



Legal Protection for Consumers Recipient of COVID-19 Vaccine in Indonesia



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Abstract

The purpose of this study was to determine the legal protection provided to COVID-19 vaccine recipients under the Indonesian consumer protection law. This study employs normative legal research methods. This study was a qualitative descriptive study and described the level of quality of infectious waste management in the household which was reviewed based on the relevant laws and regulations. The article used secondary legal materials, namely books, journals, articles, and other written works from print and internet media, and the phenomena that occurred in the field. According to the findings of this study, the type of consumer protection for recipients of the COVID-19 vaccination under Indonesian consumer protection law is the application of preventive and repressive legal protection and civil and criminal liability in line with existing laws and regulations.

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1 Introduction

At the end of 2019, the whole world was shocked by the news of the emergence of a new virus that was spreading and disrupting the health of the world's people (Benuf, 2020). This virus is known as the SARS COVID-19 virus. The first incidence was reported to the WHO (World Health Organization) on December 31, 2019, as a case of pneumonia of unknown etiology or pneumonia with an unknown origin discovered in Wuhan City, Hubei Province, China (Disemadi & Shaleh, 2020).

The COVID-19 virus can transmit from person to person not just through the air, but also through droplets created when someone infected with this virus coughs, sneezes, or talks (Dan & Nasional, 2020). Viruses can stay in the air for up to eight hours after leaving the body of a patient who sneezes or coughs and does not require a liquid medium to exist in such settings (Dan & Nasional, 2020). When a person is infected with the COVID-19 virus, they will experience a variety of symptoms. COVID-19 symptoms can appear 5-6 days or no later than 14 days after being exposed to the COVID-19 virus (COVID-19 Handling Committee and National Economic Recovery, 2020).

The symptoms that develop are determined by the type of virus that assaults and the severity of the infection. Mild symptoms include difficulty breathing with a runny nose, headache, cough, sore throat, fever, and general discomfort (Prajnaparamitha & Ghoni, 2020). Severe symptoms include bronchitis and pneumonia, which include symptoms such as a high temperature, cough with mucus, shortness of breath, chest pain, or shortness of breath, and coughing if the patient has pneumonia. These symptoms may worsen if the infection affects specific categories of people, such as persons with congenital disorders such as heart or lung disease, people with compromised immune systems, babies, and the elderly (Halodoc. Coronavirus, 2021).

Health is a human right, according to the 1945 Constitution. The Coronavirus Disease 2019 (COVID-19) pandemic is still ongoing and poses a global threat. As a result of this circumstance, several countries, including Indonesia, are still battling to stem the spread of COVID-19 (Yunizar & Suradi, 2017). Implementation in the Context of Combating the Corona Virus Disease 2019 (COVID-19) Pandemic. The Presidential Regulation was amended with a second amendment to Presidential Regulation Number 50 of 21 concerning Vaccine Procurement and Vaccination Implementation in the Context of Combating the 2019 Corona Virus Disease (COVID-19) Pandemic.

Vaccines protect the human body from various infections, including viruses and diseases. Vaccines are antigenic chemicals that induce immunity to a disease. Vaccination is used to prevent or mitigate the consequences of infections that cause disease. Vaccines typically contain substances that look like disease-causing bacteria and are frequently made from attenuated or dead microbes, their toxin, or one of their surface proteins. Vaccination is an abbreviation for vaccination. Vaccination is the most efficient technique of illness prevention. Vaccination-induced immunity is prevalent throughout the world, and it is largely responsible for eradicating smallpox and restricting illnesses such as polio, measles, and tetanus. The effectiveness of vaccinations has been extensively studied and verified, for example, vaccines are effective including influenza vaccine, HPV vaccine, and chickenpox vaccine.

According to the World Health Organization (WHO), licensed vaccinations are now available for twenty-five avoidable diseases. Vaccines are derived from the word vaccinia, which is the source of cowpox infection and, when administered to people, results in an immunological response. Vaccinations were first performed in China in the 10th century. It wasn't until 1796, however, that Edward Jenner determined that a comparatively minor cowpox infection could protect people from smallpox.

