



## The legal responsibility of the hospital on the use of fake vaccines<sup>☆</sup>



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### KEYWORDS

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### Abstract

**Objective:** The study aims to investigate legal responsibility and the supervisory functions of the Hospital of the use of fake vaccines.

**Method:** The research used the normative legal research, namely research methods using materials sourced from regulations.

**Results:** The study indicates that the Hospital of Harapan Bunda had broken the Law No. 44 of 2009 about Hospital and Health Minister's Regulation No. 72 Year 2016 of Pharmaceutical Service Standard in Hospital. The Hospital concerned has been subjected to administrative action and has been prosecuted by the victims' parents. The case is in the East Jakarta District Court. Hospital as a Corporation may be held criminally liable in accordance with Regulation of the Supreme Court of the Republic of Indonesia No. 13 of 2016 on Procedures for Handling Corporate Crime.

**Conclusion:** Hospital is considered negligent in supervising the use of fake vaccines at the Hospital. Hospitals procure any vaccine, it has to meet the Law No. 44 of 2009 about Hospital and Health Minister Regulation No. 72 of 2016 of Pharmaceutical Service Standard in Hospital.

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### Introduction

A hospital is a legal person (rechtspersoon), namely a legal entity and legal personality. Initially, criminal law makers viewed human as being subject to criminal acts, however, hospital is essentially complex organizations, the development of technology increasingly complex and increasingly becoming more complex. Capital, labor and technology

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intensive and problematic in various fields in law, economics, ethics and human rights, technology.<sup>1</sup>

Based on Law No. 44 of 2009 concerning Hospital Article 1 states "Hospital is a health service institution that organizes health services individual plenary which provides inpatient, outpatient, and emergency care services emergency". Hospitals as legal subjects have the duty to provide medical services and medical support not only to curative and rehabilitative aspects, but also preventive and promotive aspects.<sup>2</sup>

The legal responsibility of the Hospital has regulated in Article 46 of the Law No. 44 of 2009 concerning Hospitals: "The hospital is legally responsible for all losses incurred negligence committed by health workers at the Hospital".

Responsibility is a consequence of freedom action related to ethics or morals in carrying out an act. Criminal liability is an obligation to pay retribution that will be accepted by the perpetrator of someone who has been harmed.<sup>3</sup>

The Netherlands determines the corporation as a criminal offender based on Arrest "Kleuter school Babel", that the actions of individuals can be charged to legal entities, if the action is reflected in social traffic as an act of a legal entity.<sup>4</sup>

The fake vaccine circulation syndicate which was revealed by the Indonesian Police Headquarters Criminal Investigation Agency in June 2016, there were fourteen hospitals that participated in using the fake vaccine.

Circulation of fake vaccines occurs because of the scarcity of certain vaccines in the community where the preferred vaccines and not compulsory vaccines as government programs. Vaccines for immunization are grouped into mandatory immunizations and selected immunizations. Immunization vaccines must be provided free by the government, as a government program consist of BCG, Polio, DPT, Measles, Hepatitis B, and Hib is produced and distributed by PT. Biofarma.

The implementation of immunization is mandatory in Puskesmas, Posyandu, government hospitals and also carried out in private health hospitals. In this fake vaccine case was found that several private health facilities were buying from unofficial sources. In addition, after being thoroughly scrutinized by the Task Force. Fake vaccines were not found in government health facilities, the vaccines provided from the government. The results of laboratory tests of the Food and Drug Supervisory Agency, the contents of the fake vaccine were only in the form of NaCl which was put into bottles of the original Pediacel brand vaccine produced by PT. Sanofi-Aventis Indonesia. In that case the owner of the CV. Azka.

## Design of research

The research used the normative legal research, namely research methods using materials sourced from regulations. It begins with an inventory of legal regulations concerning Health, Immunization, Hospitals and supervision of drug and food circulation.

## Research sites

Based on the problems that mentioned above, research conducted at Harapan Bunda Hospital, East Jakarta, which is one of the fake vaccine users.

## Data collection

To collect the data in this study, used by collecting, reading, and tracing a number of books, documents, legislation, scientific works, internet literature, which are related and support this writing, and by interview which is intended to conduct question and answer directly by researchers and respondents to obtain information.

## Data analysis

Data collected both primary and secondary data, then analyzed descriptively qualitatively.

## Results

Data showed the Director of Harapan Bunda Hospital admitted fake vaccines circulating in her hospital. The Director said she did not know about the circulation of fake vaccines in patients, she gave the police to investigate and prosecute the perpetrators. "This was done by someone unknown to Harapan Bunda Hospital and it was being done Bareskrim was arrested".

Director of Hospital states that fake vaccines were circulating in the hospital is a Pediacel vaccine in March–June 2016. The vaccine comes to a vaccine shortage at the Hospital. Management of Hospital admitted that they were cheated on the circulation of fake vaccines and of be victims of the crime. The hospital said that a doctor in the first category and a nurse with the initials I was the culprit of the entry of a fake vaccine to the hospital.

Hospital Law No. 44 of 2009 Article 15 states pharmaceutical supply services at hospitals must follow pharmaceutical standards. The management of medical devices, pharmaceutical preparations, and consumables in hospitals must be carried out by a one-door pharmaceutical system installation.

