

MANDATORY CORONAVIRUS DISEASE-19 (COVID-19) VACCINATION IN INDONESIA: LEGAL ASPECT

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ABSTRACT

COVID-19 pandemic has spread globally and has reached a dangerous point. COVID-19 pandemic has even been declared a national health emergency in Indonesia. Various efforts have been made to overcome the Covid-19 pandemic, one of which is vaccination. The COVID-19 vaccination aims to establish herd immunity. Herd immunity requires about 70% of the population to be vaccinated. However, the vaccination raises pros and cons in the community. There are even groups of people who refuse to be vaccinated. This community group feels that mandatory vaccination violates human rights and doubts about the quality of the vaccine. The Government has taken a policy to mandate vaccination with administrative and criminal sanctions that are different from the approach of WHO and other countries. This research is a normative study with a conceptual and a normative approach analysis. Data uses secondary data from the literature, both legal and non-legal materials related to covid vaccination. The results show that vaccination is a very important policy in COVID-19 countermeasures. Mandatory vaccination must be carried out to protect all citizens according to the Indonesian constitution. Vaccination is also part of human rights that must be accommodated and implemented. However, in its implementation, there are problems with doubts and rejection of the vaccine. This obligation causes the restriction of several human rights.

However, refusal to vaccinate can violate human rights because it can harm other people and the nation. Therefore, the provision of both administrative and criminal sanctions should be the ultimum remedium. A persuasive and promotive approach and socialization should be the initial approach. However, the regulation of vaccination obligations has shortcomings ranging from the potential for errors in law-making procedures to the absence of an umbrella act. Umbrella act specifically for COVID-19 is a must-have due to an abnormal situation. And the obligation to vaccinate citizens also has implications for the state to be obliged to carry out vaccinations. The Government is obliged to run a vaccination program by ensuring the availability, access, acceptance, and quality of COVID-19 vaccinations.

Keywords: Covid-19, Health Emergency, Mandatory Vaccination

INTRODUCTION

The first COVID-19 case in Indonesia was discovered on March 2, 2020, or about four months after the first case in China. The number of COVID-19 cases continues to increase, adding cases to thousands to reach more than a million cases. The total number of confirmed patients until May 20, 2021, reached 1,758,898 cases of COVID-19 and 48,887 deaths (Handling Acceleration Task Force COVID-19, 2021b). The Government controls the COVID-19 pandemic by considering the health and economic aspects. The health protocol approach is divided into two strategies, *i.e.*, prevention and surveillance programs.

One of the programs that have been intensively implemented to control the COVID-19 pandemic is to achieve herd immunity. To achieve herd immunity in the COVID-19 pandemic, around 70% of the population must develop immunity against the Coronavirus. Therefore, the most appropriate method to achieve herd immunity is to vaccinate against COVID-19 until the target of at least 70% of the population is vaccinated (Suneel & Narasimha, 2020; Clemente-Suárez et al., 2020). It is because vaccines are one of the most effective tools for protecting people against COVID-19.

As the policymaker and implementer of the COVID-19 vaccination program, the Government must ensure that the vaccines used are safe, effective, affordable, and available. The fulfillment of the COVID-19 vaccine program is the full responsibility of the Government as a form of realizing the goals of the state following the Preamble of The Constitution of the Republic of Indonesia Year 1945 (Republican Constitution Indonesia, 1945; Republik Indonesia, 1945). Vaccination, a government program to prevent and control COVID-19, is a human right, especially the right to life and the right to be healthy. These human rights based on Law Number 39 of 1999 on Human Rights must be realized and become the Government's responsibility (Republik Indonesia, 1999).

The Government requires mandatory vaccination for citizens through Presidential Regulation Number 14 of 2021 (President of the Republic Indonesia, 2021). This vaccination obligation is also under Law Number 6 of 2018 on Health Quarantine (Republic Indonesia, 2018) and Law Number 4 of 1984 on Infectious Disease Outbreak (Republic Indonesia, 1984). In addition, the Law on Health in Article 56 paragraph (2) of Law Number 36 of 2009 on Health also permits mandatory vaccination where the right to refuse medical intervention does not apply to infectious diseases that threaten the community (Republic Indonesia, 2009).

Despite the importance of COVID-19 vaccination in controlling the COVID-19 pandemic, many people still doubt and even refuse to be vaccinated. Based on a survey by the Ministry of Health with the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) in November, 7.6% of respondents refused the vaccine, while 52% of respondents still had doubts. Even in some areas, such as Aceh and West Sumatra, the rejection of the COVID-19 vaccine is very high (46% and 47%) (Zain, 2021). People who refused the COVID-19 vaccination reasoned because they are unsure about the vaccine, especially its safety and efficacy.

This refusal has hampered the success of the COVID-19 vaccination program to achieve herd immunity. So that the target of controlling the COVID-19 pandemic by 2022 is difficult to achieve. It has caused the Government to take a policy to require people to be vaccinated or mandatory vaccination. Considering that the COVID-19 vaccination aims to prevent the spread of infection and can reduce the high number of deaths in the community (to maintain human rights, specifically the right to life and the right to health), the Government has imposed limitations on human rights, in this case, the right to refuse vaccination. However, the regulations that oblige all people to vaccinate were made during an unfavorable situation. In addition to being faced with a health crisis, the Indonesian Government is also faced with a crisis of confidence. The crisis of trust that arose in the community towards the Government then prompted various unlawful acts, including refusal to vaccinate. As a result, WHO (World Health Organization) stated that vaccination programs, including COVID-19 vaccination, are not recommended to be mandatory (Nisa & Giger, 2012; Millard, 2020). Furthermore, other countries such as the United States and the United Kingdom have not issued specific regulations requiring COVID vaccination (The United Kingdom, 2020).

