

Law stated - 03 November 2022

Best practices and practical tips

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

The use and management of anonymised data are exempt from personal data protection requirements, as long as the

data cannot be used to identify an individual in any way whatsoever. However, in handling raw data and any other data that constitute personal data, the collection, use, and sharing thereof through electronic media must be processed lawfully in accordance with the PDP Law, as well as take into consideration the requirements for medical records, as applicable.

With regard to the sharing of data, it is possible to share personal data provided that it complies with the PDP Law.

Law stated - 03 November 2022

INTELLECTUAL PROPERTY

Patentability and inventorship

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

The most noteworthy rules and considerations cover software and algorithms used for operating digital health platforms.

An 'invention', as defined in Law No. 13 of 2016 on Patents (Patent Law) is an inventor's idea utilised in a specific problem-solving activity in the field of technology in the form of a product or process, or improvement and development of a product or process.

A patented invention must fulfil the criteria below:

- it is considered new (on the filing date, the invention is not the same as previously disclosed technology);
- it contains an inventive step; and
- it is applicable to industry.

Invention does not cover:

- aesthetic creativity;
- scheme; and
- rules and methods for carrying out activities:
  - involving mental input;
  - games (involving physical or human pastimes); and
  - business (generic business methods);
- rules and methods containing only computer programs;
- presentation of information; and
- findings (discoveries) as:
  - new uses for existing or known products; and (or)
  - a new form of an existing compound that does not result in a significant increase in efficacy, and known differences exist in the associated chemical structure of the compound.

Inventions that cannot be patented include:

- processes or products of which the announcement, use, or implementation is contrary to statutory regulations, religion, public order or morals;
- methods of examination, treatment, medication or surgery applied to humans or animals;

- theories and methods in science and mathematics;
- living entities, except microorganisms; or
- a biological process essential for producing a plant or animal, except a non-biological or microbiological process.

For the above, it is necessary first to identify the form of the digital invention and decide whether it is patentable or copyrightable, or whether it cannot be protected by an intellectual property (IP) regime in Indonesia.

For example, software in Indonesia can be protected either by patent or copyright, depending on its nature. Software is not patentable if it only contains a computer program, without having characters (instructions), technical effects and problem-solving (tangible and intangible) features. Instead of protection under a patent, it should be protected by copyright.

Other examples include:

- patentable: algorithms; and
- non-patentable (but can be classified as other intellectual property):
  - AI-generated content (which can be copyrightable, depending on whether human input has been involved in its development). AI-generated is copyrightable if it involves human-related effort and creation to produce the work so it can be protected. Otherwise, the AI-generated content is not copyrightable, but only the software can be protected under copyrights:
  - databases (a database is copyrightable);
  - healthcare apps are not patentable because they are categorised as computer programs, which are copyrightable;
  - healthcare wearable software can be protected by copyright and by industrial design (ID) for the form or shape of the item;
  - software as a medical device is considered a computer program; thus it is protected by copyright (see the information above on patentable and copyrightable software); and
  - electronic health records considered a database are not patentable but protected by copyright.

Other aspects of digital health are treated as follows:

- telemedicine as a method of examination and treatment applied to humans is not patentable nor protected by copyright;
- big data and data analytics cannot be protected if it is purely produced by AI and machine learning; and
- electronic health records considered a database are not patentable but protected by copyright.

Further, as for the ownership of an invention, as regulated by the Patent Law, a patent holder of an invention created by an inventor within a working relationship is the party that provides the job, unless agreed otherwise. Within a copyright regime, the creator or copyright holder of works made within a working relationship or based on an order is the party that produced the work, unless agreed otherwise.

Law stated - 03 November 2022

Patent prosecution

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

There is no specific procedure within Indonesian jurisdiction. The procedure for digital health technologies will be treated the same as for other patent application and registration procedures, with due regard to the following:

Terms and procedures

A patent application is submitted by the applicant or his or her proxy electronically or non-electronically to the Directorate General of Intellectual Property (DGIP) of the Ministry of Law and Human Rights in writing, in the Indonesian language, accompanied by the fee.

The application contains at least the data of the applicant and his or her attorney, and the application must be accompanied by data such as title, description, claim and a summary of the invention.

Administration examination

The DGIP will stipulate a receipt date that indicates the receipt of complete data for a patent application and records the application.

If the requirements and completeness of the application are not yet complete, the DGIP will notify the applicant in writing to complete the requirements and the application within a period of three months from the date of notification.

Announcement

Once an application is complete and there is no pending request from the DGIP, it will announce the patent application (electronically or non-electronically) for a period of six months, during which anyone may file a written objection or comment with the DGIP. Further, the written objection or consideration will be forwarded by the DGIP to the patent applicant.

Upon receipt of the written objection or consideration, the patent applicant will have a chance to respond to it within a certain period, and the DGIP will consider all this input during the substantive examination.

