

LEGAL RESPONSIBILITY OF VACCINE PROVIDER ON THE IMPACT OF POST IMMUNIZATION FOLLOWING EVENT (AEFI) AFTER VACCINATION

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ABSTRACT

Health has a broad meaning and dimension according to the definition according to WHO and the Health Law, namely a healthy state which includes physical, mental, spiritual and social aspects and can be socially and economically productive. This shows that a person's health status is not only measured from physical and mental aspects, but is also assessed based on social or economic productivity. In early 2020 the world was shocked by the outbreak of a new virus named by the World Health Organization (WHO) Severe Acute Respiratory Syndrome Coronavirus-2 and the name of the disease as corona virus disease 2019 (Covid-19). One way to suppress its growth rate is that the Central Government will take action to vaccinate people in Indonesia so that the spread of the Covid 19 virus does not increase. However, Recently, there have been several reports related to the administration of vaccines with the type of vaccine that experiences a lot of Post-Immunization Adverse Events (AEFI) such as fever, chills, headache, and body aches and weakness. For the impact of the AEFI, the public often blames health workers and even accuses them of medical malpractice In the implementation of the COVID-19 vaccination, it is also obligatory for every citizen to vaccinate. Regulation of the Minister of Health of the Republic of Indonesia Number 10 of 2021 concerning the Implementation of Vaccination in the Context of Combating the 2019 Corona Virus Disease (Covid-19) Pandemic Article 46 Paragraph (1), Paragraph (2), and Paragraph (3) then the government has legal responsibility, if the vaccine organizers follow the Operational Standards that have been established. It is recommended to the central government in issuing new rules related to the handling of Covid 19 and the implementation of vaccinations must be in line with and must not conflict with existing laws and regulations, especially regarding Human Rights (HAM) and the rights of citizens to determine systems and procedures. ways to maintain their health in a responsible manner, including vaccination, which should be one of the choices in health care society and not to be forced.

Keywords: Legal responsibility, Vaccination.

INTRODUCTION

Health is a human right and one of the elements of welfare that must be realized by the state in accordance with the ideals of the Indonesian nation as referred to in Pancasila and the Preamble to the 1945 Constitution of the Republic of Indonesia. Therefore, every activity and effort to improve the health status of the community which is carried out at the highest level based on the principles of non-discrimination, participation, protection, and sustainability which are very important for the formation of Indonesian human resources. So that every violation of human rights that occurs must be condemned and condemned by giving the appropriate punishment.

In today's era, health problems are one of the most important things in addition to economic problems in all corners of the world, especially in Indonesia. In the past year, a new virus has emerged that has taken the world by storm, not only in Indonesia. This virus is said to be a deadly virus, this is evident from the number of fatalities it has taken. In early 2020 the world was shocked by the outbreak of a new virus named by the World Health Organization (WHO) Severe Acute Respiratory Syndrome Coronavirus-2 and the name of the disease as corona virus disease 2019 (Covid-19). It is widely known that this virus originated from Wuhan, China, which was discovered at the end of December 2019 and was identified in Indonesia for the first time in the Depok area at the end of March 2020. At first it was not possible to determine whether the transmission of this virus could be transmitted between humans and humans and the number of cases continued to increase over time. Finally, after conducting various studies, it has been confirmed that the transmission of pneumonia can be transmitted from human to human.

One way to suppress its growth rate is that the Central Government will take action to vaccinate people in Indonesia so that the spread of the Covid 19 virus does not increase. With vaccination, the immune system of people who have been vaccinated will be different from people who are not vaccinated. However, recently there have been several reports related to the administration of vaccines with the Astra Zeneca type of vaccine, which experienced many Post Immunization Adverse Events (AEFI) such as fever, chills, headache, and body aches and weakness. So with the large number of reports, the service in the covid 19 vaccination is temporarily suspended while waiting for an official explanation and statement from the Ministry of Health and WHO to Representative Indonesia. For the impact of the AEFI, people often blame health workers and even accuse them of medical malpractice. The accusation of malpractice is based on Article 55 Paragraph (1) of Law Number 23 of 1992 concerning health which reads "everyone has the right to compensation due to errors or omissions committed by health workers". Even though in the implementation of the covid 19 vaccination, it is also inseparable from the role of the government as an institution that obliges every citizen to vaccinate.

Based on the description of the background above, the author is interested in conducting research which is outlined in the form of a thesis entitled "Legal Responsibility of Vaccine Providers on the Impact of Post-Immunization Adverse Events (AEFI) After Vaccination".

