DENTONS HPRP

INDONESIA: THE LEGAL FRAMEWORK FOR DIGITAL HEALTH PLATFORMS

The challenges of the COVID-19 pandemic have established a sense of urgency in the need for accurate, reliable, and timely data to respond to people's health concerns. Now that going to hospitals, clinics, or pharmacies for medical attention is perceived as inconvenient, it is crucial for people to receive immediate medical guidance and medicine through such means as teleconsultations and telemedicine. We also recognize that an immediate demand for digital transformation has emerged, necessitating the possibility of remote working and the continued provision of health care services in the face of pressures to maintain safety measures, causing the health services sector to become one of Indonesia's fastest growing sectors today.

In this post-pandemic era, patients' expectations of health care and services are at their highest. Patients are more aware of their needs and rights, including their options and desire to easily access their health information and obtain the best healthcare and treatment at the best price, location, and schedule most suitable to their needs. With the foregoing needs in mind, digital health which provides easy access to health care is a solution sought after by patients.

Further, considering the fact that Indonesia is the largest archipelago in the world, access to health care may be restricted in remote areas, providing opportunities for digital health, which, through health applications, has the potential to improve the general accessibility and efficiency of healthcare. Telemedicine, e-pharmacy, and online lab testing (online appointments and home services) are just a few of many examples of medical services that can be provided and enhanced through health applications as an intermediary platform. In this article, we will discuss a brief overview of the establishment of health apps as an intermediary platform for people to gain better access to health care services.

WHY INDONESIA?

With the rise of digital health, including the establishment of digital health apps, the investment climate for digital health technology in Indonesia is favourable and promising, both offshore and onshore. This is consistent with the opportunities with significant potential that have resulted from the rapid expansion of internet accessibility and consumption (the fastest growing in South East Asia). Indonesia, the world's fourth-biggest country by population, has a young demographic and is positioned to become the biggest market for technology-driven products, such as digital apps.

With the COVID-19 pandemic making digital health tools essential, now is the time and opportunity to develop strategies to preserve such added value and address the role of stakeholders in this market. To accommodate such a rapidly expanding business, the Ministry of Health issued the *"Blueprint for Digital Health Transformation Strategy 2024"* in 2021, which includes numerous areas and approaches that Indonesia will be using to build digital health in Indonesia.

The future of Indonesia's expanding health-tech industry is promising. While the lack of a comprehensive legal framework creates uncertainty for investors, entrepreneurs, and medical professionals, the COVID-19 pandemic has spurred regulatory reforms from the government as well as the medical profession's response to this sector's rapid innovation.

INVESTMENT AND ESTABLISHMENT

The business activities of digital health apps which only act as an intermediary platform for medical services may be categorised under Klasifikasi Baku Lapangan Usaha Indonesia (*Indonesian Standard Industrial Classification* - "**ISIC**") No. 63122 (Web Portal and/or Digital Platform With Commercial Purpose). According to the Indonesian Positive Investment List[1], ISIC 63122 is open to 100% foreign investment, which provides massive investment opportunities for foreign investment.

As an investment mechanism, offshore investors can participate in establishing a foreign investment company in Indonesia ("**PMA Company**"), regarding which BKPM Reg 4/2021[2] provides that a PMA Company (i) must have a minimum of IDR 10,000,000,000.00 (ten billion Rupiah) (around USD 700,000 depending on the exchange rate at the time of investment) issued and paid-up capital and (ii) must have a investment value equal to or greater than IDR 10,000,000,000.00 (ten billion Rupiah) for each KBLI number (line of business), excluding land and building.

LICENSES

As to the preparation stage prior to commencing its business, a PMA Company must obtain a business identity number (*Nomor Induk Berusaha* or "**NIB**") through the Online Single Submission ("**OSS**") platform.

In addition to the above, a PMA Company may only be able to begin its operational/commercial activity upon obtaining a business license which needs to be assessed based on a risk-based approach as mandated by GR 5/2021. A business license will be granted after the PMA Company has met certain requirements and been verified by the relevant government body.

Given its role as an intermediary platform, generally, there is still no specific operational licensing requirement for the health apps platform itself. However, investors must be aware that any individual, business entity, or the public which has portals, sites, or applications that are utilized to provide services and process personal data for operational activities by way of an electronic system falls under the scope of a Private Electronic System Operator (*Penyelenggara Sistem Elektronik Privat* or "**Private PSE**").

Further, it is worth noting that such Private PSE must obtain an Electronic System Operator Certificate (*Sertifikat Penyelenggara Sistem Elektronik* or "**PSE Certificate**") from the Minister of Communications and Informatics of the Republic of Indonesia. An article on the detailed registration process for obtaining a PSE Certificate can be found here.

PHARMACEUTICAL ELECTRONIC SYSTEM OPERATORS

For the health app intermediary platform which provides e-prescribing and sale of medicines to the users or patients (e-pharmacy), there is a licensing requirement that must be taken into consideration by both the merchant and the intermediary platform actors.

The National Agency of Drug and Food Control ("**NADFC**") regulates that licensed pharmaceutical manufacturers including pharmaceutical wholesalers, pharmacies, and/or drugstores are authorised to supply medicines (including cosmetic products and food supplements) through electronic systems, provided that the electronic systems, such as health apps, have obtained a PSE Certificate.

[1]Presidential Regulation No. 10 of 2021 concerning Investment Business Fields as amended by Presidential Regulation No. 49 of 2021.

[2]Regulation of The Investment Coordinating Board of The Republic of Indonesia No. 4 of 2021 concerning Guidelines and Procedures for Risk-Based Business Licensing Services and Investment Facilities.

Several points should be noted, among others that business actors providing medicines are required to submit periodic reports on their activities to the NADFC. Additionally, the NADFC requires pharmaceutical manufacturers and wholesalers to sell medicines online exclusively through their own electronic systems. In contrast, pharmacies (which provide medications to patients and end-consumers) may utilize third-party electronic systems to complement their own.

Third-party electronic systems utilized by pharmacies such as health apps must also apply for Pharmacy Electronic System Operator Certificate (*Sertifikat Penyelenggara Sistem Elektronik Farmasi* or "**PSEF Certificate**") as required by NADFC Reg 8/2020[3].

Digital health services are also subject to the same licensing and authorization requirements as are applicable to other business methods for the provision of health services. A party involved in the e-commerce industry (e.g., doctors, pharmacies, pharmaceutical manufacturers, and wholesalers) must obtain the necessary licenses to undertake their activities. Similarly, any medicine provided online must be registered and have the relevant permits, including marketing authorization, as if it were distributed offline.

[3]The National Agency of Drug and Food Control Regulation No. 8 of 2020 concerning Supervision of Drugs and Food Distributed Online as amended by National Agency of Drug and Food Control Regulation No. 32 of 2020.

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