



INDONESIAN MINISTRY OF HEALTH'S REGULATORY SANDBOX POLICY ON DIGITAL HEALTH INNOVATION

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Abstract. The collaborative approach to regulatory development is known as the Regulatory Sandbox, a regulatory development approach designed to encourage more adaptive regulations for digital innovation. The Regulatory Sandbox is designed to test digital innovation products or business models in a limited environment (sandbox) with direct government oversight. However, since the implementation of the regulatory sandbox for digital health innovation in 2023, no specific regulations have been established for digital health innovation. The purpose of this study is to inventory the legal basis for digital health innovation in health legislation and analyze their synchronization. This study uses a normative juridical method with specifications for legal inventory and legal synchronization. The results of this study indicate that the Decree of the Minister of Health Number HK.01.07/MENKES/1280/2023 concerning the Development of a Digital Health Innovation Ecosystem Through a Regulatory Sandbox is not in sync with Government Regulation No. 28 of 2024 concerning the Implementing Regulations of Law No. 17 of 2023 concerning Health, so it is necessary to immediately formulate regulations in the form of a Regulation of the Minister of Health that regulates the regulatory sandbox for digital health innovation with a new term, namely health technology innovation.

Keywords: Digital Health Innovation, Policy, Indonesian Ministry of Health, Regulatory Sandbox, Synchronization.

1. Introduction

Global technological developments have driven various digital innovations in technology, management, and healthcare services. One strategic aspect of the development of healthcare digitalization is the growth of healthcare innovations developed by digital healthcare providers. The government must respond to this situation by providing adaptive incentives and emphasizing a collaborative approach, so as not to hinder the sustainability of innovation. At the same time, the government also has an obligation to ensure the protection of healthcare workers and the public as beneficiaries of the services provided by digital healthcare providers.

The government's initiative to respond to digital health innovations is implemented through adaptive regulatory development. Therefore, a collaborative regulatory approach is needed, in which the government acts not only as a policymaker but also participates in monitoring and evaluating the business processes of digital health innovation providers, then collaboratively formulates regulatory substance deemed accommodative within a regulation.

The collaborative approach to regulatory development is known as the Regulatory Sandbox, a regulatory development approach designed to encourage more adaptive regulations for dynamic, disruptive digital innovation. Simply put, the Regulatory Sandbox is designed to test digital innovation products or business models in a limited environment (sandbox) with direct government oversight. This approach is also expected to help regulators anticipate the impact and uncertainty of new technologies, both intentional and unintentional, on the public and all components of the ecosystem, while also providing opportunities for digital health innovation



providers to continue growing and developing. The Regulatory Sandbox is considered a solution to encourage more adaptive regulation for digital innovation because it is based on real-world conditions from various processes that are gone through and assessed together (1).

Approach was initially used by the financial technology industry in more than fifty countries, including Indonesia through the Financial Services Authority and Bank Indonesia, to accommodate innovation in the financial services sector. Otoritas Jasa Keuangan (OJK) Regulation Number 13 /POJK.02/2018 concerning Digital Financial Innovation in the Financial Services Sector defines the Regulatory Sandbox as a testing mechanism conducted by the Financial Services Authority to assess the reliability of business processes, business models, financial instruments, and governance of the Organizer. The OJK in Indonesia uses the Regulatory Sandbox to oversee the development of fintech financial technology innovation businesses (2).

The era of digital disruption in healthcare cannot be achieved as quickly as in other sectors, such as e-commerce and banking. The healthcare sector needs to adopt healthcare technology in a gradual and measured manner. One form synonymous with digital health innovation is telemedicine technology. Furthermore, rapidly developing healthcare technology business models in Indonesia include teleconsultation, on-demand healthcare, e-learning systems, e-commerce, and marketplaces.

Telemedicine is a remote health service provided by healthcare professionals using information and communication technology. This service includes the exchange of information on diagnosis, treatment, disease and injury prevention, research and evaluation, and continuing education of healthcare providers for the benefit of improving individual and community health (3). Telemedicine has positive impacts, including reduced travel time, increased access to healthcare services, particularly for rural populations, and reduced disparities in healthcare among hard-to-reach populations. Despite its positive impact, telemedicine also requires additional analysis regarding interventions where providers encounter patients with multiple diagnoses and require physical examinations, diagnostic tests, or both (4).

Telemedicine refers to healthcare services provided by healthcare providers through information and communication technology. One aspect of this service is providing information for diagnosis, treatment, disease progression, injury management, research, and educational evaluation. Patient safety and service quality are ensured while upholding the authority and competence of doctors, as evidenced by the Registration Certificate obtained in accordance with the doctor's competence and authority. Telemedicine services are now not only audio-based but also visual through video, thereby improving the effectiveness of consultations as well as supervision (5). The Regulatory Sandbox is crucial because it is expected to accommodate several functions, including monitoring and testing business models, bridging the needs of businesses and the government, ensuring business continuity for digital healthcare providers, and protecting the public as beneficiaries of healthcare services.

