

LEGAL PROTECTION FOR CITIZENS AFFECTED BY AEFIs AFTER COVID-19 VACCINATION

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ABSTRACT

This article aims to find out, First, about the foundation of the legal protection of citizens affected by AEFI after vaccinating covid-19 based on the theory of state functions and human rights; Second, the form of legal protection provided by the state to citizens affected by AEFI after vaccinating covid-19 for the fulfillment of the right to health owned by citizens. The study used normative juridical methods. The results showed that: First, one of the functions of the state function theory is the function of general well-being. The functions of general well-being include maintaining people's health and the maintenance of spiritual material well-being. It is also supported by Article 28 H paragraph 1 of the Constitution of the Republic of Indonesia of 1945, "which states that the protection, promotion, enforcement, and fulfillment of human rights is the responsibility of the state, in particular, the government". Realizing the health services of citizens is the responsibility of the government to fulfill the human rights of all citizens. In light of the Covid19 pandemic, the government has fulfilled its obligations and functions in the fight against the virus, including the implementation of vaccination programs currently carried out across Indonesia. Second, the form of legal protection for citizens affected by AEFI after vaccinating COVID-19 is Presidential Regulation Number 99 of 2020 concerning Vaccine Procurement and Vaccination Implementation in the Context of Combating the Corona Virus Disease 2019 Pandemic, which includes what citizens can make provisions. Countries if affected by AEFI. Presidential regulations are considered sufficient in providing legal protection because one form of delegation regulation in Indonesia is a Presidential Regulation. After all, Presidential Regulation is considered faster in solving problems. It was considered that in a state of law, all government actions must be based on rules.

Keywords: Covid-19, State Functions, AEFI, Legal Protection, Vaccination

INTRODUCTION

Based on the constitution in force in Indonesia, human rights are rights that must be fulfilled by the government. One of the rights is related to health, it has regulated in One of the human rights that the Government must fulfil is the Right to Health, which is stipulated in Article 28 H paragraph 1 of the 1945 Constitution, "which states that everyone has the right to live well, physically or mentally, have a space, and stay safe and healthy to live in the environment, and receive the right to health services.". Since the Covid-19 virus hit the world, there have been various efforts to combat the Covid-19 virus. Some of the ways include issuing a PSBB policy in mid-2020 until the implementation of PPKM, which is still applied. Other guidelines above, suppressing the enhancement rate of positive COVID-19 confirmations, the government has additionally issued insurance associated with the implementation of COVID-19 vaccination. Its vaccination is expected to break the chain of transmission of the Covid-19 virus from one to another. It is expected to create 'herd immunity' or 'community protection' (Orenstein & Ahmed, 2017). From this implementation, Government Health Service Facilities and Private Parties have various requirements, including a *community health center*, Clinics, Covid-19 Vaccination Service Posts, Hospitals, and Health service units owned by the Port Health Office to carry out Covid-19 Vaccinations (Dewi et al., 2021). After Covid-19 vaccination, everyone will get a vaccination certificate in the form of a card or electronic certificate from the officer, which they can access independently. The function of the card or electronic mail can later use for the requirement of travel both domestically and abroad and to anticipate if an AEFI occurs after the covid-19 vaccination.

A person who experiences AEFI after the Covid-19 vaccination will have recorded and reported. Following the medical indications and treatment protocols, an investigation has been followed up with treatment and care (Dewi et al., 2021). According to medical terms, AEFI is an empirical fact whose actions refer to the phenomenon of medical activity. AEFI is detrimental effects on health after vaccination. Non-serious AEFIs include fever, nausea, vomiting, dizziness, pain, and headaches. However, it is unknown whether the cause is due to symptoms after the Covid-19 vaccination. Previously, a few days ago, there were only two people who allegedly died after being vaccinated against AstraZeneca. Following this incident, the Food and Drug Supervisory Agency temporarily suspended the use of the AstraZeneca CTMAV5 7 Corona vaccine lot for toxicity and sterility tests (Iqbal, 2021). The Covid19 vaccination program was carried out on a large scale, legally and publicly regulated, regulating the legal relationship between the state/state and citizens/residents (Purwadianto, 2016).