The right to refuse medical treatment without consent has been reflected in Article 7 of The International Covenant on Civil and Political Rights (ICCPR) (United Nations, 2016). It can also be found in Article 6 of The Universal Declaration on Bioethics and Human Rights (UNESCO, 2009), which essentially states that medical treatment may only be carried out with consent and without coercion. The Indonesian Legal Aid and Human Rights Association (Assembly of Legal and Human Rights Bodies Indonesia) explained that criminal sanctions and administrative sanctions for refusing vaccination are considered inappropriate (Alam, 2021). Although the Government can restrict human rights for public health reasons in the mandatory COVID-19 vaccination, the policy must also follow the Siracusa Principles on Limiting and Reducing Provisions in the ICCPR (Siracusa Principles) (American Association for the International Commission of Jurists, 1985).

There is a discrepancy in the implementation of mandatory COVID-19 vaccination from the human rights aspect. WHO and a trend of other countries not to mandate COVID-19 vaccination are different from Indonesia's strategies and policies. This mandatory vaccination is also accompanied by uncertainty in government regulations and policies in its implementation, especially in the aspect of sanctions given if the community refuses vaccination. The research will elaborate on the implementation of mandatory vaccination in Indonesia.

METHOD

The data source used is secondary data, consisting of primary, secondary, and other legal sources related to the study. The primary legal source includes Indonesian laws, regulations and policies, and other regulations from different countries and institutions. Secondary legal sources were obtained from materials related to this research, such as textbooks, law and non-law books, journals, and other articles that help explain primary legal sources. All data used is related to the topic under study, specifically about COVID-19 vaccination in Indonesia.

Data collection in this study used the library (literature) method. This study uses normative legal research with a normative approach and conceptual approach. A normative approach is to analyze laws applied in Indonesia. At the same time, a conceptual approach used to analyse data based on legal theories, legal concepts, legal doctrines, and principles relevant to the problem in this study. The conceptual approach is used to explain the concept and implementation of the COVID-19 vaccine's regulations and policies. Qualitative analysis of research data was applied in this study. The data obtained were then compiled systematically and then analyzed with descriptive and prescriptive analytics to explain and provide recommendations on the problems studied.

RESULT AND DISSCUSION

Vaccination and Human Rights

Human rights are inherently natural and fundamental rights as a gift from God that must be respected, guarded, and protected by every individual, society, or state. Human Rights based on Article 1 of Law Number 39 of 1999 on Human Rights (the Republic of Indonesia, 1999):

"Human Rights are a set of rights that are inherent in the nature and existence of humans as God's creatures and are His gifts that must be respected, upheld and protected by the state, law, government, and everyone for the sake of honor and protection of human dignity."

The right to health as a human right has been recognized and regulated both nationally and internationally. Several international instruments that regulate the right to health are:

1. Article 25 of the Universal Declaration of Human Rights (UDHR).
2. Article 7 of the International Covenant on Civil and Political Rights (ICCPR).
3. Article 12 of International Covenant on Economic, Social and Cultural Right (ICESCR).
4. Article 11, 12 and 14 of Convention on the Elimination of All Forms of Discrimination against Women (Women's Convention).
5. Article 24 of Convention on the Rights of the Child (Children's Convention, or CRC).

In Indonesia, protection and fulfillment of the right to health are stated in Article 28H, paragraph (1) of the Constitution of the Republic of Indonesia Year 1945. It firmly says that (Republic of Indonesia, 1945) that "Everyone has the right to live in physical and spiritual prosperity, to live, and to have a good and healthy living environment and the right to health services." It was implemented in Law No. 36 of 2009 concerning Health, wherein Article 4 states that everyone has the right to health.

Vaccination is an effort to actively generate or increase a person's immunity to a specific disease so that when exposed to the disease, the person will not get sick or only experience mild illness through the vaccine. For example, the COVID-19 vaccination aims to protect a person from COVID-19 not to get sick or become infected with COVID-19. Thus, vaccination is part of efforts to prevent someone from getting sick so that vaccination is included in fulfilling human rights to health.

With the right to health contained in the constitution, the right to health is a positive legal right that must be protected. The Government is obliged to fulfill the health rights of its citizens, including the COVID-19 vaccination. It emphasizes that public health in COVID-19 vaccination is one form of realization of the fulfillment of human rights. Even the COVID-19 vaccination also aims to reduce the mortality rate of COVID-19 patients. It shows that vaccines also aim to maintain life. The right to life is the most basic human right and cannot be reduced for any reason (non-derogable rights). Under Article 9 paragraph (1) Law Number 39 of 1999 on Human Rights, everyone has the right to live and maintain life (the Republic of Indonesia, 1999). By vaccinating, the risk of infection

and death from COVID-19 is reduced in line with efforts to maintain a life that is a human right, so the effort to reduce the death rate is also a fulfillment of the human right to life.

Mandatory Vaccination Policies

Vaccination protects a person from the disease as well as others by reducing the transmission of the disease. The more people vaccinated the less chance the disease will spread. This term is known as herd immunity. Herd immunity refers to a state where a significant proportion of the population is immune to an infection, leaving few susceptible people infected and transmitting the infection. Herd immunity can be achieved through vaccination or infection (Public Health Ontario, 2021). Estimated at least 70% of the population needs to be vaccinated to achieve herd immunity *via* vaccination (Suneel & Narasimha-Kumar, 2020). Therefore, herd immunity to form requires around 70% of Indonesia's population or at least 181 million people to be vaccinated and to do so. In addition, it requires the availability of vaccine needs of about 400 million doses of vaccine, and the vaccination program is targeted to be completed within 15 months (until 2022).

The COVID-19 vaccination is still in the research process, with an average entering clinical phase 3 trials. By looking at the benefits and importance of COVID-19 vaccination in controlling COVID-19, WHO permitted for each country to issue emergency use of vaccination (Emergency Use Authorization/EUA). As the agency that regulates drug circulation in Indonesia, the Indonesian Food and Drug Supervisory Agency (Food and Drug Supervisory Agency/BPOM) issued EUA vaccines recommendations from Corona vaccine (Sinovac), Astra Zeneca, and finally Sinopharm.

