

LEGAL POLICY ON SIDE EFFECT OF THE COVID-19 VACCINE ACCORDING TO HEALTH LAW

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ABSTRACT

Health of the Republic of Indonesia Number: 10 of 2021 concerning the Implementation of Vaccination in the Context of Combating the Corona Virus Disease 2019 (Covid19) Pandemic which refers to Law Number: 36 of 2009 concerning Health, Law Number: 4 of 1984 concerning Outbreaks of Infectious Diseases and Law Number 6 of 2018 concerning Health Quarantine. According to the regulation of the minister of health that vaccination is carried out at health facilities, however, vaccination can be carried out outside health facilities; The government's responsibility for the side effects of the covid-19 vaccine has not yet been seen in the community so that it has the impact of refusing vaccination because the most fatal side effect of the covid-19 vaccination is that it can cause death apart from concerns about the halalness of the covid-19 vaccine. In addition, there is no specific rule regarding compensation as referred to in the existing regulations for people who die after being vaccinated; The legal impact if the community refuses to be vaccinated can be given sanctions based on the 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 (Covid19) Pandemic which is linked to Article 14 paragraph (1) of the Republic of Indonesia Law Number: 4 1984 concerning Outbreaks of Infectious Diseases, but the narrative of the article in question is not in line with the intention of refusing vaccines so that it can lead to multiple interpretations in enforcing sanctions on people who refuse to be vaccinated.

Keywords: Legal Policy, Vaccination, Covid-19

INTRODUCTION

The COVID-19 vaccination program in Indonesia has started in mid-January 2021 but many groups refuse to be vaccinated, adding to the long list of challenges for the vaccine program which is expected to be completed in the next 10 years. Based on the results of clinical trials in Indonesia, the vaccine developed in China recorded an efficacy rate of 65.3 percent. Reported on the detikNews.com page in a statement, BPOM explained that the potential side effects of the COVID-19 vaccine, such as headaches, skin disorders, muscle pain, and fever, were considered harmless and could be recovered.

The risk of side effects of the covid-19 vaccine due to its very short production is an important thing in mass vaccination. Vaccine procurement contracts have forced the government to consider whether it should provide legal redress to vaccine makers. Several countries have enacted laws to clarify who is responsible when vaccines cause side effects. Many developed countries are willing to take risks and compensate vaccine makers, to ensure they get their share of the limited supply.

In relation to vaccination, the Government of Indonesia has made several policies in the context of controlling the spread of the covid-19 virus, namely three sanctions for people who refuse the Covid-19 vaccination based on Presidential Regulation Number: 14 of 2021 concerning Vaccine Procurement and Vaccination Implementation as stated in article 13a paragraph 4 The Indonesian Ministry of Health said that this step was taken so that the target of group immunity against the corona virus was achieved. But an epidemiologist and public health expert said the sanctions were unnecessary because they didn't guarantee everyone was willing to be immunized. What happened, according to them, was that people's doubts were getting stronger.

An Epidemiologist from Griffith University Australia, Dicky Budiman, believes that the sanctions mean that the Indonesian government requires its citizens to vaccinate against Covid-19, but this method will not work. Scientific studies and the history of pandemics in the world show that the effectiveness of vaccines by coercion does not work well and even tends to fail. That's why other countries don't require their citizens to be injected with the corona virus vaccine.

There are still people who believe in the Covid-19 vaccine hoax, which shows that government communication has not had a significant impact. The Ministry of Health's notes when referring to the Law on Outbreaks of Infectious Diseases state that anyone who intentionally obstructs the implementation of epidemic control is threatened with one year's imprisonment and a maximum fine of Rp.1 million.

James E. Anderson argues that policy is a series of actions that have a specific purpose that is followed and carried out by an actor a group of actors in order to solve a certain problem. Meanwhile, Richard Rose suggested that policy should be understood as a series of activities that are more or less related and their consequences for those concerned rather than as a stand-alone decision. Heinz Eulau and Kenneth Prewith argue that policy is a permanent decision that is characterized by consistency and repetition of behavior from those who comply with decisions by way of giving rewards and sanctions. Centrally, policy is a technical, rational and action-oriented instrument to solve problems. Policies are blueprints for actions that lead and influence the behavior of the people affected by these decisions. Policies are deliberately formulated and designed to make the behavior of the targeted people (target groups) patterned according to the sound and formulation of the policy.