Substantive examination

A substantive examination is carried out by the DGIP upon a written request and payment of the patent applicant, which must be submitted within 36 months from the date of receipt.

After the substantive examination process, the DGIP will agree either to grant or reject the patent application.

If an application does not fulfil patent requirements, the DGIP will notify the applicant in writing and provide an opportunity for the applicant to make adjustments as necessary for the review of the application.

Patent granted

The DGIP will issue a patent certificate to a patent applicant upon the grant of a patent.

The protection of a patent is granted from the receipt date for 20 years, which is non-extendable.

Law stated - 03 November 2022

Other IP rights

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

The following includes other IP rights relevant in the context of digital health offerings.

Copyright

Copyright is the exclusive right of an author that arises automatically, based on the declarative principle after creation is manifested in tangible form without restrictions, in accordance with the provisions of laws and regulations.

A creation is creative work in the field of science, art or literature produced by inspiration, ability, thought, imagination, dexterity, skill or expertise, and is expressed in a tangible form.

Although the exclusive right of a creation (copyright) arises automatically from the declarative principle, after a creation is manifest in tangible form, however, for proof of copyright ownership in the territory of Indonesia, it is important to hold the notification of copyright recordation with the DGIP, which can only be obtained upon submission of a copyright recordation application.

Trademark or mark

A mark is a sign that can be displayed graphically as an image, logo, name, word, letter, number, colour arrangement, in two or three dimensions, sound, a hologram or a combination of two or more of these elements to distinguish goods or services produced by persons or legal entities when trading goods or services.

To secure the right, the trademark must be registered with the DGIP under the name of the applicant. Upon registration, the trademark registrant will have a right to use it or allow another person to use it by means of a licence agreement.

ID

ID is a creation involving the shape, configuration, or composition of lines or colours, or a combination thereof in three- or two-dimensional form that gives an aesthetic impression and can be realised in three- or two-dimensional patterns and can be used to produce a product, goods, industrial commodity or handicraft.

To obtain an exclusive right to an ID, the ID holder must first apply for registration to the DGIP under the name of the applicant. Upon obtaining the exclusive right, the ID registrant will have the right to use it or allow another person to use it.

In addition to the above, we understand that ‘domain names’ are recognised worldwide, to identify the unique name of a website. Domain names are not protected under the intellectual property law of Indonesia.

However, the Electronic Information and Transactions Law (Law No. 11 of 2008 on Electronic Information and Transactions) stipulates that the protection of domain names is based on the first-to-file principle. The use and ownership of a domain name are based on good faith, without breaching fair competition and other party rights. A domain name is managed by the government or the public. Foreign-registered domain names outside Indonesian territory are acknowledged in Indonesia, to the extent that they do not breach the laws and regulations.

Law stated - 03 November 2022

Licensing

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

A licence agreement must be recorded with the DGIP. Otherwise, it will not be valid for third parties. Therefore, a licence agreement must be made in writing and must be translated into the Indonesian language.

The licence agreement must at least stipulate the following matter:

- the date, month, year and place of the licence agreement signing;
- the name and address of the licensor and licensee;
- the object of the licence agreement;
- a provision on whether the licence is exclusive or non-exclusive, including a sub-licence provision;
- the term of the licence agreement;
- the territory of validity of the licence agreement; and
- the annuity payment requirement (only for patents).

The licence agreement shall not:

- be detrimental to the Indonesian economy and Indonesia's national interests;
- contain restrictions that hinder the ability of the Indonesian people to transfer, control and develop technology;
- result in unfair business competition; or
- be contrary to the provisions of laws and regulations, religious values, decency and public order.

A licensor shall not be able to licence his, her or its IP rights if the IP rights are lapsed or are deleted from the IP register.

Law stated - 03 November 2022

Enforcement

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

The enforcement of IP rights is based on registration. An IP owner must prove ownership via documentary evidence of ownership. The strongest evidence in Indonesia is ownership of a registration certificate or written notification of recordation (for copyright) issued by the DGIP, while enforcement related to IP infringement is covered by civil and penal procedures. A criminal act concerning IP is a complaint-based offence. We are not aware, to date, of any notable enforcement action involving digital health technologies in our jurisdiction. In practice, we have seen that the general terms and conditions of digital health service providers include the protection of their own IP or the IP of parties related to the digital health platform.

Law stated - 03 November 2022

ADVERTISING, MARKETING AND E-COMMERCE

Advertising and marketing

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

In accordance with Food and Drug Authority (BPOM) Regulation No. 2 of 2021 on Guidelines for Supervisory of Drugs Advertising, only over-the-counter (OTC) drugs can be advertised through visual media, audio media or audiovisual media, including social media. OTC drugs to be advertised to the public must obtain an approval for advertising from the head of the BPOM.