With the importance of COVID-19 vaccination in controlling the COVID-19 pandemic, there are still pros and cons regarding vaccination in the community. There are still many people who have doubts and even refuse to be vaccinated. The Indonesian Political Indicators Survey Institute survey shows that 41% of the population rejects the vaccine (Pradila, 2021). Until May 20, 2021, vaccination coverage has only reached around 10 million people (5.82%) of 181 million target vaccine participants (Indonesian Task Force for COVID-19, 2021). Even though this is currently Phase II of the vaccination program, which should end in April 2020, around 40 million people have been vaccinated (Ministry of Health, 2021). The refusal occurred because the public was still unsure about the safety and efficacy of vaccines, fear of vaccine side effects, conspiracy issues and hoax information, to aspects of the halalness of the vaccines used. This obstacle will cause the COVID-19 vaccination program to achieve herd immunity and control the COVID-19 pandemic, which is targeted for completion in 2022, to be difficult to achieve.

The COVID-19 pandemic has been considered a national health emergency that all policies to overcome must be carried out (President of the Republic of Indonesia, 2020). Therefore, the Government takes a policy to require vaccination at the targets set by the Government. The Government requires mandatory vaccination for citizens through Presidential Regulation Number 14 of 2021 (President of The Republic of Indonesia, 2021). The regulation requires that every participant of the vaccine target must participate in vaccination, and there is a threat of criminal and administrative sanctions if they refuse vaccination. Even previously, the Special Capital Region of Jakarta issued fines for residents who refused vaccines based on article 30 of Special Capital Region of Jakarta Regional Regulation Number 2 of 2020 COVID-19 countermeasures.

However, this vaccination obligation can become an obstacle in implementing vaccination and cause the movement to reject vaccination to become widespread. The commitment to vaccinate against COVID-19 is considered a violation of human rights. Vaccination, a medical procedure, should be refused because medical treatment is also considered a human right. On principles of health matters, every citizen has the right to determine the health services needed for himself under Article 5 paragraph (3) of Law Number 36 Year 2009 concerning Health (Health Law). In Article 56 paragraph (1) of the Health Law, it is even emphasized that everyone has the right to accept or refuse medical interventions after receiving information on health data.

The right to refuse medical treatment is also recognized and regulated in international instruments. For example, article 7 of ICCPR states that no one shall be subjected to torture, inhuman or degrading treatment. In particular, no one shall be subjected without his free consent to medical treatment or experiment (United Nations, 2016). Article 6 of the Universal Declaration on Bioethics and Human Rights also states that any medical intervention, including vaccination, is only to be

carried out with the person's prior, free and informed consent, based on adequate information (UNESCO, 2009).

The list of vaccines used in the program is considered by the vaccine refusal to have poor efficacy compared to the types of vaccines used by other countries. Moreover, even some of the vaccines used, for example, Coronavac, have not been recognized by developed countries such as America, Saudi Arabia, and Europe. So that the obligation to vaccinate where there are still doubts about the efficacy and safety of vaccines without being able to choose is considered a violation of human rights.

This vaccination obligation must be studied and analyzed from various legal aspects to see the benefits and justice in addition to law enforcement as a legal benefit from the obligation.

- a) Mandatory vaccination limits a person's rights, but restrictions on a person's freedom are justified if an act can harm another person (harm principles). The utilitarians believe that coercion of action can be carried out if it can provide great benefits to society. JS Mill and J Bentham argue that an action is only judged by its consequences. The result of actions that produce maximum equity with happiness in the majority of people. (Rachels, 2004).

The principle of utility or the principle of greatest happiness asserts that actions must be principled (when choosing a course of action, always pick the one that will maximize happiness and minimize unhappiness for the greatest number of people) (Salman, 2010). So that based on the principle of utilitarianism, for the common good, the basic rights of individuals can be eliminated.

Refusal to vaccination has the potential to harm other people and society. A person who is not vaccinated has a high risk of contracting and transmitting Covid-19 to others. In addition, fewer people being vaccinated slows down the process of herd immunity, increasing the risk of an increase in COVID-19 cases. Therefore a policy that requires COVID-19 vaccination can be justified.

- b) The law, according to Roscoe Pound, is "a tool of social engineering". Social engineering is the main concept of Roscoe's thought which transforms law in a realistic setting (to bring the law in books into direct contact with the law in action). The law must not be isolated and backward from the dynamically developing social reality (Leiboff & Thomas, 2004). The law is used to strengthen the patterns of habits and behavior in society, direct them to the desired goals, eliminate habits deemed inappropriate, and create new behavior patterns in society. (Fuady, 2013).

Roscoe Pound considers law as a tool of social engineering, dividing it into three kinds of interests: (1) public interest, (2) social interest, (3) and private interest (Masnun, Sulistyowati & Ronaboyd, 2021). The Covid-19 vaccine obligation policies are in accordance with this theory as a form of human rights protection, not only general and social but also personal protection, namely the right to life and Health.

- c) The COVID-19 pandemic has been considered a national health emergency that all policies to overcome must be carried out (President of Republic of Indonesia, 2020). In the event of a national emergency, state emergency law (*staatsnoodrecht*) applies. However, Fatovic said that there are limitations of positive law and the need for extralegal action in emergencies beyond the reach of established legal provisions (Fatovic, 2009).

State emergency law is a legal concept implemented in certain situations and conditions where an emergency condition threatens the state and/or naturally or non-naturally citizens (Hunter, 2009). According to Dullemen, state emergency law must meet three conditions (Dullemen, 1947): (1) Actions are taken to save the state with no other choice, (2) There is a statement that the country is in a condition of emergency to parliament, (3) This action is temporary.