Therefore, to find out more about legal policies in controlling the spread of the COVID-19 virus through vaccination, it is deemed necessary to conduct a scientific study on "Legal Policies Against the Side Effects of the Covid-19 Vaccine According to the Health Law".

CONCEPTUAL FRAMEWORK

This study uses a normative juridical approach, namely by reviewing or analyzing secondary data in the form of secondary legal materials by understanding the law as a set of regulations or positive norms in the legal system that regulates problems in research so that this research is understood as research. literature. The data source used is primary legal material in the form of legislation. Data analysis was carried out qualitatively by collecting primary, secondary and tertiary legal materials related to research.

DISCUSSION

A. Rules for the Implementation of Covid-19 Vaccination to the Community According to the Law

Due to the high spread of COVID-19 in Indonesia, the Central Government has taken a policy to vaccinate all citizens according to the people who can be vaccinated. Hessel Nogi argues that policy making is a goal-directed activity, as having its own characteristics from purely physical and expressive activity, which aims to influence the future of desired alternatives. This view of policy-making as an activity that affects the future has comprehensive implications for overall policy analysis and policy development and underlies this part of the whole. The main presumption is the need to base decision making on the greatest possible knowledge of the developing situation and its dynamics [4]. If viewed from this opinion, it can be seen that the covid-19 vaccination policy is a rule in the implementation of the covid-19 vaccination that is applied to the community or citizens who are the target of these regulations based on planning, formulation and decision making and implementation of the decision which is then evaluated on the impact of the implementation of the decision.

The policy made by the Government as a legal basis for the implementation of vaccinations in the context of dealing with the Covid-19 pandemic is regulated in the 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 Corona Virus Disease 2019 (Covid19) Pandemic. This refers to Law Number: 36 of 2009 concerning Health, Law Number: 4 of 1984 concerning Outbreaks of Infectious Diseases and Law Number 6 of 2018 concerning Health Quarantine.

In the Minister of Health of the Republic of Indonesia No. 10/2021 it is stated that vaccination is the administration of a vaccine that is specifically given in order to cause or actively increase a person's immunity to a disease, so that if one day he is exposed to the disease, he will not get sick or only experience mild illness and will not get sick. be a source of infection. Vaccination is one way to stop the virus pandemic, so vaccination is very much needed because it accelerates the existence of community immunity or herd immunity in the community in the hope that the pandemic can end faster. Vaccination is a form of fulfilling the government's obligation to protect public health through a policy.

Furthermore, in Article 8 paragraph (3) of the Minister of Health of the Republic of Indonesia No. 10/2021 it is stated that vaccine recipients are health workers, assistant health workers, supporting staff working in health service facilities, elderly people and public service personnel/officers, vulnerable communities. from geospatial, social, economic and other community aspects. This COVID-19 vaccination policy is implemented through a vaccination program and also mutual cooperation vaccination as stated in Article 9 paragraph (2) of the Minister of Health of the Republic of Indonesia No. 10/2021. From the article and paragraph it shows that the government makes vaccination policies carried out by the government and also non-government.

The Covid-19 vaccination policy also states that to obtain vaccinations, the government collects data based on the targets that have been set as stipulated in Article 8 paragraph (3)

of the Minister of Health of the Republic of Indonesia No. 10/2021. Meanwhile, Article 22 states that mutual cooperation vaccination services are only carried out in public/private health service facilities that meet the requirements. From the articles stated above, it is known that vaccination can only be carried out at government or private health facilities that meet the requirements.

