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HEALTH-TECH IN INDONESIA

MARKET TRENDS, REGULATORY OVERVIEW AND DEVELOPMENTS DURING THE COVID-19 PANDEMIC

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Health-tech in Indonesia

As the Covid-19 pandemic continues to affect day to day life in Indonesia, Indonesians are increasingly turning to online means to obtain health-related information and advice, to consult with doctors, and to purchase medication.

The availability of reliable medical information and treatment options through online sources is crucial at a time when millions of people face government-imposed restrictions on their movement. With traditional brick-and-mortar hospitals and clinics experiencing large numbers of patients and individuals staying at home to avoid exposure to the new coronavirus, health-tech businesses in Indonesia are experiencing a surge of user activity in terms of the number of downloads and return users.

With the fourth largest population in the world, Indonesia has immense potential for the development of digital health technology business in the medium and longer term. Health technology innovations are anticipated to facilitate Indonesia's population of more than 260 million to obtain fairer access to quality health services. Access to quality health services and medical advice, particularly in remote areas of Indonesia's 17,000+ islands is often lacking. Big cities in Indonesia such as Jakarta face traffic congestion issues, where it can take hours to get to and from a medical appointment.

The sudden onset of Covid-19 is accelerating the rate of user acquisition for health-tech start-ups and shifting perceptions around the need for face-to-face consultations much faster than anyone could have predicted. This trend, coupled with increased awareness by the Indonesian government (as a result of Covid-19) of the importance of health security[1] is creating impetus for growth and new opportunities in this sector.

On 7 April 2020 the Indonesian Food and Drug Authority (BPOM) issued Regulation No. 8 of 2020 on the Supervision of Online Circulation of Food and Drugs (New BPOM Regulation), which establishes a clearer legal basis for the sale, distribution and delivery of medication via online platforms. Draft versions of the regulation have been publically available and in circulation since late 2018. The issuance of the New BPOM Regulation is a timely development to address the sudden and increased need of Indonesians to purchase medication online as a result of the Covid-19 pandemic. An overview of the New BPOM Regulation is provided below.

In addition to the New BPOM Regulation, two other regulations have been issued which give a legal basis for the temporary provision of online medical practices during the pandemic, namely:

- Regulation of the Indonesian Medical Council (Konsil Kedokteran Indonesia) No. 74 of 2020 on the Clinical Authority and Medical Practice through Telemedicine during the Corona Virus Disease 2019 Pandemic in Indonesia (IMC Covid-19 Regulation), which was issued on 29 April 2020; and
- Circular Letter of the Indonesian Ministry of Health dated 29 April 2020 (MOH Covid-19 Circular Letter).[2]

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1. https://asia.nikkei.com/Spotlight/Coronavirus/Indonesia-deals-with-dueling-outbreaks-as-dengue-cases-spike

2. Circular Letter No. HK.02.01/MENKES/303/2020 on the Implementation of Healthcare Services through the Utilisation of Information Technology and Communication in order to prevent the Spread of Coronavirus Disease 2019.

In essence, the intent of the IMC Covid-19 Regulation and MOH Covid-19 Circular Letter is to provide legal certainty and guidance for doctors to conduct online medical practices via information technology/electronic systems during the pandemic.

Unlike the New BPOM Regulation, the IMC Covid-19 Regulation and MOH Covid-19 Circular Letter are valid only for the duration of the Covid-19 pandemic in Indonesia, and will be suspended once the Indonesian government has declared that Indonesia is no longer facing a Covid-19 health emergency. The post-pandemic legal status of online medical practices remains unclear. Some further considerations on the IMC Covid-19 Regulation and MOH Covid-19 Circular Letter are set out below .

On 5 May 2020 the Indonesian Honorary Board of Medical Ethics (Majelis Kehormatan Etika Kedokteran or MKEK) issued Decree No. 017/PB/K. MKEK/05/2020 (MKEK Decree), which encourages healthcare services facilities, associations and doctors to use telemedicine services and other online health-tech platforms during the Covid-19 pandemic while still taking into account applicable laws and medical codes of conduct and ethics. The use of online medical practices will be reassessed by MKEK post-pandemic.