One of the characteristics of emergency constitutional law is that it allows certain "deviations" from principles, theories, concepts, and rules and regulations in a country. If the country is in normal conditions, this must be obeyed and implemented. However, normal legal norms cannot be applied to abnormal cases. In an abnormal situation that is an emergency and endangers the state, special arrangements are needed in that situation (Gostin & Hodge, 2020). State emergency law implemented in certain legal forms must meet the

requirements for an open declaration, making regulations, and socialization (Asshiddiqie, 2007).

The regulation of emergency conditions where the norm in this abnormal condition in Indonesia is regulated in Article 12 of The Constitution of the Republic of Indonesia Year 1945 as a "dangerous/emergency" condition (Republik Indonesia, 1945). According to the article, the President has the authority to declare a national hazard or emergency. Furthermore, article 4 of the ICCPR also gives power to the state to reduce the state's obligations in fulfilling the rights of citizens as stated in the ICCPR. Therefore, in an emergency that threatens the nation's life declared, the states party to the covenant can take a policy to reduce the state's obligations to fulfil individual or group rights (United Nations, 2016).

In April 2021, the President of the Republic of Indonesia declared a national health emergency due to the COVID-19 pandemic through Presidential Decree Nomor 11 of 2020. Therefore, all regulations aimed to control the COVID-19 pandemic must be implemented to immediately resolve the public health emergency (President of Republic of Indonesia, 2020). The COVID-19 vaccination is one policy issued to accelerate the control of pandemic, which is expected to be completed in 2022. To make COVID-19 vaccination during the pandemic become an obligation, it must have an emergency law and policy. Therefore, the President issued Presidential Regulation Number 14 of 2021, which mandate every target vaccine participant to vaccinate. With this stipulation, Indonesia is in a state of emergency. Therefore, the COVID-19 vaccination is the obligation of citizens to carry out vaccinations during this health emergency.

In addition to the President's right, other government officials can carry out an emergency policy called discretion. According to Widodo & Disantara (2021), discretion is a policy from central and local officials that allows them to issue policies that "deviate" the law in the public interest on the condition that it is within their authority and not violating the general principles of good governance. Special Capital Region of Jakarta government issues fines for residents who refuse vaccines based on Article 30 of Regional Regulation Number 2 of 2020 for COVID-19 countermeasures (Governor of the Special Capital Region of Jakarta, 2020). From the authors' point of view, discretion is an exception to the rules; however, it must be issued in the forms of regulations with the same level of commandments. Discretion may not violate a higher level rule in commandment.

- d) The implementation of emergency law is generally related to human rights. Principally every human right, including refusing medical treatment, must be protected, fulfilled and enforced by the Government. But not all rights must be fulfilled absolutely. Some rights can be limited in their fulfillment. Article 73 of the Human Rights Law states that rights and freedoms in human rights can only be limited by and based on laws. It shall aim to guarantee recognition and respect for human rights and based on the basic freedoms of others, morality, public order, and interests of the nation (the Republic of Indonesia, 1999).

These human rights generally experience restrictions due to implementing regulations for the state's safety and Indonesian people. There is *Salus Populis Suprema Lex* proposition that the safety of the people is the highest law. The condition of the COVID-19 pandemic that threatens public safety is a state threat where the Government must make regulations that prioritize public safety even though they have to deviate from existing regulations. In these conditions, there are always elements that reduce and limit certain human rights. However, the reduction, or limitation, must be (Matompo, 2014): (1) It is temporary, (2) Aiming to overcome the crisis, (3) and intends to restore normal conditions.

However, this limitation of human rights does not apply to non-derogable rights. Non-derogable rights include the right to life, the right not to be tortured, the right to freedom of thought and conscience, the right to religion, the right not to be enslaved, the right to be recognized as a person before the law, and the right not to be prosecuted based on retroactive law (The Republic of Indonesia, 1999). In addition, rights other than those mentioned may be subject to restrictions on rights in the public interest (derogable rights). These rights include the right to health.

Choosing or refusing medical treatment is a human right that must be respected. It is under the provisions of the ICCPR and the Universal Declaration on Bioethics and Human Rights. However, this right can be limited to pandemic conditions which are a national health emergency. Thus, mandatory vaccination, where individuals cannot refuse vaccination actions, can be justified in an emergency situation.

Human rights restrictions must refer to the standards regulated through the Siracusa Principles on the Limitation and Derogation of Provisions in the International Covenant on Civil and Political Rights, which are based on five criteria (American Association for the International Commission of Jurists, 1985): (1) Determined by law and cannot be determined arbitrarily, (2) the regulation of rights restrictions that are carried out do not conflict with democratic principles, (3) for public order and interest, (4) must be based on basic human values, moral values, and not discriminatory, and (5) Restrictions aimed at national security interests.

United Nation General Comment No 29 on Article 4 of ICCPR requires two basic conditions must be met to limit human rights (United Nations, 2016). They are: (1) The situation must amount to a public emergency which threatens the life of the nation, (2) and The State party must have officially proclaimed a state of emergency. In fact, vaccination is also a right to health that must be recognized. Even vaccination in an emergency has a function for public safety with the threat of death from COVID-19. So based on human rights, vaccination in an emergency can have a human rights function for life, a non-derogable right that cannot be reduced under any circumstances.

- e) The mandatory COVID-19 vaccination regulation is an implementation of the Health Quarantine Law and the Infectious Disease Outbreak Law. The two laws are specific laws that underlie outbreaks, including the COVID-19 pandemic countermeasures, compared to other laws, including the Health Law. It is under the legal principle of *Lex Specialis derogat lege generali* so that COVID-19 pandemic countermeasures must be based on these laws. In the explanation of Article 12 of the Infectious Disease Outbreak Law (the Republic of Indonesia, 1984) and Article 15 paragraph (2) of the Health Quarantine Law (the Republic of Indonesia, 2018), it is emphasized that vaccination is one of the actions that need to be taken in an infectious disease pandemic.