Medical equipment, the use of which does not require professional assistance, may be advertised via print, electronic or IT media or outdoor media (hoardings).

Further, with regard to general health services advertising or publication, Ministry of Health Regulation No. 1787/MENKES/PER/XII/2010 on Health Services Advertising and Publication emphasises that advertising or publication by health facilities via the internet cannot be used as a remote medical consultation facility (telemedicine). Therefore, an advertisement or publication must not provide medical consultancy services. Other than the foregoing, there is no specific regulation on the advertising and marketing of digital health products and services in Indonesia.

However, the government issued a regulation on the publication and advertisement of health facilities, containing some rules and restrictions, including those published and advertised through electronic media, which we believe are applicable to digital health products and services offered in Indonesia.

Some of the rules and restrictions state:

- the advertisement or publication should be accurate, evidence-based, informative, educational and be accountable or responsible; and
- the advertisement or publication should not, among other things:
  - include incorrect, false, deceptive or misleading information or statements;
  - include superlative statements or information on the excellence of the health facility;
  - advertise health facilities or health workers not located in Indonesia or that are unlicensed; or
  - advertise medicine, supplements or medical devices:
    - that have no marketing authorisation or do not comply with safety and quality standards;
    - are available only on prescription;
    - psychotropic substances; or
    - narcotic substances, except in a medical science magazine or forum;
  - provide testimony as an advertisement or publication in mass media; or
  - promote sales (including discounts) or earn commission on the use of a health facility, or multi-level marketing schemes.

Law stated - 03 November 2022

e-Commerce

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

No specific regulation governs e-commerce for digital health offerings in Indonesia. However, the following rules that govern e-commerce, in general, might be relevant:

Aspect	Notes	Material licences
E-commerce activities that are carried out either: 1. by using e-commerce facilities created and managed directly by themselves; 2. through a facility owned by a foreign e-commerce operator; or 3. other electronic systems that provide an e-facilities platform.	Relevant to any undertakings that carry out e-commerce activities under points (1), (2) or (3) must obtain the E-Commerce Trading Licence (SIUPMSE)	the SIUPMSE
Operation of an electronic system (for both commercial and non-commercial purposes)	Covers all electronic transaction	Registration as an electronic system provider with the MCIT Certification of Security of Electronic System (either by the International Organization for Standardization or National Cyber Encryption Agency, as relevant)
Operation of payment services that include the operation of payment gateway, electronic wallet or electronic money	Held by various companies that act as payment services providers such as Midtrans, DOKU, iPaymu, GoPay, Ovo, DANA, LinkAja, and others	Licence of Payment Service Provider issued by Bank Indonesia

Electronic contract related to digital health	Certain prescribed terms are mandatory (regardless of the governing law of the contract) in an electronic contract between the digital health services undertakings and the user (patients or customers). These include the identity of parties (including the capacity and authority of the representative of the buyers to enter into the contract), specifications of the traded goods and services, the legality of the goods and services, value of transactions, terms and timing of payment, delivery procedures, return and cancellation rights, and governing law of the agreement. In addition, the contract with the Indonesian party (eg, patients, buyers of medicines, etc) is subject to the requirement under Indonesian language regulations where any agreement entered into with an Indonesian national or Indonesian entity must be made and signed in Bahasa Indonesia. The English-language version can be agreed upon as the prevailing language in the contract. In an electronic contract, an e-signature is considered approval from the relevant signatory.	

Digital signature for electronic contracts	E-signatures are deemed valid and of equal value as conventional signatures, with legal force and effect, if they meet the following requirements: • the data related to the creation of the e-signature (the creation data) (which includes personal, biometric or cryptographic code or codes produced from a change from a manual signature to an e-signature, including any other code produced from information technology development) must be associated only with the signor (the signature owner); • during the electronic signing process, the creation data must be in sole possession of the signor; • alterations to an e-signature, after signing, are clearly accessible; • alterations to the electronic information associated with an e-signature after signing, are clearly accessible; • a specific method is adopted to identify the signatory; and • there is a specific method to demonstrate that the signatory has given consent to the electronic information related to the transaction. According to the above, an e-signature is produced in digital format from the outset, including the associated data that is an integral part of it. A scanned or photographed conventional signature converted into a digital image does not constitute an s-signature. There are two types of s-signatures; namely, certified e-signature (which is carried by the Indonesian Electronic Certification Authority that is registered with the MCIT) and non-certified e-signature. The significant difference between certified and non-certified e-signatures when presented before the Indonesian court lies in their evidentiary value. According to the elucidation of Government Regulation No. 71 of 2019 on the Provision of Electronic Systems and Transactions, the legal consequence of using a non-certified e-signature (as opposed to a certified one) would be its evidentiary value. In this case, we believe that the evidentiary value of

~~a certified e-signature would be greater than that~~ of a non-certified e-signature.