The implementation of the Ministry of Health's regulatory sandbox is based on the Decree of the Minister of Health Number HK.01.07/MENKES/1280/2023 concerning the Development of a Digital Health Innovation Ecosystem Through a Regulatory Sandbox. The Indonesian Ministry of Health, through the Center for Data and Information Technology and the Digital Transformation Office (Pusdatin-DTO), announced the results of a trial of 14 Digital Health Innovation providers participating in the Telehealth Cluster Regulatory Sandbox Program. Six Digital Health Innovation providers were 'Conditionally Recommended' and automatically received 'Mentored' status. The six Digital Health Innovation providers consist of Good Doctor, Halodoc, Alodokter, Sirka, Sehati TeleCTG, and Naluri (6).

Seeing the increasingly widespread development of digital health innovation without specific regulatory protection, resulting in minimal oversight and the risk of endangering the public as users of digital health innovation products, the Ministry of Health sees an opportunity



in implementing a Regulatory Sandbox in the field of digital health innovation as a solution to encourage the growth of safe and precise health technology. However, on the other hand, technological disruption also creates new challenges related to regulations in the health sector, particularly regarding the compliance of digital health innovation providers with applicable health regulations and ethics. Next, this paper will discuss how the regulatory sandbox for digital health innovation in Indonesia is regulated and whether it is in sync with Indonesian health laws.

2. Methods

This article uses a normative juridical method, which is a research process to examine and study law as a norm, regulations, legal principles, legal doctrines, legal theories, and other literature to address the legal issues being researched (7). The research is carried out by inventorying the legislation related to the health digital innovation regulatory sandbox, then tracing the chronology of the establishment of each piece of legislation and analyzing the substance of the regulation of the health digital innovation regulatory sandbox to determine its synchronization with Indonesian health legislation.

3. Results and Discussion

A. Regulatory Sandbox for Digital Health Innovation in Indonesia

The term digital health innovation in Indonesia was first mentioned and regulated in the Decree of the Minister of Health of the Republic of Indonesia Number Hk.01.07/Menkes/1280/2023 about Development of a Digital Health Innovation Ecosystem Through the Regulatory Sandbox. Digital Health Innovation, is business process renewal activities, business models and instruments in framework for organizing health services that provide value new additions to the healthcare sector by involving the digital ecosystem. A Regulatory Sandbox is a framework that allows new technologies or products to be tested in a limited-scale environment to test and assess the product's feasibility in a real-world setting, test regulatory boundaries, assess governance, and user and market reactions to digital health innovations.

In 2023, Law No. 17 of 2023 concerning Health was also passed. The Health Law regulates digital health innovation, termed health technology innovation. Article 337 of the Health Law stipulates that the Central Government and Regional Governments are responsible for encouraging and facilitating the sustainability of health technology innovation and ensuring the safety, benefits, efficacy, and quality of health technology innovation products to protect the public. The Central Government establishes health technology innovation policies. Further provisions regarding the implementation of health technology innovation are regulated by Government Regulation (8).

Government Regulation No. 28 of 2024 concerning the Implementing Regulations of Law No. 17 of 2023 further regulates health technology innovation (9). Article 993 of Government Regulation No. 28 of 2024 stipulates that health technology is implemented through:

- a. Research, Development, and Assessment;
- b. Implementation of Health Technology Innovation;
- c. Health Technology assessment; and
- d. Utilization of Health Technology.

Article 1015 of Government Regulation No. 28 of 2024 stipulates that health technology innovation is any form of renewal of health technology that is able to increase the accuracy, speed, safety, and quality of Health Resources and Health Efforts. The implementation of health technology innovation can be carried out by the Central Government, Regional



Governments, and/or the community. Furthermore, Article 1016 stipulates that the Central Government implements policies to ensure the sustainability and benefits of health technology innovation through limited-scale testing of health technology, as well as ease of innovation in the form of licensing, utilization of health technology products and development of the health technology innovation ecosystem. Limited-scale testing as referred to in paragraph (1) is implemented through a collaborative approach across policy stakeholders to encourage:

- a. Innovation Development;
- b. Expanding the Use of Service Products; and
- c. Innovation-Based Policy Formation.

The scope of limited scale testing includes:

- a. Quality of Governance;
- b. Guarantee of Benefits and Security of Technology;
- c. Licensing and Consumer Protection; and
- d. Medical Personnel, Health Workers, and Communities Involved In the Health Technology Innovation Ecosystem.