RESEARCH METHOD

This research uses normative legal research. Normative Legal Research is legal research done by library materials or secondary data (Soekanto, Soerjono; Mamudji, 2003). Normative legal research is also known as doctrinal legal research. According to Peter Mahmud Marzuki, normative legal research is finding the rule of law, legal principles, and legal doctrines to solve the legal problems. (Marzuki, 2010). In this type of legal research, the law is often conceptualized as what is written in legislation or law as a rule or standard norm of human behavior that is appropriate (Amiruddin ; Asikin, 2006). Doctrinal research systematically explains the rules of specific legal categories, analyzes the relationship between provisions, explains difficulties, and possibly benefit future developments. (Marzuki, 2006).

The approach used by researchers is about the legislative approach and the conceptual approach, which is certainly relevant to this research. In this approach, the researchers will examine the reasons for the need for legal protection for citizens affected by KIPI after vaccination covid-19. Some AEFI cases will be reviewed based on the laws and legal theories. Thus, it is expected to produce research that follows the legal rules.

RESULTS AND DISCUSSION

Citizens' Rights Regarding Health Rights

The Universal Declaration of Human Rights by the United Nations in 1948 and the 1945 Constitution of the Republic of Indonesia in Article 28 H stipulated that health is a fundamental right of every individual and all citizens. In addition, Law Number 39 of 1999 concerning Human Rights, based on Article 9 contains: "Everyone has the right to live, receive his life, and improve his standard of living, and Everyone has the right to safety and a healthy environment". Talking about the Right to Health, Article 1 point 1 of Law number 36 of 2009 concerning health, it defined as healthy condition as physically, mentally, and spiritually that allows everyone to be productive socially and economically. Health becomes a measure aside from education and economy, which determines the quality of human resources (Afandi, 2008). The right to health has a broader scope related to individual rights. It includes all factors that contribute to a healthy life (healthy self-esteem) for individuals, including matters such as the environment, nutrition, housing, and others. Meanwhile, the right to health and the patient's health services are a more specific part of the right to health (Isriawaty, 2015). The right to health as a human right has been recognized and regulated in various international instruments, including Article 25 Universal Declaration of Human Rights (UDHR), Article 6 and 7 *International Covenant on Civil and Political Rights (ICCPR)*; Article 12 *International Covenant on Economic, Social and Cultural Right (ICESCR)*; Article 5 *International Convention on the Elimination of All Forms of Racial Discrimination (ICERD)*; Article 11, 12 and 14 *Convention on the Elimination of All Forms of Discrimination against Women (Women's Convention)*; Article *Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Convention, or CAT*; *Punishment (Torture Convention, or CAT)*; Article 24 *Convention on the Rights of the Child (Children's Convention, or CRC)* (Farina Gandryani; Fikri Hadi, 2021).

The widespread of Covid-19, which has been designated as a public health emergency in Presidential Regulation No. 11 of 2020, has become the main gateway that places the Right to Health in handling Covid-19 in the field of public rights. In a stricter concept, Health Law no. 36 of 2009 regulates the right to personal health; although it is still legal, its validity cannot apply. Sanctions as a means of coercion are a rational consequence that can support the public's right to health to prevent the massive transmission of the Covid-19 disease through mandatory vaccination for all.

Reasons for Legal Protection for Citizens Affected by AEFI

In the Regulation of the Minister of Health No. 42 of 2013 concerning the Implementation of Immunization, immunization defines as an effort to actively create or increase one's immunity against the disease he gets one day. Vaccination is also not a way of strengthening immunity against infection from a mildly ill or not at all ill person in sick or slightly ill people so that impunity can be actively and passively promoted. (Directorate of Community and Clinical Pharmacy Development, 2009). Quite a few people believe that there is a common understanding of vaccination and immunization. According to the University of California's Centers for Disease Control and Prevention (CDC), vaccination is the activity of introducing a vaccine into the body to create immunity to a specific disease. Meanwhile, immunization is a process by which a person becomes immune to certain diseases through vaccination, concluding that vaccination is the receipt of a vaccine. In contrast, immunization is the result of vaccination, namely the formation of an Immunity. (dr. Sara Elise Wijono, 2019)