The COVID-19 vaccine was developed at the beginning of the global pandemic and can finally be used globally in early 2021. COVID-19 is a pandemic of a highly contagious disease that has caused many deaths. Therefore, the state is obliged to carry out vaccinations to prevent infectious disease outbreaks based on Law No. 4 of 1984 and as part of health quarantine based on Law No. 6 of 2018. People who refuse the COVID-19 vaccination program based on these two laws can subject to criminal sanctions.

- f) Law No. 36 of 2009 concerning Health (Health Law) guarantees everyone's freedom to make their own choices in Health. Everyone has the right to determine the Health needed for himself following Article 5 paragraph (3) Health Law. It is even emphasized in article 56 paragraph (1) Health Law that everyone has the right to accept or refuse medical intervention after receiving health data information.

However, the Health Law also stipulates that there are restrictions on these rights. These rights are limited under certain conditions. Article 56 paragraph (2) states that the right to accept or refuse medical treatment does not apply to diseases quickly spread in the community.

COVID-19 is an infectious disease that spreads quickly and causes a pandemic. So the policy regarding medical measures that apply during the COVID-19 pandemic must be adhered to and cannot be rejected. The COVID-19 vaccination is part of the policy so that mandatory vaccination can be justified.

- g) People refuse to vaccinate because of doubts about the choice of vaccine used by the Government. According to the people who objected, they argued that the public should be free to choose which vaccine they would use instead of being determined unilaterally by the Government. Unilateral coercion is considered a violation of human rights.

However, it should be noted that drugs circulating in Indonesia, including vaccinations, have their regulations. The regulation of drugs used in general in Indonesia is regulated by the Food and Drug Supervisory Agency (BPOM). Drugs (vaccines) in circulation must meet the requirements in clinical drug trials to obtain approval for circulation in Indonesia. Clinical trials are conducted to ensure the effectiveness and/or safety of the drug under investigation. It is required for licensing registration based on Article 4 letter (a) Regulation of the Minister of Health of the Republic of Indonesia No. 1010 of 2008 on Drug Registration (Ministry of Health, 2008). Clinical trials are also regulated in the Regulation of the Head of the Food and Drug Supervisory Agency Number 21 of 2015 on Procedures for Approval of Clinical Trials (BPOM, 2015).

Premarketing Clinical Trials are trials using medicinal products that do not have authorization. Clinical trials can be divided into premarketing clinical trials and post-marketing clinical trials. Premarketing clinical trials consist of phase 1, phase 2, and Phase 3 clinical trials. To be distributed in Indonesia, drugs must at least pass clinical trials up to phase 3 before obtaining authorization from BPOM.

Doubts about the quality of the vaccine used to cause many people to refuse the vaccine. The doubts are mainly about the efficacy and safety also side effects of the selected vaccines, Coronavac and Astra Zeneca, used in the mandatory vaccination program. Even though the Government determines vaccination procurement, the vaccine will be used if BPOM approves it.

If a drug is considered to have great benefits in the case of a health emergency, approval for the use of an emergency drug known as a EUA can be issued. Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic (Food Drug Administration, 2020). WHO states that the issuance of the EUA must meet five requirements, namely (1) There is a health emergency by the Government, (2) Has scientific evidence of sufficient safety and efficacy aspects of the drug/vaccine based on non-clinical data, and available clinical data, (3) Have quality data that meets applicable standards and is produced in facilities that meet Good manufacturing practices, (4) Has a greater benefit than risk (risk-benefit analysis) based on clinical and non-clinical data studies, and (5) Not yet available an adequate and approved alternative treatment or management for the treatment of disease in a public health emergency.

BPOM has evaluated the vaccine quality data, including supervision from raw materials and manufacturing processes to finished vaccine products under internationally accepted vaccine quality assessment standards. Based on the evaluation results of the Coronavac and Astra Zeneca vaccine safety data obtained from phase 1 to 3 clinical trials in several places, overall, it shows Coronavac and Astra Zeneca vaccines are safe. While evaluating the efficacy data, the vaccine has shown good immunogenicity, which has been seen since phase 1 and 2 clinical trials with a monitoring period of up to 6 months. The results of the analysis of the efficacy of the CoronaVac and Astra Zeneca vaccines in the phase 3 test (preliminary study) obtained good efficacy results above 50%. These results have met the WHO requirements with a minimum vaccine efficacy of 50%.

Quality assurance of each batch to be used has also been guaranteed by conducting testing of Lot Release. Therefore, based on collected data and referring to the guidelines from WHO in granting EUA approval for COVID-19 vaccine, which has a minimum of safety and efficacy monitoring data for three months in the test phase 3 clinic, with a minimum vaccine efficacy of 50%, the Coronavac and Astra Zeneca Vaccines meet the requirements to be approved under EUA.

Vaccine monitoring did not stop after the EUA was published. Monitoring is still done, and the use of vaccines is still evaluated, especially if side effects occur. The Government formed the National Committee of *Adverse event following immunization (AEFI)* to monitor the implementation, efficacy, and safety of the COVID-19 vaccine. So that the selection and use of vaccines used in government programs can be justified because the responsibility for vaccine selection in this context is shifted to BPOM.

- h) The legal basis for mandatory vaccination is also strengthened in the Indonesian Penal Code contained in Article 216 Penal Code. This article regulates criminal acts for any person who does not comply with the provisions of the law and officials who carry out the functions of the law. If the Government determines a policy that empowers officers such as doctors and police to carry out their duties to carry out government policies to save the people from COVID-19, Article 216 Penal Code applies. The officials in carrying out their duties can take action against anyone who opposes or refuses vaccine obligations and can even be given sanctions

Criminal Law in COVID-19 Vaccination

Government regulations regarding COVID-19 vaccination must be implemented with sanctions or penalties for people who refuse the vaccine. Threats of administrative sanctions to criminal sanctions are given to people who refuse. In addition, the regulation mentions the threat of sanctions for residents who are the targets of the COVID-19 vaccination who refuse.

