International Journal of Multidisciplinary Research and Growth Evaluation.

Civil Liability of pt Kimia Farma Diagnostika in the Context of Antigen Rapid test Reuse and Consumer Protection

Warningsih [1*], Neni Sri Imaniyati [2], Alma Lucyati [3]
Faculty of Law, Universitas Islam Bandung, Indonesia

* Corresponding Author: **Warningsih**

Article Info

ISSN (online): 2582-7138
Volume: 05
Issue: 06
November-December 2024
Received: 23-09-2024
Accepted: 26-10-2024
Page No: 722-725

Abstract
The COVID-19 pandemic has rapidly spread across the globe, including Indonesia. In an effort to control the transmission of the virus, one of the preventive measures implemented requires all air travelers to present a certificate confirming a negative rapid antigen test result. At Kualanamu International Airport, Deli Serdang Regency, North Sumatra, PT Kimia Farma Diagnostika deliberately reused rapid antigen test equipment. This study aims to examine the civil liability of PT Kimia Farma Diagnostika for using repeated rapid antigen tests during passenger screenings that resulted in consumer harm, in accordance with the Civil Code. Additionally, the study seeks to explore the legal protection afforded to consumers who have suffered losses due to the reuse of these tests, with reference to Law Number 8 of 1999 concerning Consumer Protection. The research employs a normative juridical approach, utilizing both secondary and primary data. Data collection is conducted through document studies and interviews, followed by qualitative analysis. The study concludes that PT Kimia Farma Diagnostika, as a corporate entity engaging in the reuse of rapid antigen tests, bears vicarious liability, specifically substitute liability, and is accountable for committing an unlawful act under Article 1365 of the Civil Code. Legal protection for affected consumers is provided through both external and internal legal safeguards, ensuring the fulfillment of their rights as consumers.

Keywords: Foreign Direct Investment, Economic Growth, Cameroon

Introduction

Medical devices are a crucial component of health services, complementing medicines and healthcare professionals. The field of medical device technology is advancing rapidly, driven by innovations in information technology. These advancements range from basic medical devices to sophisticated high-tech solutions. The applications of medical devices are diverse, spanning household use, primary healthcare facilities, and tertiary healthcare institutions. Given their significance, governments have a responsibility to ensure that medical devices in circulation meet stringent standards for safety, quality, efficacy, and affordability. During the COVID-19 pandemic, one example of an in vitro diagnostic device that saw widespread use was the rapid antigen test, highlighting the critical role of medical devices in public health responses.

On March 2 2020 or about 4 months after the first case in Wuhan China, the first COVID-19 case in Indonesia was announced, namely 2 cases were found and continues to increase. On October 11 2021, the number of COVID-19 cases in Indonesia had reached 4 million cases. The first peak of COVID-19 cases occurred in January 2021 with the number of daily cases reaching 14,000 new cases. The second peak of cases occurred in July 2021 with the number of daily cases reaching 51,000 new cases with a death rate reaching 2000 cases per day (Erlina Burhan dkk, 2022).

One of the policies implemented by the government to prevent the transmission and spread of Coronavirus Disease (COVID-19) across regions involved enforcing strict health protocol requirements for individuals traveling, particularly via air transportation. These requirements were outlined in Circular Letter Number 7 of 2021 from the Task Force for Handling Coronavirus Disease (COVID-19). This regulation, titled "Extension of Travel Provisions for Domestic People During the Coronavirus Disease (COVID-19) Pandemic," specified that all air travelers must present a certificate showing negative results

from either a Rapid Test-Polymerase Chain Reaction (RT-PCR) or a rapid antigen test (Indah Wahyuni & Dian Ratnasari, 2021) [4].