CONCEPTUAL FRAMEWORK

Theories or theoretical frameworks have several uses, according to Soerjono Soekanto, these uses include:

- a. The theory is useful to further sharpen or further specialize the facts to be investigated or tested for truth.
- b. Theory is very useful in developing systems of classification of facts, establishing the structure of concepts and developing definitions.
- c. Theory is usually an overview of things that have been known and tested for truth concerning the object under study.
- d. Theory provides the possibility of predicting future facts, because the causes of the occurrence of these facts are known and it is possible that these factors will arise again in the future.
- e. Theory provides clues to deficiencies in the researcher's knowledge

Conceptual framework:

- a. Legal responsibility
- b. Vaccination
- c. Adverse Events After Immunization (AEFI)

METHODOLOGY

In simple terms, research methods are procedures for conducting research. The nature and type of this research uses normative juridical research or as Soerjono Soekanto and Sri Mamudji say, namely library law research. The approach method used in this study uses a statutory approach. The statutory approach is carried out by reviewing all laws and regulations related to the legal issues raised. Types of data collection tools, namely the study of documents or library materials, observations or observations, and interviews or interviews. The data collected through library research were abstracted and analyzed qualitatively.

DISCUSSION

1. Regulation of the legal responsibility of vaccination providers for the impact of post-immunization follow-up events (AEFI) after vaccination

a. Citizens' Rights and Obligations in the Health Sector

Vaccines come from the Latin word Variolae vaccine Cinae (cowpox) while vaccination comes from the word "vaccine" which is a substance that can stimulate the emergence of active immunity such as BCG, Polio, DPT, Hepatitis B, and others. Vaccines are "biological elements that have certain characteristics and require special handling of the vaccine chain from production in the factory to use in service units, one of which is by monitoring the temperature of the vaccine to determine whether the vaccine is still suitable for use or not".

Health as a human right has a very important meaning for human life, this is because health is everything because without health life becomes meaningless. Health workers are the main element to realize health services in a safe, orderly, optimal, and professional manner that takes place on an ongoing basis. In accordance with the mandate of the state law which is based on the principle of Pancasila, this regulation regarding health has been promulgated in Law Number 23 of 1992 concerning Health and specifically for health workers, Government Regulation Number 32 of 1996 concerning Health Workers has been re-issued.

b. Government Obligations in Health Services

The implementation of health services for the community has a broad scope, which does not only include the health of certain individuals but also includes all factors that can provide health insurance such as nutrition, environmental problems, housing, and others. the philosophy of the existence of human rights guarantees on individual health is human dignity. This is because the right to health is a basic human right. In addition, the implementation of health services in Indonesia is also a manifestation of the welfare state which demands the state to realize social justice for all its people. The implementation of

health services is not only regulated in Article 28H paragraph (3) and Article 34 paragraph (2), however, its real realization was only seen when Law No. 40 of 2004 was passed on the National Social Security System (SJSN). Through this regulation, public health insurance will be guaranteed because this health insurance has several programs such as "health insurance, work accident insurance, old age insurance, pension insurance, and death insurance".

c. Regulation of the Legal Responsibilities of Vaccination Providers Against the Impact of AEFI

In relation to the implementation of vaccination, the government has prepared the vaccination since mid-2020 and for its implementation it was only carried out on January 13, 2021, with the first vaccine being received by the President of the Republic of Indonesia, Joko Widodo. In addition to the implementation of vaccinations, the government has also implemented various regulations to prevent, reduce, and slow down the spread of the COVID-19 virus. Starting by issuing Presidential Decree Number 11 of 2020 concerning the Determination of the Corona Virus Disease 2019 (Covid-19) Public Health Emergency which stipulates the status of a health emergency. Carry out 3T obligations (Testing, Tracing, Treatment) and build an emergency hospital.

Based on Article 11 paragraph (1) of Law No. 36 of 2014 it is stated that health workers consist of "medical personnel, clinical psychology staff, nursing personnel, pharmaceutical workers, midwifery workers, community health workers, nutrition workers, physical therapy personnel, and technicians. medical personnel, environmental health personnel, biomedical engineering personnel, traditional health workers, and other health personnel".

