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Abstract

This study aims to describe the procedures and barriers associated with compensating disease sufferers who are not eligible to receive the COVID-19 vaccine. The research method used is normative research, which focuses on analyzing legal aspects based on legal regulations, including Presidential Regulation Number 99 of 2020, concerning Procurement of Vaccines and Implementation of Vaccinations in the Context of Overcoming the 2019 Coronavirus Disease (COVID-19) Pandemic, as well as regulations other relevant matters. Research data was obtained through literature study and document analysis, including primary and secondary legal materials. Data analysis was carried out descriptively and qualitatively with a deductive approach, which refers to general legal principles. The research results identified various obstacles, including technical problems such as a lack of public discipline in undergoing health checks before receiving vaccination and a lack of compliance from medical personnel who manage vaccination procedures per established guidelines. As a result, some groups of people who should not receive the COVID-19 vaccine still receive vaccination, which can ultimately cause side effects. The research also highlights Presidential Regulation Number 14 of 2021 concerning Procurement of Vaccines and Implementation of Vaccinations in the Context of Overcoming the COVID-19 Pandemic, which provides compensation guarantees following applicable regulations if a Post-Vaccination Adverse Event (AEFI) occurs which has the potential to cause disability or death in sufferers of the disease who are not eligible to receive the COVID-19 vaccine. The results of this research provide a deeper understanding of the challenges and obstacles in implementing COVID-19 vaccination, especially in the context of disease sufferers who do not meet the requirements to receive the vaccine, as well as the importance of guaranteeing compensation in AEFI situations that have the potential to have profound impacts.

Keywords: Communication Competence, Disease Sufferers, Providing Competence, Covid-19 Vaccine

1. Introduction

COVID-19 is a virus that has highly contagious transmission characteristics, namely a type of virus that can spread quickly within certain groups (Pratiwi et al., 2020; Octafia, 2021). Due to the nature of this transmission, the spread of the COVID-19 virus can easily infect someone if someone in their group is already infected (Ramdani, 2021). This transmission can occur through touch or exhaled air. With transmission characteristics like these, the COVID-19 virus has the potential to be very dangerous and must be taken seriously (Rosyanti & Hadi, 2020).

People constitutionally have the right to life, which must be protected by the state as stated in the 1945 Constitution of the Republic of Indonesia, Article 28H paragraph (1), which reads: "Everyone has the right to live in physical and spiritual prosperity, to live in, and to have a good and healthy living environment and the right to obtain health services" (Article 29 Paragraph 1, 1945 Constitution). To realize this right, the government of the Republic of Indonesia issued Perpu number 1 of 2020 concerning State Financial Policy and Financial System Stability for Handling the 2019 Corona Virus Disease (COVID-19) Pandemic and/or in order to face threats that endanger the national economy and/or financial stability country. The DPR RI then

approved the Perpu to become Law No. 2 of 2020. Law No. 2 of 2020 is an implementing legal instrument that is subordinate to Law Number 6 of 2018 concerning Health Quarantine.

According to Law Number 6 of 2018, health quarantine is an effort to prevent the entry or exit of diseases and/or public health risk factors that can potentially cause a public health emergency. Every person who is in the territory of Indonesia is obliged to comply with the health quarantine rules as regulated in Article 9 paragraph (1), which reads: "Every person is obliged to comply with the implementation of health quarantine" (Article 9 Paragraph 1, "Law No. 6" of 2018). Some sanctions will be given to people who violate health quarantine. This is confirmed in Article 93, which reads, "any person who does not comply with the implementation of Health Quarantine as intended in Article 9 paragraph (1) and/or obstructs the implementation of Health Quarantine thereby causing a Public Health Emergency shall be punished with a maximum imprisonment of 1 (one) year and/or a maximum fine of IDR 100,000,000.00 (one hundred million rupiah) (Mona, 2020).

Implementation of preventive measures originating from the Health Quarantine Law includes the implementation of Large-Scale Social Restrictions (PSBB) throughout Indonesia, as outlined by Permadi & Sudirga (2020). Regulations related to PSBB are explained in Presidential Regulations, Presidential Instructions, and other legal regulations. At the same time, local regions also regulate PSBB through Circulars, Regional Head Regulations, and various other legal regulations, as expressed by Ramdani (2021). When COVID-19 cases increased sharply at the beginning of 2021, the President officially implemented Community Activity Restrictions (PPKM) from 3 to 20 July 2021 in the Java and Bali regions, according to a report from Hani (2021). However, PPKM continues to be extended without a precise time limit. This shows that although prevention efforts through restrictions on community activities such as PSBB and PPKM have been implemented, another effort taken by the government to reduce the spread is through the vaccination program.