Indonesian health-tech market

The Indonesian health tech sector is relatively nascent compared to other countries. However, changes in the medical system over the last 10 years uniquely position Indonesia in this space. Internet and smartphone penetration continues to grow across the archipelago, and technology infrastructure is increasingly moving to cloud-based services. These trends have led to a growing ecosystem of health-tech start-ups at various stages of development.

Key health-tech innovations in Indonesia to date are primarily focussed on platforms which connect patients to doctors, healthcare services facilities (eg, hospitals and clinics) and medicine through mobile application marketplaces. Other businesses are focussed on SaaS solutions for hospitals and clinic administration, and the provision of technology and digital solutions for delivery of healthcare services (eg, medical device technology and smart clinic vehicles).

In 2019, the Minister of Health of the Republic of Indonesia (MOH) issued Regulation No. 20 of 2019 on the Implementation of Telemedicine Services among Healthcare Services Facilities, which established a legal basis for qualified hospitals to provide telemedicine consultation to other hospitals, clinics and other healthcare service facilities (eg, countryside clinics) that are in need of certain expertise which is not yet available. The adoption of telemedicine services between healthcare services facilities would require application of reliable technology which would in turn create more opportunities for health-tech players that provide innovative healthcare technology solutions.

We explore below how the Covid-19 pandemic has accelerated development of the health-tech sector in Indonesia, with more regulatory guidance being issued to deal specifically with the Covid-19 situation. The extent to which this development can be sustained once the immediate emergency is over remains to be seen.

Overview of regulatory framework for health-tech platforms

The terms telemedicine, telehealth, eHealth and health-tech are often used interchangeably to describe a broad concept within the healthcare sector involving the use of information technology (through mobile and desktop software applications) to facilitate access to medical services for the general population, and software solutions for medical and other institutions. For purposes of this article, we will use "health-tech" as the umbrella term.

Indonesia's health-tech regulatory framework is still in its infancy, with developments in the sector outpacing the ability of regulators to regulate the various activities that may fall under the term "health-tech". Aside from the IMC Covid-19 Regulation and MOH Covid-19 Circular Letter ,which only provide a temporary legal basis for provision of online medical practices via information technology/electronic systems during the pandemic, the broader regulatory framework is a piece-meal collection of regulations dealing with various aspects of the health-tech business.

Below we highlight some of the key regulatory points and recent developments that need to be considered in relation to health-tech businesses.

The future looks bright for Indonesia's emerging health-tech industry.

Foreign ownership restrictions

Depending on the type of health-tech business model, foreign ownership restrictions may apply. The applicable foreign ownership restrictions depend on the thresholds permitted under the Indonesian Negative List[3] by reference to the KBLI code[4] applicable to each relevant business activity.

For example, companies providing health-tech platforms acting as a "two-way" or intermediary platform between users and healthcare service providers are likely to be categorised as conducting a digital platform business activity under KBLI Code 63122. A company providing health-tech technology solutions and health-tech SaaS software to clients, such as data processing software or management solutions for hospital or clinic administration, is likely to be categorised as a general software publisher, computer programmer, integrated hardware and software solutions provider, or data processor (KBLI Code 58200, 62019, 62029 or 63111).

The KBLI Codes mentioned above are currently open to 100% foreign ownership. However, for a KBLI Code 63122 business to be 100% open to foreign investment, a minimum capital investment of at least IDR100 billion (USD6.7 million) is required. For the other KBLI codes, there is a general requirement for a minimum investment of more than IDR10 billion (USD660,000). In relation to KBLI Code 63122, if the capital investment is below IDR100 billion, foreign ownership will be restricted to a maximum of 49%.

From a legal standpoint, the core principle for companies engaging in the health-tech business is that they should focus on the scope of activities permitted under their KBLI Code, and as far as possible avoid undertaking any activities outside the permitted scope of their KBLI Code. For example, health-tech platform providers should avoid engaging in activities as a healthcare services facility, such as clinics, which are subject to stricter foreign investment restrictions and more complex MOH licensing requirements.