The responsibility of the state in the field of health services to citizens so that the rights of these citizens are fulfilled, the government must have a role in making policies and also play a role as a supervisor. The implementation of health services is not only regulated in Article 28H paragraph (3) and Article 34 paragraph (2), but its real realization is only seen when Law Number 40 of 2004 concerning the National Social Security System (SJSN) is passed. In addition, Law Number 39 of 1999 concerning Human Rights also supports health insurance for the community, which is contained in article 8. The regulation regarding health administration in the field of vaccination can be found in several regulations, namely Article 28H paragraph (1) 1945 Constitution of the Republic of Indonesia, Article 28J paragraph (2) of the Constitution of the Republic of Indonesia,

2. Legal responsibility to the organizers of the implementation of vaccination due to the impact of post-immunization follow-up events (AEFI) to the vaccine recipient community

a. Definition of Medical Action

Health workers are the main element to realize health services in a safe, orderly, optimal, and professional manner that takes place on an ongoing basis. In accordance with the mandate of the state law which is based on the principle of Pancasila, this regulation regarding health has been promulgated in Law Number 23 of 1992 concerning Health and specifically for health workers, Government Regulation Number 32 of 1996 concerning Health Workers has been re-issued.

b. Legal Liability for Medical Action

Based on Article 11 paragraph (1) of Law No. 36 of 2014 it is stated that health workers consist of "medical personnel, clinical psychology staff, nursing personnel, pharmaceutical workers, midwifery workers, community health workers, nutrition workers, physical therapy personnel, and technicians. medical personnel, environmental health personnel, biomedical engineering personnel, traditional health workers, and other health personnel". Furthermore, Article 11 paragraph (2) states that: "medical personnel include doctors, dentists, specialist doctors, and specialist dentists". In providing health service efforts, certain types of health workers such as medical personnel including doctors and dentists must have permission from the Minister of Health in order to carry out their activities.

Based on Article 46 paragraph (2) of Law Number 36 of 2014 concerning health workers, a person in order to become a medical worker is required to have knowledge and skills in the health sector which is stated by a diploma from an educational institution. Then health workers who already have the expertise are placed in all regions of Indonesia. The procurement and placement of health workers is held with the aim of evenly distributing the need for health workers to the community. So that rural communities are able to receive access to health services from the government.

c. Legal Liability by Medical Personnel

The enactment of Law Number 8 of 1999 concerning Consumer Protection has become a new direction to discuss the legal relationship between patients and health workers. Legal relationships that occur between patients and health workers in practice often cause problems. This is because the relationship that is built between the two parties is special so that in binding the agreement, standards must be established in medical care.

When talking about health law, the applicable legal norms in its implementation refer to Law Number 36 of 2009 concerning Health, while if there are deviations from the implementation of the law, criminal law is used. In Law Number 36 of 2009 concerning Health there are also sanctions, but the sanctions contained in the law are in the form of administrative sanctions and also do not regulate the types of irregularities that can be carried out by health workers against patients. So in this case, if there is an error in the vaccination service, either in the form of disability or death, it will still refer to criminal law and if there is a loss it will refer to civil law.

The application of criminal law in the world of health as a sanction law classifies people who can be held accountable with those who are unable to take responsibility. A person is considered capable of being responsible if that person is able to make a good choice from several available options. To be able to make these choices, the person must be mature, capable, healthy, and able to take responsibility for the choices to be made. If in making the decision, the person makes the wrong decision or in the sense that it is prohibited by law, the person is not immediately liable to be made guilty.

Talking about accountability for vaccination services carried out by puskesmas doctors as field officials, if there is a deviation from the patient in the form of AEFI, a lawsuit can be filed with the Administrative Court in the form of an administrative lawsuit. If the

health worker violates his position, he can be subject to criminal sanctions. Then for the losses suffered by the patient due to the emergence of AEFI, it can be sued in a civil manner.

For administrative irregularities, it can be done in a tiered way by adhering to the principle of subsidiarity, meaning that if it can be resolved from the bottom first, there is no need to submit it to the superiors. This is done if it can be resolved through administrative procedures, then the court route does not need to be carried out. However, previously the procedure could only be carried out if it had been regulated in a decision or stipulation made by an official of the Ministry of Health. The procedure can also serve as a reservoir for patient referrals. In this case, if you file a lawsuit administratively, it will be difficult to bring health workers and other health department officials to the Administrative Court, this is due to the neat public policies made to protect these health officials.