However, the Indonesian Ministry of Health updated the rules regarding the implementation of vaccinations in the context of dealing with the COVID-19 pandemic to increase the coverage of the national vaccination program. This provision is contained in the Regulation of the Minister of Health of the Republic of Indonesia Number: 18 of 2021 concerning Amendments to the Regulation of the Minister of Health of the Republic of Indonesia concerning the Implementation of Vaccination in the Context of Combating the Corona Virus Disease 2019 (Covid-19) Pandemic which was ratified by the Minister of Health of the Republic of Indonesia on May 28, 2021 with a number of amendments. adapt to situations and conditions. The Indonesian Ministry of Health allows the use of the same type of covid-19 vaccine between the government's vaccination program and the mutual cooperation vaccination provided that the type of covid-19 vaccine for program vaccination is obtained from grants, donations or gifts from the community or other countries. The Covid-19 vaccine in question cannot be traded and must be given a special sign that can be recognized by naked eye. The new RI Minister of Health also regulates the handling of follow-up events after the COVID-19 vaccination that requires treatment and care at health facilities in accordance with medical indications and treatment protocols. As for the financing aspect, active participants of the National Health Insurance (JKN) will be covered through the JKN mechanism and can be carried out in all health care facilities. Non-active participants and non-JKN participants will be funded through other funding mechanisms sourced from the state revenue and expenditure budget in accordance with statutory provisions. The health services to be provided are equivalent to class III of the National Health Insurance program or above class III of their own volition with the difference in costs borne by the person concerned. The renewal of this provision is an effort by the Indonesian Ministry of Health as the organizer of the national vaccination program to accelerate vaccination activities in order to achieve group immunity by continuing to pay attention to the need for COVID-19 vaccination in Indonesia. To implement the COVID-19 vaccination program, the Government through the Ministry of Health of the Republic of Indonesia issued a Decree of the Director General of Disease Prevention and Control Number: HK.02.02/4/1/2021 concerning Technical Guidelines for Vaccination Implementation in the Context of Combating the Corona Virus Disease 2019 (Covid-19) Pandemic. In the implementation of the Covid-19 vaccine, there are four stages or 4 tables that the person to be vaccinated must go through.

B. Government Responsibility for the Side Effects of the Covid-19 Vaccine

According to the Indonesian Ministry of Health through the Decree of the Director General of Disease Prevention and Control Number: HK.02.02/4/1/2021 concerning Technical Guidelines for Vaccination Implementation in the Context of Combating the Corona Virus Disease 2019 (Covid-19) Pandemic, it is stated that vaccines are biological products containing antigens in the form of dead or alive microorganisms that are attenuated, still intact or parts thereof or in the form of microorganism toxins that have been processed into toxoids or recombinant proteins added with other substances which when given to a person will cause active specific immunity against certain diseases.

It was reported from kontan.co.id that after the vaccine was given to health workers, the Covid-19 vaccine is now being intensively given to public service officers and the elderly (elderly). Like vaccines in general, the Covid-19 vaccine also causes side effects. The side effect of the Covid-19 vaccine is the body's response when the vaccine is doing its job to boost our immune system. The side effects of the Covid-19 vaccine that appear are generally only mild side effects, including fatigue, headache, to low-grade fever. Side effects in the form of fever often occur one day after the Covid-19 vaccine. Therefore, many doctors recommend that people do not choose a vaccine schedule before a busy work day, so as not to be lethargic and tired the next day.

Other news also explained that there were two cases of Riau residents who died a week after being injected with the Covid-19 vaccine, as reported by detiknews. The two residents who died were from Rokan Hulu and Indragiri Hulu. The death of the two residents after being vaccinated against Corona was conveyed by the Head of the Regional Commission for Post-Immunization Adverse Events (Komda KIPI Riau). In total there were 56 cases of people experiencing KIPI after being injected with the Corona vaccine. Of these, 49 cases of mild KIPI and seven severe or serious KIPI.

Some of the existing cases show that the COVID-19 vaccine has side effects ranging from mild effects to death. However, from the CNN Indonesia page, the Indonesian Ministry of Health confirmed that 29 reports of post-vaccination deaths were not related to the administration of the corona virus vaccine (Covid-19). While one other case is still under investigation. A vaccination spokesman from the Indonesian Ministry of Health said so far there have been 27 reports of deaths of residents after Sinovac vaccination and three reports of deaths after receiving injections of AstraZeneca vaccine doses. Reports of suspected post-vaccination deaths from Sinovac, all clear that there is no relationship with the vaccine. AstraZeneca does have 3 cases, the first one is still not finished with the results of the investigation until the autopsy, but the other two are due to covid-19 and inflammation in the lungs.

From the description above, it can be seen that there are two differences of opinion regarding the side effects of the Covid-19 vaccine where from some news circulating that there are people who died after being vaccinated while from the government side based on Post-Vaccination Adverse Events (KIPI) denied any side effects. to cause death. This is what makes people reluctant to get vaccinated because people think the vaccine is not safe when used because it can cause side effects to death. Based on this, the government must re-examine the side effects that can occur after being vaccinated because the covid-19 vaccine appeared when the corona virus pandemic phenomenon occurred in Indonesia and even in the world. This needs to be done because the law mandates that the government has an obligation to improve the health status of all its citizens.