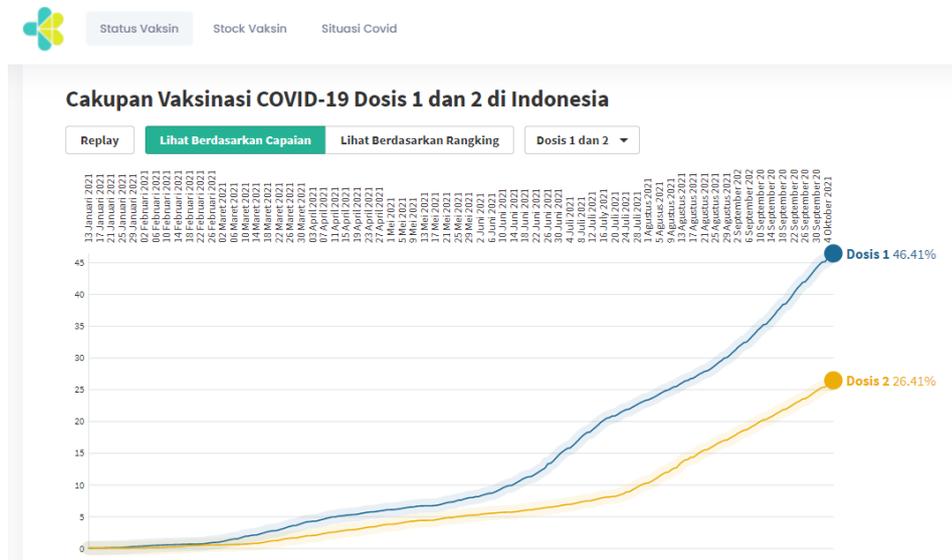
According to its definition, AEFI is a medical event related to a vaccine, whether it causes effects or side effects, toxicity, sensitivity reactions, pharmacological effects or program errors, coincidences, injection reactions, or indeterminable causal relationships (Ranuh I.G.N Hariyono Suyitno, Hadinegoro, 2008). AEFI includes all incidents of illness and death that occur within one month after immunization. In general, reactions to medicines or vaccines can bring harmful reactions or other reactions that do not happen due to the direct effects of the vaccine (Tanjung A ; Yuniastuti E., 2014). This means that reactions do not occur directly with the vaccine recipient, but are necessary for a few days. Immunogen side effects include drugs, appearance, drug interactions, intolerance, individual reactions, and allergic reactions, often difficult to distinguish clinically. Allergic reactions can occur to egg protein (measles, mumps, flu, and yellow fever vaccines), antibiotics, preservatives (neomycin, mercury), or other components of vaccines (Ranuh I.G.N Hariyono Suyitno, Hadinegoro, 2008).

Every citizen, of course, must be given protection in all aspects of life without exception. The protection also applies to recipients who are affected by AEFI after vaccinating against COVID-19, either lightly or seriously, resulting in death. In terms of protecting citizens, this is in line with the theory of state functions proposed by Mac Iver in his book entitled *Web Government*. On the authority of Mac Iver, the state's position can be viewed from an internal perspective, which means the basic function of the State is on the needs of the state itself. Meanwhile, in terms of transformation, several things become the scope of state functions. One of them is the general welfare function (Dr. Sri Kusriyah, S.H., 2017). In the development, Mac Iver views that if it is based on the public welfare function, the state is no more considered as the most powerful position but it becomes a service instead (Marilang, 2012). Concerning the general welfare function, this refers to all activities that carry out by all societies. The functions of general welfare include maintaining people's health and supporting material and spiritual welfare (Dr. Sri Kusriyah, S.H., 2017).

The theory of the classical legal state (*rechtsstaat in engere zin*) has been abandoned and began to embrace the welfare-state theory that puts the function of service to society as the primary function of the state or government (Miriam Budiarmo, 1985). The welfare state embraces the understanding of providing services to the community or social service state to protect and promote its citizens' economic and social welfare. In a welfare state or nation, the government must actively take care of its citizens' various interests. The regulation and management of government must be based on the law because this is a principle in the state of law. If the law has not been regulated when the technical affairs have not settled the rule of law yet, so the government must act based on the discretionary power or "*freies ermesen*". Therefore, following his legal principles in implementing the Covid19 vaccination to combat the spread of the Covid19 virus, the President has formulated a Regulation, namely Presidential Regulation No. 99 of 2020, to provide legal protection in connection with the implementation of Covid19 vaccination.