The need for RT-PCR or rapid antigen test service providers is increasing in Indonesia, making individuals take advantage of these situations and conditions to gain profit. This action was carried out by PT Kimia Farma Diagnostics which deliberately recycled the rapid antigen test equipment, then used the used rapid antigen test equipment to the people who carried out the test. The case of using a used antigen rapid test device occurred at Kualanamu International Airport, Deli Serdang Regency, North Sumatra. Based on information, "the use of used rapid antigen tests has been carried out for 3 months, namely since December 2020, with an estimated victim of around 9,000 people and an estimated profit of around IDR 1.8 billion (Haryanti Puspa Sari, 2021).

The enactment of Law No. 8 of 1999 concerning Consumer Protection (hereinafter referred to as UUPK) establishes a legal framework to safeguard the rights of consumers as users of goods and/or services within society. Article 7 of the UUPK outlines the obligations of business actors, which include demonstrating good faith in conducting business activities, providing accurate, clear, and honest information regarding the condition and guarantees of goods and/or services, and offering explanations on their usage, repair, and maintenance.

In addition to Article 8(a) of the UUPK, which prohibits business actors from producing and/or trading goods and services that fail to meet or comply with the standards set forth in legislation, legal consequences for such actions are further outlined in the Civil Code. Article 1365 of the Civil Code stipulates that any unlawful act that causes harm to another party obligates the person responsible for the harm to provide compensation. This establishes a legal duty for the perpetrator of a violation to compensate the injured party for losses resulting from the unlawful act (Ahmadi Miru & Sakka Pati, 2019) [1].

Based on this background, this legal research aims to examine civil liability and legal protection for consumers who have suffered losses due to the reuse of rapid antigen tests by PT Kimia Farma Diagnostika at Kualanamu Airport, Deli Serdang Regency, North Sumatra. This study is conducted in relation to the provisions of Law Number 8 of 1999 concerning Consumer Protection.

Research Method

The writing of this article uses normative legal methods, because this research is based on the analysis of legal norms contained in statutory regulations which is carried out by examining library materials or secondary data as basic material for research by conducting searches of regulations and literature. -literature related to research problems (Soerjono Soekamto & Sri Mamudji, 2021). The nature of this research is analytical descriptive, as it seeks to comprehensively explain and describe the object of study or the phenomena being examined. This approach aims to clarify the circumstances and conditions within the aspects under investigation. The data utilized in this research is secondary data.

Secondary data used in this research includes statutory regulations, books, as well as data consisting of the 1945 Constitution of the Republic of Indonesia Second Amendment, Law no. 8 of 1999 concerning Consumer Protection, Law of the Republic of Indonesia Number 13 of 2003 concerning Employment, Law of the Republic of Indonesia Number 36 of 2009 concerning Health, Civil Code (KUHPerdata), Government Regulation of the Republic of Indonesia Number 72 of 1998 concerning Safeguarding Pharmaceutical Supplies and Medical Devices, Minister of Health Regulation Number 14 of 2021 concerning Standards for Business Activities and Products in Implementation Health Sector Risk-Based Business Licensing, Regulation of the Minister of Environment and Forestry Number P.56 of 2015 concerning Procedures and Technical Requirements for Management of Hazardous and Toxic Waste from Health Service Facilities, Decree of the Minister of Health of the Republic of Indonesia Number Hk.01.07/Menkes/446/ 2021 concerning the Use of Rapid Diagnostic Test antigen in Corona Virus Disease 2019 (Covid-19) Examination, and Covid19 Control Unit Circular Number 7 of the Year 2021 concerning Extension of Travel Provisions for Domestic People during the Covid 19 Pandemic.

Data collection for this research was conducted through library research, which involves examining secondary data. The secondary data utilized in this study includes books, articles from print and electronic media, government documents, and statutory regulations. Additionally, field research was undertaken to complement and enhance the library data. This was achieved by conducting interviews with relevant parties, including health laboratory practitioners at the West Java Provincial Health Service and the Bandung City Regional Health Laboratory, as well as health law experts at the Islamic University of Bandung. All secondary data collected is processed and analyzed qualitatively. This involves grouping and selecting data based on its relevance, quality, and accuracy, and then correlating it with theoretical frameworks from the literature. This process aims to derive answers to the research problems.