The legal basis for implementing vaccination in Indonesia is in Presidential Regulation (Perpres) Number 99 of 2020 concerning Procurement of Vaccines and Implementation of Vaccinations in the Context of Overcoming the 2019 Corona Virus Disease (COVID-19) Pandemic. This Presidential Regulation has undergone two changes, namely the first through Presidential Decree Number 14 of 2021 and the second amendment through Presidential Decree Number 50 of 2021. In Presidential Decree Number 99 of 2020, the scope of vaccine procurement and COVID-19 vaccination includes: a) procurement of the COVID-19 vaccine; b) implementation of COVID-19 vaccination; c) funding for the procurement of the COVID-19 vaccine and implementation of the COVID-19 vaccination, and d) support and facilities for ministries, institutions, and regional governments.

Some diseases are prohibited from receiving the COVID-19 vaccine, one of which is an autoimmune disease (Lupus). Lupus sufferers' immune systems will attack healthy cells, tissues, and organs (Simatupang, 2022). The immune system in Lupus patients will experience a loss of the ability to see the difference between foreign substances (non-self) and the body's cells and tissues. The World Health Organization or WHO records that the number of Lupus sufferers worldwide today has reached five million people (Yuwindry, I. (2020; Maria & Ediati, 2020). Of the approximately 1,250,000 Indonesians affected by Lupus (assuming a prevalence of 0.5%), very few know they suffer from Lupus (Damayat & Wardani, 2023). Most of them are women of reproductive age, and every year more than 100 thousand new sufferers are found (Yuwindry, 2020).

Several studies have been carried out regarding Covid-19. First, research conducted by Mufidah & Tejomurti (2021) explains the legal basis for vaccine procurement in handling the Coronavirus Disease 2019 (COVID-19) pandemic and the procurement process's technical procedures. Furthermore, the research explains the lump sum contract, which is the basis for

the goods procurement contracting the form of a vaccine. Second, study conducted by Susanti & Murniati (2018) explains that government procurement of goods/services is included in the category of authority and scope of civil law because it is based on a procurement contract as the basis for the engagement between the Provider and the User of Goods/Services, represented by the Manufacturer's Official. Commitment or PPK. The funds used to procure goods/services come from APBN/APBD funds. The process of procuring government goods/services is included in the scope of State Administrative Law and Criminal Law because implementing government procurement of goods/services can potentially cause violations of statutory regulations, which have serious consequences. Administrative and criminal (Susanti & Murniati, 2018). However, previous researchers have not studied the impact or side effects of COVID-19 vaccine recipients. However, the study above has provided the beginning of the study of COVID-19. Therefore, it is necessary to survey this matter.

2. Methods

This research is included in the type of normative research, which focuses on analyzing legal issues originating from specific legal sources, such as Presidential Regulation Number 99 of 2020 concerning Vaccine Procurement and Implementation of Vaccinations in the Context of Overcoming the 2019 Coronavirus Disease (COVID-19) Pandemic, and various other related regulations. Researchers use a normative approach with two different sub-approaches to study research objects. First, the juridical-positivistic approach (statute approach), focuses on analyzing the text of the laws and regulations. Second, the conceptual approach takes its basis from the views and concepts that have developed in legal science. The research data required was obtained through library study methods or document analysis of primary legal materials (such as laws, presidential regulations, etc.) and secondary legal materials (such as journals, articles, etc.). Data analysis was conducted using a descriptive-qualitative approach, including an in-depth explanation of the legal context and deductive methods. This reasoned approach refers to taking legal logic from general legal principles and applying them to the specific case being studied.

3. Results and Discussion

Providing the Covid-19 Vaccine in Efforts to Handle the Covid-19 Pandemic Emergency in Indonesia

Organizing the COVID-19 vaccination is one of the steps taken by the Indonesian Government to deal with the spread of the COVID-19 virus. To support this initiative, the Government has issued Presidential Regulation No. 99 of 2020 concerning Procurement of Vaccines and Implementation of Vaccinations in the Context of Overcoming the COVID-19 Pandemic. Article 1 of the Presidential Decree explains that this Presidential Decree aims to accelerate the response to the COVID-19 pandemic, which includes the procurement of vaccines, implementation of vaccinations, funding, and support from ministries, institutions, and regional governments.