The Minister of Health of the Republic of Indonesia Number: 10 of 2021 concerning the Implementation of Vaccination in the Context of Combating the Corona Virus Disease 2019 (Covid-19) Pandemic in Article 37 paragraph (1) states that "in the event that there are cases of Post-Vaccination Adverse Events that are affected by the Covid-19 vaccine product based on the the results of the causality study as referred to in Article 35 paragraph (3), and the case causes disability or death, compensation is given by the Government and in paragraph (2) it is stated that the form of compensation as referred to in paragraph (1) is in the form of disability compensation or death compensation.

Based on the Decree of the Minister of Health of the Republic of Indonesia No. 10/2021, it is very clear that the government is responsible for post-vaccination events. But the fact is that from several cases of people who died after vaccination, all of them were denied by the government as stated above. There are denials from the government while the facts from several post-vaccination incidents show that the government is not responsible as stipulated in the Minister of Health Regulation No.10/2021.

In addition, if referring to Permenkes RI No.10/2021 regarding responsibilities in the form of compensation provided, the government does not yet have a legal basis for providing the compensation in question. This can be seen through the national.kompas.com page from the statement of the Minister of Health of the Republic of Indonesia who stated that he was preparing a special Government Regulation for coverage in the event of an KIPI.

By looking at the above, it can be seen that the government is not fully responsible for the policies made in the implementation of vaccinations to deal with side effects or what is known as AEFI which has an impact on post-vaccination death due to the vaccine given. Before the vaccination was carried out, the Government should have prepared all legal instruments or protection for the community if something unwanted happens even though the Covid-19 vaccination has been declared suitable for use and there is no need to worry about the side effects caused.

C. Legal Impact If People Refuse Vaccination

The government has made a policy to vaccinate the community as a step to overcome the covid-19 outbreak with a target of 70% of the total population of Indonesia, but in fact many people from a group or individual are not willing to be vaccinated against Covid-19 even though the vaccination is carried out for free. There are various reasons for people's refusal to receive vaccines, including lack of confidence in the halalness of the Covid-19 vaccine, to the side effects that can be caused if vaccinated. The background factors generally vary in each country because they are related to local socio-cultural conditions such as religion. Religion is one of the reasons for the rejection of vaccines in Indonesia, which has a Muslim majority.

In Indonesia, a video showing House of Representatives member Ribka Tjiptaning's vehement rejection of the COVID-19 vaccination went viral just moments after President Joko "Jokowi" Widodo received his first vaccine. He saw the distribution of the COVID-19 vaccine as a new form of business that would only benefit the company. Research shows a lack of trust in the pharmaceutical industry is an important factor driving the emergence of vaccine hesitancy and the anti-vaccine movement in general. Vaccine skepticism refers to the length of time a person accepts or refuses, usually a parent, to vaccination. While the anti-vaccine movement refers to active campaigns by various groups against the use or idea of the vaccine itself. The lack of trust in the pharmaceutical industry itself stems from the pharmaceutical industry's longstanding negative reputation. Pharmaceutical companies are accused of being involved in many cases, such as bribery of health workers and lack of transparency in clinical trials of vaccines. The presence of industry players on the GAVI Board, therefore, risks further lowering public confidence in the governance of global vaccine distribution.

Nogi argues that policy-making is a goal-directed activity, as having its own distinct characteristics from purely physical and expressive activity aimed at influencing

alternative futures in the desired direction. This view of policy-making as an activity that affects the future has comprehensive implications for overall policy analysis and policy development and underlies this part of the whole. The main presumption is the need to base decision making on the greatest possible knowledge of the evolving situation and its dynamics. If you look at Nogi's opinion which is related to the covid-19 vaccination policy, it is very clear that the covid-19 vaccination policy is implemented towards the future of the Indonesian people to improve the health status of the Indonesian people to the highest as mandated in Law No. 36 of the Republic of Indonesia. of 2009 concerning Health because health is a human right and one of the elements of welfare that must be realized in accordance with the ideals of the Indonesian nation as referred to in the Pancasila and the Preamble to the 1945 Constitution. Therefore, every activity and effort to improve the highest level of public health is carried out based on non-discriminatory, participatory, protective and sustainable principles which are very important for the formation of Indonesian human resources, increasing the nation's resilience and competitiveness and national development.