The Central Government is developing the Health Technology Innovation ecosystem by prioritizing local resources and leveraging domestic and international collaborations. Further provisions regarding limited-scale testing and facilitating innovation are regulated by Ministerial Regulations.

Indonesia does not yet have a Minister of Health Regulation that regulates limited-scale testing of health technology innovations, however, limited-scale testing is regulated through a Decree of the Minister of Health of the Republic of Indonesia Number Hk.01.07/Menkes/1280/2023 about Development of a Digital Health Innovation Ecosystem Through the Regulatory Sandbox. This means that the limited-scale testing arrangements do not comply with Government Regulation No. 28 of 2024. The Decree of the Minister of Health of the Republic of Indonesia Number Hk.01.07/Menkes/1280/2023 about Development of a Digital Health Innovation Ecosystem Through the Regulatory Sandbox, limited-scale testing is regulated under the term regulatory sandbox and health technology innovation is still referred to as digital health innovation.

Decree of the Minister of Health of the Republic of Indonesia Number Hk.01.07/Menkes/1280/2023 about Development of a Digital Health Innovation Ecosystem Through the Regulatory Sandbox regulates the objectives, benefits, targets and guidelines for the stages of implementation of the Regulatory Sandbox. The implementation of the Regulatory Sandbox consists of five stages: registration, recording, testing, recommendations, and coaching. The scope of regulatory sandbox test material covered in the scenario test setup includes: (1)

1. User Acceptance Test (UAT) includes: test plan, test scripts, findings log, a summary of issues and resolutions, User Interface, performance testing;
2. Integration Testing and Technology Standards;
3. Safety Test;
4. Privacy Policy Test;
5. Cluster Specific Test;
6. Inclusivity Test;

The implementation of the new Regulatory Sandbox begins when digital health innovation organizers are selected by the Regulatory Sandbox Implementation Team to enter the Regulatory Sandbox mechanism. Digital health innovation organizers can start by following the registration at the time specified by Ministry of Health. If the digital health innovation organizer is selected, then the organizer will proceed to the Regulatory Sandbox process. The implementation of the Regulatory Sandbox at the trial stage was carried out



until the issuance of recommendations depends on the respective process organizers of digital health innovation. If the organizers of digital health innovation have obtained recommendations will then be included in the first year of coaching. Coaching can be extended or renewed by submitting a request. extension of recommendations to the Ministry of Health.

Ministry of Health will determine the duration of the coaching and will regulate mechanism for revoking or extending the status of foster care. The Ministry of Health will request periodic reports to the organizers of digital health innovations that must be fulfilled as material for evaluation and extension of recommendations, as well as providing other directions if necessary.

The Regulatory Sandbox implementation team can involve associations or the public in overseeing the implementation of the Regulatory Sandbox , in the form of:

1. Support the formulation of operating rules, industry standards, competencies, and codes of ethics, according to different types of businesses;
2. Receive and forward reports and receive complaints from the public or association members;
3. Be a liaison between the Ministry of Health and digital health innovation organizers to improve regulatory support and exchange of information;

Digital health innovation organizers who participated in the implementation Regulatory Sandbox gets incentives in the form of rights to support to obtain participant status identity with include the Ministry of Health logo on business products carried out in accordance with the provisions of the Minister of Health Regulation Number 7 2017 concerning the Use of the Ministry of Health Logo as attached in this guide, with the following provisions:

1. Registered Status, given to digital health innovation organizers who have registered, recorded in the database and announced on the channel official publication of the Ministry of Health after passing verification and validation. Digital health innovation organizers do not have the right to include the Ministry of Health logo on the business platform which are made.
2. Supervised Status, awarded to selected digital health innovation providers following the Regulatory Sandbox since the trial stage. This announced on the official publication channel of the Ministry of Health. Digital health innovation organizers are required to include the Ministry's logo with statement "Supervised by the Indonesian Ministry of Health" on business platform created.
3. Fostered Status, given to digital health innovation organizers who have get recommendations during the coaching stage at Regulatory Sandbox. This was announced on the official publication channel Ministry of Health. Digital health innovation providers are required to include Ministry logo with the caption "Developed by the Ministry RI Health" on the business platform created.

Regulatory Concept Sandbox built by the Ministry of Health on the basis of protection users on the reliability of the technology used by digital health innovations through monitoring and supervision mechanisms, while also being actively involved in provide input to business actors.

B. Synchronization Analysis Regulatory Sandbox for Digital Health Innovation in Indonesia

Synchronization activities are the alignment and harmonization so that the substance regulated in the legislation products does not overlap, is complementary, interrelated, and the lower the type of regulation, the more detailed and operational the content material. The purpose of synchronization activities is to create a regulatory basis for a particular field that



can provide adequate legal certainty for the efficient and effective implementation of that field (10).