The world is still facing the COVID-19 pandemic, which is spreading at a speed unprecedented in human history. This crisis has had significant social and economic impacts, affecting families, communities, and countries worldwide. In Indonesia, there are signs of decreasing cases of COVID-19 infection. On December 24, 2021, 204 new disease cases were recorded, with an average of 181 patients in the last seven days. This marks a significant decrease compared to the peak of cases on July 15, 2021, when there were 56,757 new cases and a seven-day average of 44,145 patients (COVID-19 Handling Task Force, 2021). This decline is the result of the hard work of the community and government in reducing the number of COVID-19 cases, including through mass vaccination programs.

The COVID-19 vaccination program in Indonesia started on January 13, 2021, with the President of Indonesia, Joko Widodo, as the first person to receive the Sinovac vaccine. Then, government officials, community leaders, religious leaders, and representatives of organizations and professions also participated in vaccinations. As of 24 December 2021, approximately 155,414,524 individuals in Indonesia had received at least one dose of vaccine (56.8% of the total population), and 109,955,752 individuals had received complete vaccination (40.2% of the total population). Even though it is still far from achieving herd immunity, at least half of Indonesia's population has been vaccinated. On January 6, 2021, Indonesia imported 122.5 million doses of the Sinovac vaccine, 50 million doses of Novavax, 54 million doses from COVAX/Gavi, 50 million doses of AstraZeneca, and 50 million doses of Pfizer. Vaccine distribution to 34 provinces in Indonesia began on January 7, 2021, and vaccination implementation started in the second week of January 2021 after BPOM issued an Emergency Use Authorization. On June 21, 2023, President Joko Widodo announced the lifting of the COVID-19 pandemic status in Indonesia, marking the transition to an endemic period. During its journey from pandemic to endemic, Indonesia faced various problems, including vaccination-related ones.

One of the main problems in implementing vaccination is people's doubts about immunization. In particular, the safety and efficacy of the COVID-19 vaccine is being debated, with the view that vaccine development feels rushed and considerations about whether the vaccine is halal.

Safety and Efficacy of COVID-19 Vaccine

Because the work and implementation were carried out very suddenly, many people questioned the safety and efficacy of each vaccine used. For Sinovac itself, in the phase 3 clinical trial carried out at UNPAD Bandung, West Java, it obtained an efficacy of 65.3% from 1620 people who were subjects. For Pfizer, the effectiveness obtained was 70% in Brazil and England and 95% in clinical trials conducted in the United States. AstraZeneca obtained an effectiveness of 62.10% after completing clinical trials on a large population. As for the most severe side effects, the US Centers for Disease Control and Prevention (CDC) published the most recent record of such statistics. According to the CDC, these are the proportional numbers of cases of the most serious side effects known so far: Anaphylaxis (severe allergic reaction after vaccination): five cases per million doses administered; Janssen vaccine-associated thrombosis: four cases per million doses issued; Guillain-Barré syndrome linked to the Janssen vaccine: there are no official figures, but there was a "small increase" in men over 50 who took this vaccine, compared with those who received the Pfizer dose;

Myocarditis and pericarditis (inflammation of the heart) in young people who have taken the Pfizer vaccine: from 12-15 years of age: 70.7 cases per million doses administered; from 16-17 years old: 105.9 points per million doses administered; from 18 to 24 years: 52.4 points per million doses distributed. The CDC reports that "most patients with myocarditis or pericarditis who receive drug treatment and good rest find their condition improves quickly." The CDC continued: "Multiple studies and reviews of data from safety monitoring systems continue to demonstrate that the vaccine is safe." In terms of deaths, US records show that of the 657 million doses administered in the country through December 7, 2022, there were 17,800 identified deaths following vaccination (or 0.0027% of the total), even if vaccine administration was not identified as the direct cause of the deaths. This. Investigation of all these cases through analysis of medical records and autopsies found only nine deaths related to using the Janssen vaccine. Dr. Ballalai emphasizes that no drug, vaccine, or procedure is risk-free (Biernath, 2022)

Halal COVID-19 Vaccine



The halalness of vaccines in Indonesia is determined by the Fatwa of the Indonesian Ulema Council based on the Koran and Sunnah as the primary sources, followed by expert opinions. In developing the COVID-19 vaccine, several vaccines were determined to be haram, including Pfizer, AstraZeneca, and Sinopharm. However, a "haram" vaccine will be permitted (mubah) if conditions occur: (1). An urgent need (hajar syar'iyah) that occupies a syar'iy emergency (dilarurah syar'iyah); (2). There is information from a competent and trusted expert about the dangers (fatal risk) if COVID-19 vaccination is not immediately carried out; (3). The availability of a halal and holy COVID-19 vaccine is insufficient for the implementation of COVID-19 vaccination to achieve herd immunity (4). There is a guarantee of safety for its use by the government; and (5). The government cannot choose the type of COVID-19 vaccine, considering the limited number of vaccines available (MUI Fatwa No. 14 of 2021) (Biernath, 2022).