Scope of online consultation services

As mentioned above, the IMC Covid-19 Regulation and MOH Covid-19 Circular Letter provide a temporary legal basis for doctors to perform their medical practice through a health-tech platform. In particular, the MOH Covid-19 Circular Letter set outs the authority of doctors to perform health-tech services, covering:

(i) performing anamnesis;

(ii) performing physical examinations through audio-visual media;

(iii) providing advice based on physical and/or supporting examination;

(iv) establishing diagnoses;

(v) performing medical treatment;

(vi) issuing prescriptions; and

(vii) issuing reference letters for further physical examination at healthcare services facilities and laboratories.

The IMC Covid-19 Regulation also states that doctors may issue a "letter of illness" (surat keterangan sakit) to their patients, but are restricted from issuing health certificates (surat keterangan sehat) to patients. We note that under the IMC Covid-19 Regulation doctors are prohibited from conducting online medical practices directly for patients without going through a healthcare services facility (such as a hospital or clinic). Accordingly, third party health-tech platforms must cooperate with healthcare services facilities to allow doctors from those facilities to provide online medical practices.

In providing online medical practices, doctors must also ensure that medical records are stored with the relevant healthcare services facility and that they obtain a registration certificate (Surat Tanda Registrasi or STR) and practice licence (Surat Izin Praktik or SIP) at the relevant healthcare services facility. Doctors are also prohibited from charging fees that differ from the tariffs set by the healthcare services facility concerned.

3. The "negative list" is a series of Presidential Regulations issued over time by the Indonesian Government which sets out an evolving list of sectors that are either completely closed or partially open to foreign direct investment.

4. The Indonesian Standard Business Classifications (Klasifikasi Baku Lapangan Usaha Indonesia or KBLI List) codifies various lines of business and details their associated business activities under KBLI codes. Each company has its KBLI codes on its business licence, setting out the activities it may undertake. The KBLI list is updated by the Indonesian government from time to time, most recently in 2017.

Looking beyond the current pandemic, when the IMC Covid-19 Regulation and MOH Covid-19 Circular Letter may no longer be valid, it appears that the regulatory framework will again become silent in relation to online consultations carried out by doctors through health-tech platforms. Accordingly, post-pandemic, the permitted scope and method of online consultations by doctors through health-tech platforms remains unclear.

However, in performing medical practices, doctors are bound by their code of conduct, which is issued and administered by the Indonesian Medical Association (Ikatan Dokter Indonesia or IDI), including the relevant diagnostic protocols applicable to each patient's condition when providing online consultations. In practice, doctors may interpret their obligations under the IDI code of conduct differently. With respect to online consultations, this may influence the assessment of whether a doctor can make a diagnosis and issue prescriptions solely via an online consultation, or whether further physical examination is required in order to do so.

As such, post-pandemic, precisely how health-tech platform operators determine the type and permitted scope of online consultations that can be provided by medical professionals through their platform requires careful consideration. Considering the lack of a regulatory framework, once the Covid-19 emergency passes in Indonesia (and in the absence of substitute regulations to replace the IMC Covid-19 Regulation and MOH Covid-19 Circular Letter), the safest approach might be to revert to the position commonly taken by health-tech platforms prior to the pandemic. This would mean that online consultations conducted by doctors through health-tech platforms would be limited to providing general health advice or else be structured as non-medical practices, particularly where the health-tech platform partners directly with individual doctors (ie, not through a healthcare services facility) who provide online consultations directly to customers and patients.

Facilitating the sale and delivery of drugs (Pharmaceutical Electronic System Operators)

As mentioned above, on 7 April 2020 BPOM issued the New BPOM Regulation. The scope of the New BPOM Regulation goes beyond the sale and delivery of drugs to also cover the sale and delivery of health supplements, cosmetics and processed foods using e-commerce facilities.

Under the New BPOM Regulation, licensed pharmaceutical manufacturers, pharmaceutical wholesale traders (and branches) and pharmacies are permitted to supply drugs online using electronic systems, provided they make periodic reports to BPOM on these activities.