Because of its obligation to uphold the right to health as a human right, the government has a legal basis, namely Article 28 I Paragraph (4) of the 1945 Constitution of the Republic of Indonesia, "which states that the protection, promotion," and application Fulfilling human rights is the responsibility of the state, especially the government." This state obligation has also been confirmed in Article 8 of Law No. 39 of 1999 on Human Rights. In the health sector, Article 7 of Health Act No. 36 of 2009 states that the government is responsible for organizing affordable and equitably distributed health care. Article 9 of the Health Act No. 36 of 2009 states that the government is responsible for improving the community's health. (Wahid, 2014).

It is the government's responsibility to implement health services for citizens to uphold the human rights of all citizens. To fight the COVID19 pandemic, the government has fulfilled its commitments and functions in the fight against the virus, including the current implementation of the vaccination program across Indonesia. Today, starting with the first vaccine on January 13rd, 2021, the number of citizens vaccinated against COVID19 is increasing. Beneficiaries are health workers, civil servants, the general public, even children aged 12 and over. Here is a percentage related to citizens who have done the vaccine dose 1 and dose 2.



Graphic 1: Covid-19 Vaccination Coverage Dose 1 and Dose 2



Picture 1: Number of citizens who have participated in The Vaccine Dose 1 and Dose 2
Source: <https://vaksin.kemkes.go.id/#/vaccines> (Vaksin Dashboard, n.d.)

However, when the vaccination process was in progress, several citizens experienced AEFIs that cause death. The number of victims who died after being vaccinated against COVID19 is uncertain, but according to *Luhut Binsar Pandjaitan*, the number of deaths of Covid19 vaccination recipients in DKI Jakarta is as much as 54 out of a total of 5.1 million recipients. Although it is not known for sure what things caused the death after the covid-19 vaccination. This certainly becomes the responsibility of the government to carry out its function to maintain people's health, because AEFI is known for all incidents of illness and even death that occur within one month after immunization. In general, the reactions of medicines or vaccines can bring harmful reactions or other normal reactions (Tanjung A ; Yunihastuti E., 2014).

Legal Protection for Citizens Affected by AEFI after Covid-19 Vaccination

The main task of the government in protecting human rights is the principle of democracy. The basic principle of democracy declares that the government has given the power to protect the rights of its citizens. Remarkable capacity to act Energy were geared towards promoting and enforcing the human rights of its citizens and fulfilling the right to health, the government's obligation to fulfil them (Wahid, 2014).

By implementing legal protection for citizens affected by AEFI after the Covid19 vaccination, a Presidential Regulation No. 99 of 2020 on Vaccine Procurement and Vaccination Implementation in order to Combat coronavirus pandemic 2019 will be issued at the end of 2020 by promulgating Presidential Regulation No. 14 from 2021 on the Presidential Regulation on amendments to the Presidential Regulation No. 99 of 2020 on Vaccine Procurement and Vaccination Implementation in order to Combat coronavirus pandemic 2019 and the Presidential Regulation No. 50 of 2021 on the second amendment to the Vaccine Procurement and Vaccination Implementation in order to Combat coronavirus pandemic 2019. The main improvement in enacting the two Presidential Regulations is the government's responsibility for the AEFIs, which recipients can vaccinate. The regulation will later emphasize the responsibility of the state to provide legal compensation (damages) in the event of health problems of the vaccine recipient Presidential Regulation No. 99 of 2020, Articles 11 A and 11 B of Presidential Regulation No. 14 of 2021 Presidential Regulation No. 14 from 2021 on the Presidential Regulation on amendments to the Presidential Regulation No. 99 of 2020 on Vaccine Procurement and Vaccination Implementation in order to Combat coronavirus pandemic 2019, and Article 11 A of Presidential Regulation No. 50 of 2021 on the second amendment to the Vaccine Procurement and Vaccination Implementation in order to Combat coronavirus pandemic 2019, including :