The synchronization applied in this paper is vertical synchronization. Vertical synchronization is a synchronization carried out by examining various laws and regulations with varying degrees, where these regulations regulate the same matter. Vertical synchronization examines whether the laws and regulations applicable to a particular area of life do not contradict each other when viewed from a vertical perspective or the existing legal hierarchy. Vertical synchronization, in addition to considering the hierarchy or sequence of laws and regulations, also needs to consider the chronological aspects of the year and the stipulation number of the laws and regulations in question (10).

The regulatory sandbox for digital health innovation has been regulated in various laws and regulations, namely Law No. 17 of 2023 concerning Health, Government Regulation No. 28 of 2024 concerning Implementing Regulations of Law No. 17 of 2023 concerning Health, and the Decree of the Minister of Health of the Republic of Indonesia Number Hk.01.07/Menkes/1280/2023 about Development of a Digital Health Innovation Ecosystem Through the Regulatory Sandbox. There is a discrepancy between Law No. 17 of 2023 and Government Regulation No. 28 of 2024 and the Decree of the Minister of Health of the Republic of Indonesia Number Hk.01.07/Menkes/1280/2023. Government Regulation No. 28 of 2024 stipulates that further provisions regarding limited-scale testing and facilitation of innovation will be regulated by a Ministerial Regulation. However, the existing Decree of the Minister of Health of the Republic of Indonesia is Number Hk.01.07/Menkes/1280/2023, not in the form of a Ministerial Regulation. There are also differences in the use of terms, namely in Law No. 17 of 2023 and Government Regulation No. 28 of 2024 using the term Health technology innovation, while the Decree of the Minister of Health of the Republic of Indonesia Number Hk.01.07/Menkes/1280/2023 using the term digital health innovation.

Vertical synchronization of laws and regulations will be related to the principle of *lex superior derogat legi inferiori* which explains that if there is a conflict between a lower-level and a higher-level statutory regulation, the lower-level statutory regulation must be set aside (8). Hierarchically, Law No. 17 of 2023 and Government Regulation No. 28 of 2024 have a higher degree of authority than the Decree of the Minister of Health of the Republic of Indonesia Number Hk.01.07/Menkes/1280/2023. Based on the principle of *lex superior derogat legi inferiori*, the Decree of the Minister of Health of the Republic of Indonesia Number Hk.01.07/Menkes/1280/2023 must comply with Law No. 17 of 2023 concerning Health and Government Regulation No. 28 of 2024 concerning the Implementing Regulations of Law No. 17 of 2023 concerning Health. Based on this, new regulations in the form of a Ministerial Regulation are needed regarding limited scale testing or regulatory sandbox for health technology innovation.

Hans Kelsen's theory of the hierarchy of legal norms, posits that a legal norm always has two sides. A legal norm derives from and is based on the norm above it, and then downwards, it also becomes the basis and source for the legal norm below it. Therefore, a legal norm has a relative validity period because its validity period depends on the legal norm above it. Therefore, if a legal norm above it is revoked or abolished, the legal norms below it are also revoked or abolished (10).

Chronologically the Decision of the Minister of Health of the Republic of Indonesia Number Hk.01.07/Menkes/1280/2023 was ratified on April 4, 2023, and its formation was based on Law No. 36 of 2009 concerning Health, which was later repealed and replaced by Law No. 17 of 2023 concerning Health. Based on Hans Kelsen's theory of the hierarchy of legal norms, it can be interpreted that the Decree of the Minister of Health of the Republic of Indonesia Number Hk.01.07/Menkes/1280/2023 was revoked following the enactment of



Law No. 17 of 2023 and Government Regulation No. 28 of 2024, which mandates that further provisions regarding limited scale testing and ease of innovation be regulated by Ministerial Regulation.

4. Conclusion

The regulatory sandbox for digital health innovation in Indonesia is regulated in Law No. 17 of 2023 concerning Health, Government Regulation No. 28 of 2024 concerning Implementing Regulations of Law No. 17 of 2023 concerning Health, and the Decree of the Minister of Health of the Republic of Indonesia Number Hk.01.07/Menkes/1280/2023 about Development of a Digital Health Innovation Ecosystem Through the Regulatory Sandbox. However, there is a discrepancy between Law No. 17 of 2023 and Government Regulation No. 28 of 2024 and the Decree of the Minister of Health of the Republic of Indonesia Number Hk.01.07/Menkes/1280/2023. Based on this, new regulations in the form of a Ministerial Regulation are needed regarding limited-scale testing or a regulatory sandbox for health technology innovation.

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