The implementation of the Covid-19 vaccination in Indonesia has experienced quite a lot of obstacles in society. Some people support the COVID-19 vaccination program, but quite a few doubts the effectiveness and efficacy of the COVID-19 vaccine. Some of them even refused to be given the vaccine. The Sinovac vaccine used for COVID-19 vaccination has been clinically tested in several stages and received distribution permits from the Food and Drug Monitoring Agency (BPOM) and the Indonesian Ulema Council (MUI). However, several arguments remain from those who refuse to be vaccinated against Covid-19. Many who refuse are highly educated and even from health circles.

Sanctions for Refusal to Vaccinate Covid 19

Considering the principle of usefulness, where there are more benefits than harm, one of the Government's efforts to ensure that the vaccination process reaches all levels of society more quickly and optimally requires COVID-19 vaccination for all levels of organization. Obligations regarding vaccination have been stated in several statutory regulations, including Law Number 4 of 1984 concerning Infectious Diseases. Article 5 of the Law stipulates that prevention and immunization are actions taken to protect people who are not yet sick but are at risk of contracting the disease. The Government will also impose sanctions on people who refuse to be vaccinated against COVID-19, as stated in Presidential Regulation Number 14 of 2021. In this Presidential Decree, Article 13A paragraph (4) says that every person designated as a target recipient of the COVID-19 vaccine does not participate in the COVID-19 vaccination, which may result in administrative sanctions. Administrative sanctions delay or stop the provision of social security or social assistance, delay or stop government administration services, and/or fines. Article 13A paragraph (5) explains that administrative sanctions are imposed by ministries, institutions, regional governments, or bodies according to their authority (Biernath, 2022).

Side Effects of Disease Sufferers that cannot be given the Covid-19 Vaccine

Even though vaccination continues to be encouraged, several people should not be vaccinated. It depends on the person's body condition for immunization.

The following is a list of groups of individuals who should not be vaccinated against Covid-19, quoted from the COVID-19 Task Force.

- a) People have a fever with a temperature > 37.5 degrees Celsius.
- b) People with uncontrolled hypertension, blood pressure > 180/110 mmHg (if blood pressure > 180/110 mmHg, blood pressure measurement is repeated 5 (five) to 10 (ten) minutes later. If it is still high, then vaccination is postponed until it is controlled).
- c) People with severe allergies, after being vaccinated previously, cannot get the next dose.
- d) People who suffer from autoimmune conditions, for example, asthma and lupus. Vaccination will be postponed if the infection is acute or not yet controlled.

- e) People on medication for blood clotting disorders, disorders, immune deficiencies, and recipients of blood products/transfusions. Vaccination will be postponed and referred
- f) People who are on immunosuppressant treatment such as corticosteroids and chemotherapy. Vaccination is postponed and referred
- g) People with severe heart disease are in a congested state.
- h) Elderly people who, during their examination (according to the screening format), answered more than 3 questions with the answers
- i) People with a previous history of being vaccinated against Covid-19 (Bestari, 2022).

Based on the points mentioned above, it is stated that autoimmune sufferers should not be vaccinated against COVID-19 because further research on giving the COVID-19 vaccine to autoimmune sufferers must be carried out by considering some things, including the influence of the immune system and possible drug interactions.

Vaccines work by encouraging the body's immune response. When vaccinated, substances in the virus will make the immune system respond, build resistance, and signal the disease. If in the future a virus or bacteria tries to infect, the body's immune cells already have the memory to fight and kill the infection. The risk of experiencing severe symptoms or even death can be avoided.

In general, autoimmune patients should not receive vaccines carelessly because the patient's immune condition does not protect them from disease. However, instead, it attacks the body itself. If an autoimmune sufferer receives the vaccine, it is feared that their immune system will weaken and cause autoimmune patients to be susceptible to infection with the disease they are trying to prevent, including COVID-19. As reported by Creaky Joints, several conditions must be considered further if autoimmune patients want to be vaccinated. These include autoimmune inflammatory conditions in patients, such as rheumatoid arthritis (rheumatism), axial spondyloarthritis, and lupus. Then, people with Crohn's disease, ulcerative colitis, psoriasis, and multiple sclerosis also cannot receive vaccines carelessly.