Presidential Regulation No. 99 of 2020

- “(1) In the event of force majeure as stated in the contract or cooperation, the implementation of the contract or cooperation in the provision of the COVID-19 Vaccine may be terminated.
- (2) The state of force majeure as referred to in paragraph (1) is a situation that occurs outside the will of the parties to the contract or cooperation and cannot be expected in advance so that the obligations specified in the contract or cooperation cannot be fulfilled covering the entire process of procuring vaccines until the approval of use in the emergency use authorization or issuance of the COVID-19 Vaccine Edar Permit Number (NIE).
- (3) If the implementation of the contract or cooperation as referred to in paragraph (1) continues, the parties may make changes to the contract or cooperation concerning the principles of good governance.
- (4) Follow-up after the occurrence of force majeure is stipulated in the contract or cooperation.”

Presidential Regulation No. 14 of 2021

Between Article 11 and Article 12 inserted 2 (two) articles, namely Article 11A and Article 11B, so that it reads as follows:

Article 11A

- “(1) If the procurement of vaccines is carried out through assignment to state-owned enterprises, direct appointment to the provider's business entity, or the cooperation of international institutions/bodies whose providers require a takeover of legal responsibility, the Government takes over the legal responsibility of the provider of COVID-19 Vaccine including to the safety (safety, quality), and efficacy of immune gene sites.
- (2) The takeover of legal responsibility by the Government against the provider of the covid-19 Vaccine as referred to in paragraph (1) is carried out throughout the process of production and distribution has fulfilled the excellent way of making the drug and/or a good way of distribution of drugs.
- (3) The assumption of the legal responsibility according to paragraph (1) is until the lifting of Covid19 emergencies in the area of public health and the determination of non-natural disasters in the spread of Covid19 as a national disaster following the provisions of the laws and regulations.
- (4) If at the time of the cancellation of Covid19 investigation of the public health system and the non-natural disaster investigation with the spread of Covid19 as a national disaster within the meaning of paragraph (3), there are cases of subsequent vaccination incidents, which the vaccination was carried out before the determination is revoked; the government continues to assume legal responsibility with the clarification of the case following the provisions of the laws and ordinances.
- (5) Should there still be the implementation of the Covid19 vaccination, the procurement of vaccines before the revocation of the Covid19 health emergency determination and the determination of unnatural disasters in the spread of Covid19 as a national disaster, the government will continue to assume legal responsibility. in the event of incidents after vaccination following the statutory provisions.
- (6) The taking of legal responsibility as referred to in paragraph (1), paragraph (2), and paragraph (3) is outlined in the agreement/contract.”

Article 11B

“ Other provisions relating to the acquisition of the Covid19 vaccine through the transfer referred to in Article 5, the direct appointment of the trading company of the supplier referred to in Article 6, and the cooperation with the international

institutions/agencies referred to in Article 7 was governed by the regulation of the Ministry of Health after consultation with the responsible ministries/institutions.”

Presidential Regulation No. 50 of 2021

“(1) If the procurement of vaccines is carried out through assignment to state-owned enterprises, direct appointment to the provider's business entity, or the cooperation of international institutions/bodies whose providers require a takeover of legal responsibility, the Government takes over the legal responsibility of the provider of COVID-19 Vaccine including against safety (safety), quality (quality), and efficacy immunogenicity.

(2) The government assumed legal responsibility towards the supplier of the COVID19 vaccine following paragraph (1) during the entire delivery time, the manufacturer was certified by the responsible institution in its country of origin and the COVID19 vaccine It was Food and Drug Administration approved for use, including but not limited to approval for use in the emergency phase (emergency approval).

(3) As mentioned in paragraph (1), a takeover of legal responsibility was granted until the revocation of the COVID-19 public health emergency and the determination of non-natural disasters in the spread of COVID-19 as a national disaster following the provisions of the laws and regulations..