While pharmaceutical manufacturers and pharmaceutical wholesale traders (and branches) can only supply drugs online using their own electronic systems, pharmacies (which supply the drugs to patients and end-consumers) may use third party electronic systems in addition to their own. These third parties are defined as Pharmaceutical Electronic System Operators (Penyelenggara Sistem Elektronik Farmasi or PSEF). A PSEF must report its activities in facilitating online supply of drugs to the relevant authority. Pharmacies and PSEF must take steps to:

(i) ensure the security and quality of the drugs being delivered;

(ii) include product, label and/or usage information for such drugs;

(iii) ensure confidentiality of the delivery content;

(iv) deliver the drugs in a closed container;

(v) ensure the drugs are delivered to the intended recipient; and

(vi) document the handover of the drugs from the pharmacy/third party delivery service to the intended recipient.

These obligations are broadly drafted.

Pharmacies may deliver the online supplied drugs to patients either directly or indirectly (ie, using a delivery service such as Grab or Gojek). The New BPOM Regulation states that third party delivery service providers involved in the online circulation of drugs are prohibited from providing any information on the drugs. The New BPOM Regulation does not explain this prohibition, but it may be intended to avoid patients receiving inaccurate information on the drugs from the third party provider (which will likely lack sufficient

The Covid-19 pandemic has accelerated regulatory developments in Indonesia's health-tech sector, as the government and medical profession respond to the rapid pace of innovation.

knowledge). In practice, this would require pharmacies to provide patients with as clear information on the drugs as possible, either in writing or via the online platform.

The MOH Covid-19 Circular Letter emphasises that pharmaceutical products can be delivered through a third party delivery service or PSEF while the pandemic is ongoing. The delivery service or PSEF must ensure the security and quality of the products being delivered, maintain patient confidentiality, deliver the products in a closed and non-transparent container, ensure the delivery reaches the intended person, document the handover of the product, and provide delivery documentation and a reachable contact number. The MKEK Decree clarifies that the packaging used for delivery of the drugs must be neatly sealed and must not reveal the name or characteristics of the drug to the third party delivery service or any other party. In addition, the drugs must be received and signed for directly by the patient.

The New BPOM Regulation notes that only (i) non-prescription drugs (ie, obat bebas and obat bebas terbatas) and (ii) prescription drugs that fall under the category of 'hard' drugs (obat keras) may be supplied online. This means that drug precursors cannot be supplied online. Prescription drugs must be supplied based on a valid prescription (i) which is written in electronic form and delivered via a specific feature in the electronic system, or (ii) by uploading a copy of the original prescription into the electronic system, provided that the original prescription must be delivered by the patient simultaneously with the delivery of the drugs by the pharmacy (either directly or indirectly via third parties). Further details on e-prescriptions can be found below .

Pharmacies and PSEF are prohibited from distributing the following categories of drugs:

(i) certain prescription drugs which are prohibited under prevailing regulations;

(ii) drugs which include pharmaceutical precursors;

(iii) drugs for erectile dysfunction;

(iv) insulin injections for self-use;

(v) implants requiring assistance from healthcare providers; and

(vi) drugs which fall under narcotic and psychotropic categories.

E-prescriptions

As mentioned above, the New BPOM Regulation has made it clear that prescription drugs supplied online must be based on a valid prescription in electronic form (E-prescription). The pharmacy and PSEF must ensure that the electronic system used for online supply of drugs must include a feature enabling delivery of E-prescriptions. In addition, the MOH Covid-19 Circular Letter clarifies that the authority of doctors to perform their medical practices online also covers the issuance of prescriptions (including E-prescriptions) while the pandemic is still ongoing.

Prior to the New BPOM Regulation and the Covid-19 pandemic, the concept of E-prescriptions was already recognised by MOH Regulation No. 72 of 2016 on Standards for Pharmaceutical Services in Hospitals and MOH Regulation No. 73 of 2016 on Standards for Pharmaceutical Services in Pharmacies. However, the general interpretation is that the concept of E-prescriptions under these two regulations is limited to prescriptions given by a doctor under an "integrated Hospital Management Information System" (Sistem Informasi Manajemen Rumah Sakit) – a closed-loop system where a hospital has its own system of sending prescriptions electronically to its "in-house" pharmacy after conducting physical examinations of patients.