These sanctions include the termination of social security, termination of government administrative services, or fines to criminal sanctions. Sanctions are defined as A penalty or coercive measure that results from failure to comply with a law, rule, or order (Garner, 2009). Amnesty International describes sanctions as all actions, such as legal and disciplinary sanctions, that respond negatively to unwanted behavior (Amnesty International, 2015).

According to Roeslan Saleh, punishment is a reaction to an offence. It is in the form of a misery deliberately imposed by the state on the maker of the offence (Saleh, 1983). Muladi & Arif (1992) argue that the elements of criminal understanding include: (1) an imposition of suffering or other unpleasant consequences, (2) given intentionally by the authorities, and (3) based on the applicable criminal law. Even if it is light, the imposition of a sentence is essentially a revocation of human rights. Therefore, punishment must be based on reasons that can be accountable philosophically, juridical and sociologically. Regarding the theory of punishment, in general, it can be grouped into three major groups, namely absolute theory or vengeance theory (associations theory), relative theory (doel theory), and combining theory (associations theory).

The threat of criminal sanctions in the mandatory vaccination program refers to Article 9 in conjunction with Article 93 of the Law on Health Quarantine. Article 14 of Law Number 4 of 1984 on Infectious Diseases also threatens the sanctions in the forms of crimes. The purpose of criminal sanctions in the vaccination program is under the relative theory that aims to prevent negative things such as increasing cases of COVID-19 and the uncontrolled pandemic. Criminal law is intended to maintain public order where the public will participate in the vaccination program to reach the target to control the pandemic. Criminal sanctions are under the objectives of criminal law in the theory of objectives, namely prevention, deterrence, and reformation (Muladi & Arif, 1992). The Government prevents the worsening of the pandemic through vaccination and changing the pattern of society.

However, this does not mean that criminal law can be applied immediately within the framework of the vaccination program in Indonesia. In general, Indonesian criminal law adheres to the principle of the ultimate cure, which means that the regulation of criminal sanctions is positioned as the last sanction. In law, the first regulated sanctions are administrative sanctions or civil sanctions. Meanwhile, criminal sanctions are regulated or placed as a form of imposition of final sanctions. In addition to criminal sanctions, the threat of administrative sanctions is regulated in Presidential Regulation Number 14 of 2021 (President of Republic of Indonesia, 2021). Administrative sanctions are broadly understood as sanctions imposed by the regulator without intervention by a court or tribunal (Maroni, 2015). Both sanctions are aimed at protecting the interests and safety of the people.

Criminal sanctions should only be used as a last resort (the ultimate cure) when other approaches have failed. The socialization and counseling approach, or the persuasive and promotive method, should be the main and first approach. Even the administration of administrative sanctions must first before the provision of criminal sanctions. When all approaches don't work while conditions in Indonesia worsen due to Covid-19 and vaccination coverage is not achieved due to people's reluctance to get vaccinated, then criminal sanctions can be imposed.

The act of prioritizing criminal sanctions as an initial approach (premium cure) is feared to only cause antipathy in the community. This antipathy can make it more difficult to promote vaccination programs, so it is feared that it will worsen. If that happens, the state has committed "Internationally Wrongful Acts," *i.e.*, the action must be linked to the state based on international law and is a violation of international obligations carried out by a country (Giovanni, 2019).

Penalties must also look at perpetrators who refuse vaccination. Punishment should be given to those who hinder the vaccination program by inviting others to refuse vaccination or spreading misleading information about vaccination. The threat of criminal sanctions against these parties is under Article 9 in conjunction with Article 93 of Health Quarantine Law (the Republic of Indonesia, 2018). For those who refuse individually with justifiable reasons such as belief or medical condition or disability. The party should respect the right to refuse vaccination unless it is a target that must be vaccinated to achieve herd immunity. And even then, administrative sanctions should not be criminal sanctions. The United States respects its citizens for refusing vaccinations because of their faith or disability (the United States of America, 1990) or pregnancy condition (the United States of America, 1964). However, they must follow other rules, such as wearing masks. The COVID-19 vaccination is the first vaccine program mandated by Indonesian legislation with the threat of sanctions if there is a refusal to be vaccinated. The vaccination program previously implemented by the Ministry of Health had a mandatory vaccination program consisting of basic immunization of children and immunization of women. Still, this program is an appeal, not coercion regulated in the regulation of the Minister of Health, and there are no sanctions (Ministry of Health, 2017).

WHO, which assists coordination and providing guidance on COVID-19 countermeasures, stated that vaccination programs, including COVID-19, are not recommended to be mandatory but are an advisory (Nisa & Giger, 2012). WHO strongly recommends prioritizing socialization to the public through public social advertisements to direct socialization through health workers, not prioritizing sanctions. Criminal and administrative sanctions can be justified to ensure the safety of the state and society in the COVID-19 pandemic but must be an ultimate cure. A persuasive and promotive approach must be prioritized in the implementation of vaccination.

Vaccination Policy and Regulation Analysis

Determination of emergency conditions in cases of national health emergencies as stipulated in Presidential Decree No.11 Year 2020 has shortcomings. Article 10 paragraph (4) of Health Quarantine Law stated that "Further provisions regarding the procedure for determination and revocation as referred to in paragraph (1) and paragraph (2) shall be regulated by a Government Regulation". Based on the article, the Government should issue a Government Regulation concerning the procedures for determining and revoking the status of a health emergency and any quarantine measures. The Government only issued Government Regulation Number 21 of 2020 on Large-Scale Social Restrictions, referring to Article 60 of the Health Quarantine Law. Still, other arrangements are not stipulated, such as Regional Quarantine and vaccination. Regulations regarding vaccination are instead stipulated in a presidential regulation, not a government regulation that should be (Widjaja, 2021).