(4) Suppose at the time of the lifting of determining the health emergency of COVID19 and the determination of non-natural disasters in the spread of COVID19 as a national disaster within the meaning of paragraph (3). There are cases of incidents after the vaccination. In that case, the implementation of the vaccination before the revocation of the If it is determined, the government's legal responsibility remains until the case is resolved following the provisions of the laws and regulations.

(5) Suppose there is still the implementation of COVID-19 vaccination, which procurement of vaccines is carried out before the revocation of the COVID-19 public health emergency and the determination of non-natural disasters in the spread COVID-19 as a national disaster. In that case, the Government still takes over legal responsibility for post-vaccination incident cases following the provisions of the legislation.

(6) The taking of legal responsibility as referred to in paragraph (1), paragraph (2), and paragraph (3) is outlined in the agreement/contract.”

Although the implementation of legal protection against the introduction of vaccines is still in Presidential Regulation No. 99 of 2020 on Vaccine Procurement and Vaccination Implementation in order to Combat coronavirus pandemic 2019 will be issued at the end of 2020 by promulgating Presidential Regulation No. 14 from 2021 on the Presidential Regulation on amendments to the Presidential Regulation No. 99 of 2020 on Vaccine Procurement and Vaccination Implementation in order to Combat coronavirus pandemic 2019 and the Presidential Regulation No. 50 of 2021 on the second amendment to the Vaccine Procurement and Vaccination Implementation in order to Combat coronavirus pandemic 2019 was considered sufficient since presidential ordinances play an essential role in the implementation of the state government, in particular in the implementation the state legislation (A. Hamid S. Attamimi, 1990). The state has authority in carrying out the general welfare for citizens. Therefore, organizing government is less than perfect just by delegated legislation. The President is considered as the highest state administration organizer who should take actions to ensure the creation of public welfare, this matter needs regulations to prove the President's existence as a leader (Listiningrum, 2019). In the formation of delegacy regulations, presidential regulations are preferred when compared to government regulations. This is because the preparation of a Government Regulation requires a longer process in its issuance. The tendency in its manufacture must be based on inter-ministries, this why the process of issuing government regulations is longer than the Presidential Regulation, it must go through the mechanism of study between ministries or agencies, approval of ministers, and study and reporting to the President. In certain conditions, Presidential Regulation is considered faster in solving problems. It was considered that in a state of law, all government actions must be based on rules (principles of legality) (Listiningrum, 2019).

CONCLUSIONS

The reason for the need for legal protection for citizens affected by AEFI after vaccination against COVID19 is that the state, under its role, has a responsibility to protect all citizens and uphold the health rights of its people. The state is an instrument used to fulfil the rights of its citizens, especially the health rights of its people. The state-guaranteed legal protection of citizens concerning health rights following Article 28 H, Paragraph 1 of the 1945 Constitution of the Republic of Indonesia. In addition, legal protection services for citizens affected by AEFI after vaccination against Covid19 have also been confirmed based on the theory of state functions. Its means that the state must do justice to the welfare of society. Compliance includes observing citizens' rights to health.

To provide legal protection services for citizens affected by AEFI after Covid19 vaccination, Presidential Regulation No. 99 of 2020 on Vaccine Procurement and Vaccination Implementation in order to Combat coronavirus pandemic 2019 will be issued at the end of 2020 by promulgating Presidential Regulation No. 14 from 2021 on the Presidential Regulation on amendments to the Presidential Regulation No. 99 of 2020 on Vaccine Procurement and Vaccination Implementation in order to Combat coronavirus pandemic 2019 and the Presidential Regulation No. 50 of 2021 on the second amendment to the Vaccine Procurement and Vaccination Implementation in order to Combat coronavirus pandemic 2019, in addition to the Presidential Regulation on the registration and investigation of AEFI reports after the Covid19 vaccination, the government also formed the National Commission and the Regional Commission AEFI Regulation is considered to be faster in solving problems Laws; therefore all government actions must be based on rules (principles of legality).

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- Presidential Regulation No. 50 of 2021 on the second amendment to the Vaccine Procurement and Vaccination Implementation in order to Combat coronavirus pandemic 2019.
- Regulation of the Minister of Health No. 42 of 2013 concerning the Implementation of Immunization.

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