- a. Article 415 of the Criminal Code regulates the embezzlement of money or securities;
- b. Article 417 regulates the elimination or elimination, embezzlement of evidence, deeds, letters, lists and others so as to make decisions that are unfair, incorrect, etc.;
- c. Articles 418 and 419 regulate the acceptance of gifts or promises;
- d. Article 421 regulates the abuse of power to force someone to do or not do or allow something;
- e. Article 422 concerning using means of coercion to extort confessions or obtain information;
- f. Article 425 regulates extortion

This responsibility in the health sector cannot be separated from civil lawsuits. In civil cases, the right to claim compensation by the patient is regulated in Article 55 paragraph (1) of Law Number 23 of 1992 concerning Health and what will be sued is in the form of a determination made by an official of the Ministry of Health that causes harm to the patient. If the criminal element that must be proven is an element of error, then for a civil case it must be proven whether there is an element against the law (*onrechtmatig*). As for the elements of being against the law, namely "First, the decision does not or does not heed, is taken contrary to the legislation, Second, *Detournement de pouvoir* is abuse of authority, deviates from the purpose of granting authority, Third, Decisions are arbitrary, careless.

d. Legal Liability by the Government

As a service provider in the health sector, the government is responsible for its implementation which must be seen first from the legal subject. In administering vaccinations, the government is divided into 2, namely First, government officials, namely the Ministry of Health and their Staff as Personal Responsible. Second, the Ministry of Health as the institution in charge of the institution. The government as the personal responsibility is actually held by the Minister of Health, whose authority is attributed to the Director General of Communicable Disease Eradication and Environmental Health in Settlements (Dirjen P2M-PLP) who is specifically tasked with making national immunization policies.

3. The government's efforts as a vaccine provider in overcoming the impact of post-immunization follow-up events (KIPI) after the implementation of the Covid-19 vaccination to the vaccine recipient community

a. Impacts After Giving Covid 19 Vaccination

The use of vaccines for health does not always have a positive impact, but there are times when they experience negative impacts in their use, this kind of thing is called Post-Immunization Adverse Events or in English it is called Adverse Event Following Immunization/AEFI. Health workers who carry out their duties as service personnel in the field of vaccination must know the various kinds of impacts and symptoms caused by this vaccination. The effects after immunization will vary and usually it depends on the condition of the immunity that a person has. There are several kinds of impacts that can arise as a result of this vaccination, namely as follows: First, local irritation usually causes pain, tenderness, and swelling accompanied by redness, Second, fever is caused by “complex reactions induced by the production of cytokines that affect hypothalamic neurons. An increase in temperature above 40°C can cause cell and organ dysfunction.” A person can only be said to have a fever if his body temperature is above 38 degrees or equal to 38 degrees. Third, Guillain-Barre Syndrome (GBS) Guillain-Barre Syndrome is a “brief neurological disorder. includes demyelinating inflammation of the peripheral nerves. Guillain-Barre Syndrome (GBS) Guillain-Barre Syndrome is a “brief neurological disorder. includes demyelinating inflammation of the peripheral nerves. Guillain-Barre Syndrome (GBS) Guillain-Barre Syndrome is a “brief neurological disorder. includes demyelinating inflammation of the peripheral nerves.

In general, a quality vaccine is a vaccine that will trigger an immune reaction from the body of the vaccine recipient which will cause minimal symptoms. This mild reaction occurs because the vaccine has worked so that when the immune system meets the vaccine, the immune system is formed. In addition, local and systemic reactions caused by vaccination in the form of pain or fever at the injection site can also occur because stabilizers and preservatives react with the immune system and the frequency of occurrence of AEFI symptoms is also influenced by the type of vaccine to be used. However, the reactions caused by some vaccines will be the same as the reactions caused by the Covid 19 vaccination,

- a. Local reactions, such as pain, redness, swelling at the injection site and other local reactions that are not severe, such as cellulitis
- b. Systemic reactions, such as fever, muscle aches throughout the body (myalgia), joint pain, weakness, and headache
- c. Other reactions, such as allergic reactions such as urticaria, edema, anaphylactic reactions (shock caused by severe allergies), and Syncope (fainting).

If there is an AEFI that is still relatively mild in the form of pain, redness, and swelling, the emergency staff can give directions to the patient to apply cold compresses to the site of the former vaccine and if there is a fever, it is recommended to take paracetamol, get enough rest, and can do a compress with warm water.

b. Government Efforts as Vaccine Provider

Medically, the implementation of immunization is a safe action because it has previously been tested in a health laboratory. However, sometimes the implementation of

immunization carried out in bulk will cause problems in the form of the occurrence of AEFI which will harm the patient's health and body. But the problems that arise will certainly provide solutions so that there is no need to file a lawsuit at the criminal, civil and state administration levels because it has involved state administration officials as the organizers.