Presidential Regulation Number 14 of 2021, which regulates the implementation of vaccinations, including setting sanctions, is not in accordance with the rules. The regulation of sanctions regarding mandatory vaccination is also not following legal principles in Indonesia. In Indonesia, there is no written law that specifically regulates administrative penal law. Penal or criminal punishment is still the domain of the field of criminal law.

So that the making of regulations that include administrative sanctions follows the rules of criminal sanctions, the regulation of criminal sanctions must be regulated in a Law or Regional Regulation (the Republic of Indonesia, 2019). This legal basis is regulated by Article 15 of Law No. 12 of 2011 as updated by Law No. 15 of 2019 concerning the Establishment of Legislation. No punishment without a previous penal law. Therefore, the formulation of criminal sanctions must be approved by the people through the people's representatives (parliament). It is because criminal law is directly limiting human rights. The problem occurs in the presentation of administrative sanctions that are not following the rules.

Procurement of vaccines based on the regulation of the Minister of Health must go through the Government and will be the Government's responsibility, including the financing. However, on the way, the Government made a policy through the Minister of Health Regulation Number 10 of 2021 to provide a Communal work vaccine which the private sector will finance for its employees (Ministry of Health, 2021). Charges on third parties can cause problems. The risk of gaps in vaccines can occur, including the private sector's internal arrangements, which risk harming employees who are Indonesian citizens. Because not all private parties are capable and qualified in carrying out the obligations delegated by the Government.

Law Number 2 of 2020 regulates financial stabilization during the COVID-19 pandemic, which is seen can cause its own legal problems. The existence of legal impunity in Article 27 paragraph (2) and paragraph (3) of the Law made the parties involved in implementing the acceleration of Covid-19 countermeasures cannot be prosecuted (the Republic of Indonesia, 2020). The implementation of the Health Quarantine Law must be carried out optimally under the rules contained in the law. However, in its implementation, the Government has not implemented arrangements following the Health Quarantine Law. Based on Article 15 of the Health Quarantine Law, health quarantine measures can take the form of measures such as quarantine, isolation, vaccination, and Large-Scale Social Restrictions (LSSR). However, the Government only implemented LSSR initially, which was then carried out with modifications such as micro-scale social restrictions that were not regulated in the law. The Government also did not establish a quarantine officer. The officer is entitled to carry out actions under Health Quarantine Law (Widjaja, 2020), including in the vaccination arrangement in the quarantine law.

The Infectious Disease Outbreak Law, which is used as the main basis for obligations and sanctions in the vaccination program, does not clearly explain that vaccination is part of the epidemic control that must be carried out. It is only explained in the explanation of article 12 Infectious Disease Outbreak Law as one option for controlling the outbreak. However, Article 14 Infectious Disease Outbreak Law is aimed at violating Article 5 Infectious Disease Outbreak Law. It does not mention vaccination as an outbreak control measure even though it can be considered a preventive measure to control the outbreak. Likewise, the criminal sanctions in article 14 Infectious Disease Outbreak Law aim at parties who deliberately hinder the implementation of epidemic control. In addition, the Law on infectious disease outbreaks issued in 1984 with many developments regarding infectious diseases should be evaluated and, if necessary, revised to adapt to the development of the times, so that outbreak management is more effective.

The Government's mandatory vaccination regulations do not have a solid foundation. Presidential regulations are not supposed to issue obligations, including sanctions in it. Regulations are also based on laws that are not synchronized from one law to another and their implementation. There is a need for a level of law that must be issued in the COVID-19 pandemic countermeasures because the mechanism must be in an abnormal state. According to states' emergency law theory, abnormal conditions require special legal norms for abnormal conditions (Asshiddiqie, 2007). So when the COVID-19 pandemic is very influential not only in the health sector but in other fields, the Government should make special rules, especially in the form of laws because there are restrictions on human rights. Umbrella act rules are needed that specifically regulate the control of the COVID-19 pandemic. If it is needed in a short time, including quick synchronization of existing regulations, it can be done in the form of a Government Regulation in Lieu of Law. And because it is at the level of the Law in accordance with Article 7 of Law 12 Year 2011, then the Government Regulation in lieu of the Law can contain sanctions including criminal.

In addition, there should be a public health law that bridges public health programs. The Health Law is more concerned with individual Health, not public health. This public health law is expected to provide strength in health from the community aspect, especially in matters that can limit human rights in personal Health. Australia has a public health law that stipulates the power of the authorities to require vaccination under certain conditions (Government of Western Australia, 2016).

The next problem is the problem of implementing regulations that require vaccination which is not working. The application of criminal sanctions, including administration, should indeed be an the ultimate cure, but that does not mean that there are only rules with no implementation. The

regulation is only a compliment that only wants to show the Government's seriousness towards the vaccination obligation.

Comparison of Vaccination Implementation in Other Countries

WHO recommends that the COVID-19 vaccination should be voluntary rather than mandatory? A persuasive and promotional approach should be the priority. This approach is considered more effective in inviting the public to participate in the vaccination program. The Government needs to convince people that vaccines are effective and safe and that vaccines reduce the risk of COVID-19 and speed up the end of the pandemic. However, in carrying out the vaccine program, each country has its obstacles and approaches.

With the rapid spread of the COVID-19 pandemic, the vaccine is one of the hopes in stopping the spread of COVID-19. COVID-19 vaccination underway or on the horizon in many countries. Some may be considering whether to make COVID-19 vaccination mandatory to increase vaccination rates and achieve public health goals. Indonesia has taken a stand by drafting a regulation that provides criminal and administrative sanctions for refusing vaccination. Penalties for refusing vaccination were introduced to Massachusetts law in 1905 during the smallpox pandemic (Jamrozik & Selgelid, 2020).