In the Presidential Regulation of the Republic of Indonesia Number: 14 of 2021 concerning Vaccine Procurement and Vaccination Implementation, it is stated about the sanctions contained in article 13a paragraph (4). In the article it is written that any person who has been designated as the target recipient of the Covid-19 vaccine who does not participate in the vaccination may be subject to administrative sanctions in the form of: postponement or termination of the provision of social security or social assistance; postponement or termination of government administration services; and/or fines. This Presidential Regulation is a legal umbrella for local governments in making regional regulations (Perda) regarding Covid-19 vaccination. Despite the sanctions, the Government will continue to prioritize an educational approach to the community, especially anti-vaccine groups in informing the importance of Covid-19 immunization. Likewise, Article 13B also emphasizes the sanctions which read "covid-19 vaccine recipients, who do not follow the covid-19 vaccination as referred to in Article 13A paragraph (2) and cause obstruction of the implementation of the prevention of the spread of COVID-19, in addition to being subject to sanctions. as referred to in article 13A paragraph (a) may be subject to sanctions in accordance with the provisions of the law on infectious disease outbreaks. From the article, it shows that the Presidential Regulation of the Republic of Indonesia is related to the Law of the Republic of Indonesia Number: 4 of 1984 concerning Infectious Disease Outbreaks.

Based on the Presidential Regulation, it is stated that vaccinations organized by the government or the state must be followed by every target citizen and if there are citizens who refuse to be vaccinated, it will have an impact on the imposition of sanctions on that person. Presidential regulation that contains sanctions for people who do not want to be vaccinated as an anticipation of various public behaviors that will arise if vaccination is applied. What is a polemic for everyone is whether the presidential regulation can be used as a legal umbrella to impose sanctions on people who do not want to be vaccinated because Indonesia recognizes the term positive law.

The contents contained in the Presidential Regulation made are in accordance with Hans Kelsen's Theory of Law which states that the law does not accumulate in a single rule but a set of rules that have a single unit so that it can be understood as a system, the consequence is that it is impossible to understand the law if it only pays attention to one rule only. This opinion is strengthened by the opinion of Omer who argues that policy

(beschiking) is a product of authority that has taken the form of rules or actions in regulating things that were not previously regulated. The law is coercive with real and firm sanctions. Law (recht) comes from Latin which means guidance or demands of government, law (ius) means to regulate or govern which stems from authority so that it can be seen that law is a coercive regulation, determining behavior in society is made an official body and violations will be given action, namely punishment [6] (Samidjo, 1985).

On the other hand, if referring to Article 14 paragraph (1) of the Republic of Indonesia Law Number: 4 of 1984 concerning Outbreaks of Infectious Diseases (Law No. is punishable by a maximum imprisonment of 1 year and/or a maximum fine of Rp. 1 million". Regarding Law No. 4/1984 regarding the sanctions that can be imposed, what needs to be studied is whether the rejection of the vaccine can be said to be "deliberately blocking the implementation of the outbreak control" because overcoming the Covid-19 outbreak has clearly stated that not only through vaccination but can also be carried out. by following health protocols such as wearing masks, washing hands, maintaining distance, reducing mobility and staying away from crowds (5M). This is a problem for the government in tackling the corona virus outbreak and on the other hand, there has been no official statement from the government stating that people who are vaccinated will be given sanctions based on Law No. 4/1984 and or other regulations related to the outbreak. For this reason, the central and regional governments must be careful when implementing or enforcing regulations related to the prevention of COVID-19 through regulations on vaccination. This is very necessary because if one is wrong in overcoming the problem of vaccination, it will create a perception in the community that the government is very authoritarian and violates the laws made by itself so that the government's image can be bad in the eyes of the public.

CONCLUSIONS

From the results of studies from various sources and data analysis, it can be concluded as follows:

1. The rules for implementing the COVID-19 vaccination to the public are regulated in the 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 Corona Virus Disease 2019 (Covid19) Pandemic which refers to Law Number: 36 of 2009 concerning Health. Law Number: 4 of 1984 concerning Infectious Disease Outbreaks and Law Number 6 of 2018 concerning Health Quarantine. According to the regulation of the minister of health that the implementation of vaccination is carried out at health facilities, however, vaccination can be carried out outside health facilities.
2. The government's responsibility for the side effects of the covid-19 vaccine has not yet been seen in the community so that it has the impact of refusing vaccination because the most fatal side effect of the covid-19 vaccination is that it can cause death in addition to concerns about the halalness of the covid-19 vaccine. In addition, there is no specific rule regarding compensation referred to in the existing regulations for people who die after being vaccinated.
3. The legal impact if the public refuses to be vaccinated can be given sanctions based on the 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 (Covid19) Pandemic which is linked to Article 14 paragraph (1) of the Republic of Indonesia Law Number: 4 1984 concerning Outbreaks of Infectious Diseases, but the narrative of the article in question is not in line with the

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