Regulation of the Minister of Health No. 72 of 2016 concerning Pharmaceutical Service Standards at the Hospital regulates the one-stop pharmacy service system. The implementation of Pharmaceutical Services at Hospitals must ensure the availability of Pharmaceutical Preparations, Medical Devices and Medical Materials, are safe quality, useful, and affordable.<sup>5</sup>

For the civil liability of Harapan Bunda Hospital was sued for compensation worth 600 million rupiah by the Counterfeit Vaccine Victims Alliance, is currently being handled in the East Jakarta District Court. Harapan Bunda Hospital as a corporation has not been asked for criminal responsibility by the parents of victims even though the Corporation as a criminal offender can be accounted for under criminal law.

## Discussion

This research shows that the Hospital as a corporation has committed administrative violations related to the use of fake vaccine which its procurement is not in accordance with the Hospital Law No. 44 of 2009 and Regulation of the Minister of Health No. 72 of 2016 concerning the Standard of

Pharmaceutical Services in Hospitals. For this reason, Harapan Bunda Hospital has received an administrative sanction in the form of a written warning as stated by the Director General of Health Services.

Administrative sanctions according to Article 54 of the Hospital Law No. 44 of 2009 can be in the form of reprimand, written warning, no extended operational license, imposition of fines and revocation of licenses.

For hospitals, the provisions of Article 46 of the Hospital Law provide clarity that the Hospital can be prosecuted only due to negligence committed by health workers carried out in the Hospital. This clearly benefits the Hospital. Losses caused by errors due to intentions made by health workers are not the responsibility of the Hospital, but are the responsibility of the health personnel even though they are carried out within the Hospital. Hospitals and patients who suffer losses due to negligence in health services at the Hospital are legal subjects and be subject to right and obligation.

The law that regulates the relationship between one legal subject and another legal subject is private law (civil law) where the domain is rights protection. Then the Law governing this legal event is the Civil Code is Article 1367 (3) which reads: "Employers and those who appoint others to represent their affairs are responsible for the losses incurred by their servants or subordinates in carrying out work for these people".

The employer's responsibility in Article 1367 (3) of the Civil Code is not only about responsibility in the workplace, but also someone who is outside the workforce ordered by someone else to do certain work. The person who is ordered to do the work independently, either on his own leadership or has carried out the work on his instructions.

As referred to in Article 1601a of the Civil Code, the employer's responsibility for unlawful acts of his employees is: "A labor agreement is an agreement with which one party, the laborer, binds himself to under the orders of the other party, the employer, to something certain time doing work by receiving wages".<sup>6</sup>

Comparing Article 46 of Law No. 44 of 2009 concerning Hospitals with Article 1367 of the Civil Code (3) above, showed that Article 46 of Law No. 44 of 2009 is a derivative or derivative of Article 1367 Civil Code applies specifically to circles Hospital, or Article 46 of Law No. 44 of 2009 is a *lex specialis*.

The superior respondent doctrine states that an employer is a person who has the right to give instructions and control the actions of his subordinates. In addition, the development of health law and the sophistication of medical technology, become hospitals responsibility of the work performed by their employees, what is done by the medical staff.

The existence of criminal responsibility must be clear who can be accounted for. This means, it must be ascertained in advance who is declared the maker of a crime. This problem concerns the subject matter of a criminal offense which has generally been formulated by the legislator for the crime in question. But in reality, ensuring that the maker of a crime is not easy. The problem of criminal liability is to distinguish the problem of the maker of a criminal act. That is, the understanding of the subject of criminal makers in two things, namely who is committing a criminal maker and

accounted for the criminal law. This depends on system of formulating the responsibilities by legislators.

One provision of corporations as the subject of criminal law, can be held accountable is Article 15 (2) Emergency Law No. 7 In 1955 concerning Economic Crimes, it was stipulated that "an economic crime is also carried out in the name of a legal entity, a company, a union of people, or a foundation, if actions are carried out by people both based on relationships and based on other relationships acting in the environment of a legal entity, company, union, or foundation does not care whether these people are each of them commits economic crime or to them together there are elements of the crime".<sup>7</sup>

Regulation of the Supreme Court No. 13 concerning Procedures for Handling Corporate Crimes has been clear in regulating the handling of criminal acts of corruption as in Article 4 (1) Corporations can be asked for criminal liability based on the criminal provisions of laws governing Corporations. In imposing criminal acts against Corporations, Judges can assess Corporate errors as referred to: Corporations may obtain profits or benefits from the crime or the crime is carried out in the interest of the Corporation; Corporations allow criminal acts to occur; or Corporation.

## Conclusion

Hospitals as a corporation being held accountable for administration can be asked for civil and criminal liability. An administrative sanction has been sent to Harapan Bunda Hospital and of sued by the Alliance of Fake Vaccine Parents Victims handled by the East Jakarta District Court.

It has regulated the responsibility of the Hospital as a corporation in the Supreme Court Regulations No. 13 concerning Procedures for Handling Corporate Criminal Acts. The Hospital is negligent in the use of fake vaccines based on the Hospital Liability doctrine that imposes responsibility for all events within the Hospital. If viewed from the responsibility, this fake vaccine case can be charged to the Head of the Hospital.

It recommends the Hospital to follow the Law No. 44 of 2009 concerning Hospitals and Regulation of the Minister of Health No. 72 of 2016 concerning the Standard of Pharmaceutical Services at Hospitals. The supply of drugs must be safe and quality. One-door procurement system through hospital pharmacy installation and purchase through authorized distributors. Supervision of the Indonesian Ministry of Health improves the quality and quantity of human resources and strengthen the role and function of the Food and Drug Supervisory Agency.

## Conflict of interest

The authors declare no conflict of interest.

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