The United States does not require its citizens to be vaccinated. The United States has a regulatory mechanism that can require workers to be vaccinated against COVID-19, but it is not implemented (the United States of America, 1990). They prefer policies for those who refuse vaccines to continue to apply health protocols such as the obligation to wear masks. The United Kingdom (UK) has a COVID-19 vaccination program. Still, it does not require vaccination under the Public Health Act 1984. Public policy may not regulate a person's treatment options, including vaccines (United Kingdom Parliament, 1984) and UK Vaccination Policy which does not require all vaccines, including during a pandemic (Rough, 2021).

The obligation of vaccination does not necessarily impose on citizens and witnesses but can be given specific restrictions if they refuse vaccines. Through the Supreme Court, Brazil ruled those who refuse a covid-19 vaccination could be banned from public space and activities (Yoon, 2021). Israel makes a policy that everyone can access public space and activities if they get green passports. Green passports are only given to those who have been vaccinated (Ministry of Health of Israel, 2021).

COVID-19 vaccination is currently not mandatory by laws and regulations in China; it is encouraged and is voluntary. China, the first spread of COVID-19 and the Corona vaccine manufacturer used in Indonesia, does not mandate vaccines. Moreover, because some cities were reportedly found to mandate vaccination to meet the country's goal, health authorities in China urged local authorities to halt mandatory vaccination orders (The Straits Times, 2021).

South Korea and Singapore use a strategy by restricting access to the vaccine, only given to serious people about getting vaccinated. South Korea will not provide vaccines to its population who are behind schedule. Residents have to repeat the procedure to get vaccinated. Singapore will not provide backup vaccines that initially refused vaccines.

State Obligations in COVID-19 Vaccination

The obligation of citizens to vaccinate against COVID-19 also has implications for the obligation of the state to vaccinate. The COVID-19 pandemic is a national health disaster declared by presidential decree (President of Republic of Indonesia, 2020). Based on the Health Quarantine Law (the Republic of Indonesia, 2018) and Disaster Management Law (the Republic of Indonesia, 2007), the determination of national health disaster is the authority of the President. When determining a disaster, people's rights must be fulfilled, one of which is fulfilling basic needs and protecting vulnerable groups. These basic needs include health services. Vaccination is a health service and protection for vulnerable groups during an infectious disease outbreak. The fulfilment of vaccination is the Government's obligation. In the 1945 Constitution, Article 34 paragraph (3) the Constitution of Indonesia 1945 also mandates that (Republic of Indonesia, 1945) that "The state is responsible for the provision of adequate health care facilities and public service facilities."

The Government must provide vaccination services with certain standards that are considered "appropriate". Based on Law Nomor 40 of 2004, the fulfilment of citizens' basic rights to health requires the Government to ensure adequate access for every citizen to health services, such as access to vaccination. The state must strive to respect, protect and fulfil the state's obligation to implement human rights norms on the right to health in obtaining vaccines.

The state's obligation to fulfil the right to vaccines is implemented in the form of government policies by taking into account the principles of respect, protection and fulfilment of the right to health (Isriawaty, 2015). The state in its policy must comply with the principles of (Afandi, 2008): (1) Availability. Countries must ensure the availability of vaccines until the vaccination target is achieved; (2) Accessibility. The state must ensure that the vaccine can be easily obtained, distributed throughout the country, and includes guarantees in terms of financing; (3) Acceptance. The vaccines must be accepted by the community. The Government must prioritize a persuasive and promotive approach in calling for vaccination; and (4) Quality. The state must ensure that the vaccine used is an effective, safe, and quality-assured vaccine.

Fulfilment of the Covid-19 vaccine is the full responsibility of the Government. It is part of the fourth paragraph of the Preamble on the Constitution of the Republic of Indonesia Year 1945. The Government shall protect the entire Indonesian nation and the entire homeland of Indonesia, advancing public welfare, educating the nation's life, and participating in carrying out world order based on independence, eternal peace and social justice. It is also the implementation of Article 28H and Article 34 of the 1945 Constitution (The Republic of Indonesia, 1945).

The state is responsible for vaccination policy, not only requiring but also ensuring the availability, access, acceptance, and quality of the vaccine. In addition, the obligation of citizens to vaccinate causes restrictions on human rights for citizens. So the arrangement of these obligations must be the state's responsibility in such a way that it must ensure that the vaccination obligations run without any human rights violations (Cornell & Salminen, 2018).

CONCLUSIONS

The mandatory vaccination against COVID-19 is in line with the protection of human rights, especially protecting the right to life and health. Restrictions on personal human rights are carried out to protect the wider community's interests and provide great benefits to the community. Therefore, laws and regulations regarding mandatory vaccination must accommodate the community's interests but not risk violating individual's human rights. Regulations about COVID-19 vaccination must be carried out correctly and systematically and harmonize between regulations while adhering to the applicable laws and regulations. Regulations "Umbrella act" are needed that regulate all aspects of controlling the COVID-19 pandemic. Several regulations must be re-evaluated and updated so that the implementation of COVID-19 vaccination will be executed well and appropriately.

Both criminal and administrative sanctions for vaccination refusal must be the last resort (*the ultimate cure*) in enforcing regulations regarding mandatory vaccination. Promotion and education strategies should be the first efforts to increase public participation in vaccination programs. The use of regulations that emphasize sanctions shows that the Government does not gain public trust and risks causing antipathy to the covid-19 vaccination.

Mandatory vaccination for society also has implications for the Government. Restrictions on human rights for the benefit of the society make the Government responsible for administering vaccinations to run properly and correctly and provide the maximum benefit to the community. The Government is responsible for regulating the implementation of vaccinations to be carried out properly and correctly to provide the maximum benefit to society. The Government is obliged to run a vaccination program by ensuring the availability, access, acceptance, and quality of COVID-19 vaccinations.

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