Results and Discussion

The case involving the reuse of rapid antigen tests by PT Kimia Farma Diagnostika was adjudicated by the court and decided through the Lubuk Pakam Court Decision Number 1980/Pid.Sus/2021/PN Lbp, dated January 27, 2022. The court sentenced the defendant, Picandi Macojaya, SKM, MM, alias Candi, who served as the Branch Manager of PT Kimia Farma Diagnostika, to 10 (ten) years of imprisonment. Additionally, the defendant was fined IDR 1,000,000,000.00 (one billion rupiah), with the provision that failure to pay the fine would result in a substitute imprisonment of 1 (one) year.

In legal interactions within society, humans are not the only legal subjects (holders of rights and obligations); there are also other legal subjects commonly referred to as legal entities (*rechtspersoon*). A corporation (*corporatie*) is a collective group of individuals who, within legal relationships, act together as a distinct legal subject.

PT Kimia Farma Diagnostika, as a legal subject, can be held accountable based on the *identification doctrine*, also known as the *Direct Liability Doctrine*, as outlined by Michael J. Allen. According to this doctrine, two elements must be satisfied to attribute liability to a corporation: the identification of an individual closely associated with the corporation and the performance of actions within the scope of that individual's position. In this case, PT Kimia Farma Diagnostika, operating as a health laboratory corporation, abused its authority by reusing rapid antigen tests under the directive of Picandi Macojaya, the Branch Manager of PT Kimia Farma Diagnostika. Macojaya, identified as a senior

officer, acted within the scope of his position, and his actions are therefore attributable to the company, reflecting its intent and conduct.

When linked to the provisions of Article 1367 of the Civil Code, the first step is to determine the extent of the civil liability of the Clinical Laboratory, in this case, PT Kimia Farma Diagnostika. This begins with identifying who qualifies as subordinates under the context of Article 1367. Subordinates, as defined by this provision, are individuals who cannot act independently in relation to their superiors and require supervision or specific instructions. In the case of the reuse of rapid antigen tests at the Clinical Laboratory of PT Kimia Farma Diagnostika at Kualanamu Airport, the actions were carried out under the orders of Picandi Macojaya, the Branch Manager of PT Kimia Farma Diagnostika. As such, the responsibility for these actions can be attributed to the corporation through the identification of Macojaya as a representative of the company acting within his professional capacity.

Vicarious liability is a legal principle commonly applied in the context of employment relationships between employers and employees. Under this principle, an employer can be held accountable for actions not directly performed by them but by an employee, provided those actions are closely related to the employee's work responsibilities. This principle ensures that victims can obtain compensation, even if the individual directly responsible for the wrongdoing is unable or unwilling to bear financial responsibility. For the effective application of this principle, it is essential to establish that the third-party exercising control over the employment relationship assumes liability for actions performed by their employee, as long as those actions fall within the lawful scope of employment (Sekar Ayu Dita & Atik Winanti, 2023).

In the case of the reuse of rapid antigen tests by PT Kimia Farma Diagnostika, it was proven to meet the three criteria necessary for applying the principle of vicarious liability. These criteria are:

1. Existence of a legal relationship: In this research, a legal relationship exists between the Clinical Laboratory as the employer and the employees as the recipients of the work.
2. Provision of wages: There is an element of compensation provided to the workers, which is commensurate with the responsibilities they carry out.
3. Occurrence of an unlawful act: This criterion is met as demonstrated by the Lubuk Pakam Court Decision Number 1980/Pid.Sus/2021/PN Lbp, dated January 27, 2022. The court sentenced the defendant, Picandi Macojaya, SKM, MM, alias Candi, and the unlawful act in question was committed during working hours.

Legal protection for consumers who suffer losses due to the reuse of rapid antigen tests by PT Kimia Farma Diagnostika can be categorized into external and internal legal protection. However, internal legal protection remains weak because the agreement was not formalized in writing. External legal protection, on the other hand, is provided by authorities through regulations established in the form of laws and statutory provisions.