Notwithstanding the above, after the Covid-19 emergency ends in Indonesia (and in the absence of regulations to replace the IMC Covid-19 Regulation and MOH Covid-19 Circular Letter), the regulatory position will once again become silent on whether prescriptions can be issued electronically based on a consultation via health-tech platforms, ie, without a doctor performing a physical examination to establish the diagnosis. Before the pandemic, the view of IDI and MOH officials was that before doctors could issue a drug prescription, they first had to make a diagnosis based on anamnesis, a physical examination and supporting tests/ examinations (as required) as part of a face-to-face consultation with the patient.

It is unclear whether the same treatment for issuing E-prescriptions will apply post-pandemic. Given the current lack of any post-pandemic regulatory basis, doctors may well have to again refer to their code of conduct when considering this issue. As noted above, doctors may interpret their obligations under the IDI code of conduct differently.

Liability for misdiagnosis and malpractice

Health-tech platforms typically adopt a business model where they act as an intermediary between doctors and patients. On that basis, any misdiagnosis or malpractice will generally become the liability of the doctor in his or her individual capacity. Broadly speaking, the liability of platforms as an intermediary marketplace is limited to the provision of the electronic system and the content management obligations associated with operating the platform. This includes obligations as an Electronic System Operator (ESO) or (if the ESO facilitates online supply of drugs) PSEF in relation to personal data protection (see below).

Insurance products

Health insurance products offered via health-tech platforms require separate consideration of the regulatory requirements of Indonesia's Financial Services Authority (OJK). Issues that need to be considered include whether the platform requires an insurance agent or brokerage license. To avoid falling under the OJK regulatory regime, health-tech platforms should focus on being a distribution platform for insurance companies offering products and patients/customers. The nuances of how insurance offerings are structured need to be carefully considered.

Patient data protection

Health-tech businesses are subject to data security requirements, which are particularly important given sensitivity of individual medical information. Please see our articles on recent regulatory developments in Indonesia's personal data protection space (here and here).

Where to from here?

The future looks bright for Indonesia's emerging health-tech industry. While the absence of a clear regulatory framework creates uncertainties for investors, entrepreneurs and medical professionals, the Covid-19 pandemic has accelerated regulatory developments and the Indonesian government and medical profession's response to the rapid innovation in this sector, as reflected in the New BPOM Regulation, the IMC Covid-19 Regulation and the MOH Covid-19 Circular Letter.

Some major hospital operators in Indonesia (including Siloam, Pondok Indah and Mitra Keluarga) have also launched online consultation or telemedicine services either via their own applications or in cooperation with a health-tech platform, in an attempt to secure a portion of the growing telemedicine market, particularly as patient visits decline during the pandemic. It is no surprise that the use of telemedicine has blossomed during the pandemic, but its continued growth may depend on the nature of any regulations introduced by the government post-pandemic.

Any future regulatory developments will be a balance between (i) the need for a clearer regulatory framework to put in place the right conditions for more investment to flow into the sector and (ii) the need to ensure that patients receive proper, safe and secure diagnostic care when consulting with medical professionals online, noting the limitations that doctors and patients face in an online consultation setting as compared with a face-to-face consultation.

Issues that may be covered in future regulations include:

- consideration of the legal basis for how doctors or healthcare services facilities partner/cooperate with health-tech platforms,
- data protection for patients utilising health-tech platforms,
- quality of care through online consultation,
- patient confidentiality,
- attribution of liability connected with standard of care, and
- patient safety.

At present, the regulatory authority governing health-tech companies is split between MOH (including professional organisations such as the Indonesian Medical Council, IDI and MKEK) and the Indonesian Ministry of Communication and Informatics. It remains to be seen whether a more consolidated regulatory approach may be possible in the future.

What is clear is that while a more fully developed regulatory framework may take time, enterprises and entrepreneurs are not letting the lack of regulation curb innovation. The growth of Indonesia's health-tech sector has been accelerated by the current pandemic, but we do not yet know how far this will be sustained once the pandemic is over.

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