The effectiveness and efficiency of the program will be balanced with juridicality and legality so that if a lawsuit arises, the legal framework for settlement and protection will be within the scope of state administrative law. When talking about AEFI, the position will be in medical action, where AEFI is a symptom that arises as a result of being integrated with medical action. Medical action can occur if an intervention has been carried out on the patient's body and soul in order to protect, prevent, treat, or diagnose patients.

In general, immunization is a medical action carried out by health workers with the aim of specifically preventing and protecting healthy people. Therefore, the legal relationship that occurs in this immunization action can be in the form of a relationship between a doctor and a client or it can also turn into a relationship between a doctor and a patient. Even if there are fatal things involving AEFI, the patient can change his name to become a victim.

Although this AEFI is rare, it is possible that this AEFI will also happen to anyone, whether it is an immunization program carried out by the government or an individual program. The occurrence of AEFIs can lead to medical disputes, which if not resolved it will lead to a prolonged conflict.

CONCLUSIONS

The conclusions that can be drawn from the discussion above:

1. The responsibility of the state in the field of health services to citizens so that the rights of these citizens are fulfilled, the government must have a role in making policies and also play a role as a supervisor. The implementation of health services is not only regulated in Article 28H paragraph (3) and Article 34 paragraph (2), but its real realization is only seen when Law Number 40 of 2004 concerning the National Social Security System (SJSN) is passed. In addition, Law Number 39 of 1999 concerning Human Rights also supports health insurance for the community, which is contained in article 8. The regulation regarding health administration in the field of vaccination can be found in several regulations, namely Article 28H paragraph (1) 1945 Constitution of the Republic of Indonesia, Article 28J paragraph (2) of the Constitution of the Republic of Indonesia,
2. The legal responsibility for implementing vaccinations due to the impact of AEFI is held by 2 people, namely health workers and the government. In terms of health services, the legal norm is the health law itself, which is contained in Law Number 36 of 2009 concerning Health, while for deviations, sanctions in the form of criminal law are used. Health center doctors as field officials and other Ministry of Health officials can be sued if they violate the patient. However, if the health worker is reported by the patient, the first thing to look at is whether there is an element of negligence or an element of intent that must be proven by medical records. However, if it is related to vaccinations carried out by the community, if an AEFI occurs, the health workers

cannot directly blame it because the informed consent has also been fulfilled by the patient and the health worker. In addition, this Covid vaccination is also a policy that is required by the government for all people. So that if undesirable things happen, such as the emergence of AEFI symptoms, health workers as professionals who carry out their duties cannot immediately be blamed. If undesirable things occur such as the occurrence of AEFI and there are demands from the patient, the responsibility follows a tiered chain of responsibilities and provides a tiered pattern of program accountability.

3. Immunization is medically safe, but sometimes it is threatened by a bad side effect called AEFI. The efforts that can be made in the event of kipi can be done in 2 ways, namely through litigation and non-litigation. Litigation efforts mean dispute resolution through the courts, where in this case the court that has the authority is the State Administrative Court. While non-litigation is carried out with alternative settlement of disputes or differences of opinion through procedures agreed upon by the parties, namely settlements out of court by means of consultation, negotiation, mediation, conciliation, or expert judgment with: First, the internal efforts of the Ministry of Health, namely the pseudo-judicial body, for example MDTK (Health Personnel Disciplinary Council), through superior officials/agencies, among others, through the monitoring and control mechanism of AEFI starting immediately after vaccination, Of the 2 paths offered for the resolution of medical disputes, the path that is often used and is considered an effective path in resolving disputes is through mediation because it can produce a win-win solution for the parties to the dispute. Provision of reimbursement for the cost of care for national patient services (JKN), and through special committees or teams such as the KIPi Working Group, Second, External State Administration Agencies, namely through (international) arbitration bodies.

The suggestion that can be drawn from the discussion above:

1. It is recommended to the central government in issuing new rules related to the handling of COVID-19 and the implementation of vaccinations must be in line with and must not conflict with existing laws and regulations, especially regarding human rights (HAM) and the rights of citizens to determine the system. and how to maintain it responsibly, including vaccination, which should be an option in health care and not be forced. Besides that, to provide legal protection to vaccination providers so that health workers in carrying out their duties are not always blamed and can carry out their duties without feeling worry. Significantly, thus things that are not desirable can be avoided.
2. It is recommended to health workers and also the government both at the regional and central levels to coordinate well, especially regarding procedures and other things that can be considered such as congenital diseases or other diseases before carrying out vaccinations to the community, so as not to raise doubts about the impact.

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