Law stated - 03 November 2022

PAYMENT AND REIMBURSEMENT

Coverage

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

Under the prevailing regulations on health security, the use of national healthcare must be done through health facilities. As digital health products and services are technically done by the platform provider without going through the health facilities, there is no basis for digital health products and services to be covered in the national healthcare system. Private insurers, upon collaborating with digital health service providers (such as in applications), can provide additional services of digital health products and other services to an existing insured client.

We have not seen the digital health products and services held by private digital health companies covered or reimbursed by the national healthcare system. However, with regard to the covid-19 pandemic treatment in Indonesia, 11 telemedicine platforms have cooperated with the government for the provision of doctor consultation and the delivery of medicine for free reserved for self-isolating covid-19 patients. These platforms include AloDokter, Get Well, Good Doctor, Halodoc, KlikDokter, KlinikGo, LinkSehat, Milfield Dokter, Prosehat, SehatQ and YesDok. Note that regular consultancies and digital health services (other than those related to the coronavirus) are not covered by the government.

In addition, Social Security-Health (BPJS Health) also launched an app on July 2021, which enables the BPJS Health participants to carry out an online consultancy with health providers, who have cooperated with the BPJS via the Mobile JKN. The consultancy is covered by the BPJS.

Law stated - 03 November 2022

UPDATES AND TRENDS

Recent developments

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

In 2019, the Ministry of Health (MoH) developed the Telemedicine Indonesia (Temenin) website that provides teleradiology, tele-electrocardiography, tele-ultrasonography and online consultation services. To date, the government is still working on expanding the type of services that can be provided by said website. This shows the government is serious in its aim to develop the digital health sector in Indonesia.

In particular, during the covid-19 pandemic, the government has paid more attention to the digital health sector as a way of preventing the spread of the coronavirus through the provision of health services between doctors and patients. The utilisation of telemedicine in Indonesia was formerly limited to services among health services facilities. However, certain regulations are now being issued to provide a basis and guidelines for doctors when using telemedicine directly with patients during the covid-19 pandemic, including the issuance of Regulation No. 74 of 2020 by the Indonesian Medical Council.

The MoH also maintains a new all-record system of big data, which is integrated with 936 laboratories in Indonesia, so that the laboratory testing of polymerase chain reactions and antigens will be sent directly to the MoH in real time.

In addition, the MCIT has now provided an app integrated with health information and facilities (including information

on vaccinations and the registration, and issuance of vaccination certificate health information and data of covid-19 patients) under the PeduliLindungi. This app is also being used as a prerequisite for tracking the entering into some public areas such as shopping malls, restaurants, airports and others.

The MoH Digital Transformation Office (DTO) has also launched its Blueprint of Digital Health Transformation Strategy 2024 , partnering with the United States Agency for International Development. In principle, the government supports and encourages the utilisation of digital technology for public health in the future, including the identification of a strategy to deal with health issues and focus on a health ecosystem, and data integration.

As a follow-up to the MoH DTO blueprint, in April 2022, the MoH launched its Indonesia Health Services (IHS) platform for beta testing. The IHS can be accessed by health service facilities and health sector business undertakings (namely, hospital owners or their management, owners of pharmacies, the management of laboratories, clinics, digital health industry practitioners, manufacturers of medical equipment and pharmaceuticals, and related professional associations). Beta-testing IHS includes résumés of medical records, health services related to the covid-19 pandemic and laboratory services. The MoH has adopted a platform-as-a-service infrastructure, which integrates all ecosystems of business undertakings in the health sector to create national health data.

In addition, the MoH aims to integrate all digital-based health services in hospitals and public health centres within Aplikasi Sehat Indonesiaku no later than December 2023, specifically for recording children's vaccinations.

Health technology aims to function as digital-based services, so that telehealth facilities can reach patients and support interactions with doctors, regardless of distance. The PeduliLindungi app, currently in use to track the incidence of the coronavirus and vaccinations, will be expanded to also integrate data on blood tests and other health scans.

Law stated - 03 November 2022

Jurisdictions

Australia	Gilbert + Tobin
Czech Republic	dubanska & co
France	Intuity
Germany	Ehlers Ehlers & Partner
India	Chadha & Chadha Intellectual Property Law Firm
Indonesia	ABNR
Ireland	Mason Hayes & Curran LLP
Israel	Naschitz Brandes Amir
Japan	Anderson Mōri & Tomotsune
Qatar	Al Marri & El Hage Law Office
South Korea	Bae, Kim & Lee LLC
Spain	Baker McKenzie
Switzerland	Lenz & Staehelin
Thailand	Baker McKenzie
United Kingdom	Latham & Watkins LLP
USA	Seyfarth Shaw LLP