Two concerns might occur if a patient is vaccinated: First, the vaccine may activate the sufferer's immune system in an unsafe or inappropriate manner. Second, immunosuppressant drugs consumed by autoimmune sufferers could interfere with the vaccine's effectiveness. Vinicius Domingues, MD, a rheumatologist in Florida, United States, said that if people with autoimmune conditions are given the vaccine, the efficacy rate could be lower than that of healthy people. Again, this is because the autoimmune person's immune response is weak. The two concerns above do not only occur during this pandemic but also with all vaccines for other diseases. During vaccine trials, researchers did not include people with autoimmune conditions. Generally, vaccine trials will begin and be given to groups that do not have disease symptoms.

Providing compensation to disease sufferers who cannot be given the Covid-19 vaccine

In carrying out the COVID-19 vaccination process, the person who will be injected must undergo a screening and anamnesis process before being injected. Here, people will be asked several questions, including whether there is a congenital disease, if there is even one item that does not meet the requirements, then they must not receive it. Vaccine. Then the question is, what if the person does not know that he already has a disease that is categorized as prohibited from receiving the Covid-19 vaccine, in this case, an autoimmune disease. Because the screening and anamnesis process is not actually carried out optimally in the form of blood pressure measurements and simple interviews, it is possible that people will be given a statement form and then have to sign the form. Without actually carrying out a comprehensive test, it would take a long time to carry out a comprehensive screening test, but the government should be more maximal in providing information about things that should not receive the Covid 19 vaccine so that people will try before going to the injection post. will carry out independent health examination efforts.

Based on Minister of Health Regulation Number 12 of 2017 concerning the Implementation of Immunization in Article 42: (1) Patients who experience health problems suspected to be due to AEFI are given treatment and care during the investigation and causality assessment process of AEFI. (2) In the event that the health problem as intended in paragraph (1) is determined to be a health problem due to AEFI, the patient will receive treatment and care. (3) Funding for case investigations and studies as intended in paragraph (1) is borne by the Central Government, provincial Regional Governments, district/city Regional Governments, as well as other funding sources in accordance with the provisions of statutory regulations. (4) Funding for treatment, care and referral for someone experiencing health problems suspected of being AEFI or due to AEFI is charged to the regional revenue and expenditure budget or other sources of financing in accordance with the provisions of statutory regulations.

And in Presidential Regulation Number 14 of 2021 concerning Amendments to Presidential Regulation Number 99 of 2020 concerning Procurement of Vaccines and Implementation of Vaccinations in the context of dealing with Covid 19 Article 15B: (1) In the event that there are cases of post-vaccination follow-up events that are influenced by the COVID-19 Vaccine product based on the results of the causality study as intended in article 15A paragraph (3) and the case results in disability or death, compensation is given by the government. (2) Compensation as intended in paragraph (1) is in the form of disability compensation or death compensation. (3) Further provisions regarding the criteria, form and amount of compensation as intended in paragraph (1) are determined by the Minister of Health after obtaining approval from the Minister of Finance.

From these two regulations, people who suffer from diseases that cannot be given the Covid-19 vaccine accidentally carry out the Covid-19 vaccination due to ignorance and unawareness of the disease they are suffering from as well as the result of the government's lack of strictness in carrying out the screening and anamnase process for potential Covid vaccination recipients. Causes sufferers of the COVID-19 vaccine prohibition disease to experience post-immunization follow-up events (KIPII), which result in increasingly severe illness, disability, or even death due to receiving the COVID-19 vaccine injection and are entitled to compensation.

4. Conclusion

Based on the discussion above, conclusions can be drawn: (1) The government, in handling the COVID-19 pandemic, has carried out its duties as well as possible, namely by making efforts to provide the COVID-19 vaccine to all levels of society through presidential Regulation (Perpres) Number 99 of 2020 concerning Procurement of Vaccines and Implementation of Vaccinations in the Context of Overcoming the 2019 Corona Virus Disease (Covid-19) Pandemic. (2) In implementing the COVID-19 vaccination, not all groups can be given the Covid-19 vaccine injection. (3) Sufferers of diseases prohibited by the COVID-19 vaccine who experience high-risk post-immunization adverse events (AEFI), which can worsen the previous disease and can cause disability and even death after receiving the COVID-19 vaccination, can be given compensation by the rules and laws applicable.

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