In the issue discussed by the author regarding consumer protection, patients examined in the laboratory are considered consumers of the laboratory, with PT Kimia Farma Diagnostika acting as the business entity. As consumers, patients are entitled to legal protection as stipulated in the UUPK (Law No. 8 of 1999 concerning Consumer Protection). According to Article 1, number 1 of the UUPK, legal protection for consumers involves efforts to ensure legal certainty and safeguard consumer rights. This protection includes enhancing consumer dignity, providing access to information about goods and/or services, and fostering an attitude of honesty and accountability among business actors. Article 4 of the UUPK outlines several points regarding the types of protection required for consumers of PT Kimia Farma Diagnostika. This includes the right to comfort, security, and safety when consuming goods and/or services. This means that consumers must be informed about the products they are using and understand the procedures for their use. Such knowledge allows consumers to be aware of the benefits and purposes of the products and to make informed choices regarding the rapid antigen tests available at the PT Kimia Farma Diagnostika medical laboratory.

Regarding the right to accurate, clear, and honest information about the conditions and guarantees of goods and/or services, consumers should be able to understand the usefulness of the products they use and be assured of the safety of the rapid antigen test products provided by PT Kimia Farma Diagnostika. This contributes to a sense of security among consumers. Additionally, consumers have the right to receive compensation, reimbursement, and/or replacement if the goods and/or services do not meet the terms of the agreement or are otherwise defective. This means consumers have the right to lodge complaints and seek compensation if they believe PT Kimia Farma Diagnostika has failed to meet their rights or has caused them harm.

Conclusion

The civil liability of PT Kimia Farma Diagnostika, as a corporation operating a health laboratory that reused rapid antigen tests for examining passengers at Kualanamu Airport, Deli Serdang Regency, North Sumatra, and thereby caused harm to consumers, is linked to the Civil Code, specifically the principle of vicarious liability. Legal protection for consumers affected by the reuse of rapid antigen tests by PT Kimia Farma Diagnostika can be categorized into external and internal legal protection. However, internal legal protection remains weak due to the absence of a written agreement. External legal protection is provided by authorities through regulations, including laws and statutory provisions such as Law Number 8 of 1999 concerning Consumer Protection (UUPK). This law safeguards public consumer rights, including the right to comfort, security, and safety when consuming goods and/or services, as well as the right to choose products and/or services based on accurate, clear, and honest information. In the event of detrimental deviations, consumers are entitled to be heard, receive advocacy, guidance, fair treatment, compensation, and restitution.

References

1. Ahmadi Miru, Sakka Pati. Hukum Perikatan Penjelasan Makna Pasal 1233 sampai 1456 BW. 1st ed. Jakarta: PT Raja Grafindo Persada; c2019.
2. Burhan E, *et al.* Pedoman Tata Laksana Covid 19, Edisi 4. 4th ed. Jakarta: Perhimpunan Dokter Paru Indonesia (PDPI); c2022.
3. Sari HP. Kasus Alat Rapid Antigen Bekas: Klarifikasi Kimia Farma dan Ancaman Sanksi Berat. Kompas.

c2021 Apr 29. Available from: https://nasional.kompas.com/read/2021/04/29/07012441/kasus-alat-rapid-test-antigen-bekas-klarifikasi-kimia-farma-dan-ancaman?Page=all.
4. Wahyuni I, Ratnasari D. Analisis Tindak Pidana Penggunaan Alat Rapid Test Antigen Bekas Oleh Oknum Petugas Medis Kimia Farma. Jurnal Yurispruden. 2021;4(2).
5. Dita SA, Winanti A. Analisis Asas Vicarious Liability dalam Pertanggungjawaban Pengganti atas Perbuatan Melawan Hukum Pegawai Bank. Jurnal USM Law Review. 2023;6(2).
6. Soekamto S, Mamudji S. Penelitian Hukum Normatif Suatu Tinjauan Singkat. Jakarta: Rajawali Pers; c2021.