Vaccines stimulate the immune system to recognize and manufacture antibodies in response to incoming invaders. The goal is to teach the immune system how to combat organisms that attack the body. This procedure does not cause discomfort, but some patients may develop adverse effects, the most common of which are a painful arm and a short fever. Following that, the body will acquire natural immunity to the condition. According to the Centers for Illness Control and Prevention (CDC) in the United States, this is why vaccines are so effective: unlike most drugs that treat or cure a disease, vaccines prevent disease. A study conducted by specialists in Norway examined severely disabled people who had been vaccinated for any concerning signs or adverse effects. Doctors in Norway analyzed the health of severely disabled and critically

ill patients to determine whether the benefits of vaccination outweighed the dangers of side effects (Schmidt et al., 2008; Peay, 2015).

Many complaints of vaccine side effects have been received by the National Commission for Post-Immunization Adverse Events (Komnas KIP). There were multiple occurrences of post-vaccination incidents ranging from mild to severe to death during the deployment of AstraZeneca's COVID-19 vaccine.

In the COVID-19 vaccination program, beneficiaries of the AstraZeneca brand of COVID-19 vaccine are also referred to as consumers because the state purchases the vaccine and distributes it to the public for free. Customers should be given complete protection by the government in this scenario because people's safety is the highest law (*salus populi suprema lex esto*) so that consumers do not feel concerned and are not hurt by business actors and consumers rights can be obtained (Oerke & Dehne, 2004; Ludlow et al., 2008). Based on the description above, the authors are interested in carrying out research entitled "Legal Protection for Consumers Recipient of the COVID-19 Vaccine in Indonesia".

2 Materials and Methods

The type of this research is normative legal research with two approach methods, namely the legal approach and the conceptual approach. The types and sources of legal materials used are primary law and secondary law. The primary law is a law that has binding legal force in the form of regional regulations, regional governments, etc. Meanwhile, secondary legal materials explain primary legal materials. On the other hand, tertiary law is legal material that is not only a primary method but also secondary method material such as normative dictionaries and registers, and others. The technique of collecting legal materials is library research and electronic media. The analysis used in this research is a descriptive qualitative analysis method using deductive reasoning. Conclusions are drawn based on general to specific.

3 Results and Discussions

The development of the COVID-19 vaccine in Indonesia

Presidential Regulation of the Republic of Indonesia Number 50 of 2021 concerning the Second Amendment to Presidential Regulation Number 99 of 2020 concerning the Procurement of Vaccines and Implementation of Vaccinations in the Context of Combating the Corona Virus Disease 2019 (COVID 19) Pandemic reads: "The Ministry of Health and the Food and Drug Supervisory Agency together with the government provincial regions and district/city governments monitor and control follow-up events after the COVID-19 vaccination."

The procurement of the COVID-19 vaccine is specifically regulated in the Regulation of the Minister of Health of the Republic of Indonesia No. 16 of 2021 concerning the Implementation of Vaccine Procurement in the Context of Combating the Corona Virus Disease 2019 (COVID-19) Pandemic. The implementation of the procurement of vaccines is regulated in Article 7 paragraph (1) letter an of the Regulation of the Minister of Health of the Republic of Indonesia No. 16 of 2021 concerning the Implementation of Vaccine Procurement in the Context of Combating the Corona Virus Disease 2019 (COVID-19) Pandemic which reads: The implementation of the procurement of the COVID-19 vaccine as referred to in Article 6 paragraph (1) is carried out through Assignments to state-owned enterprises.

Immunity is the body's natural fight against sickness. In addition to vaccination, proper nutritional intake, adequate rest, regular exercise, and stress reduction are all necessary to enhance the body's immunity. The benefit of administering vaccines is that they help to reduce disease transmission, particularly infectious diseases because vaccines train the body to recognize the bacteria or virus that causes disease, allowing it to fight back more swiftly (Ayunda et al., 2021). Following vaccination, serological tests can be performed to determine whether the body has developed antibodies or immunity to the Coronavirus. This antibody test, however, is not required for the general population, but only for research participants or certain groups. The goal of conducting a series of clinical trials in the development of vaccines is to ensure the vaccine's safety and effectiveness before it is offered to the public. Because the COVID-19 vaccine is still in its early stages, research and assessment are ongoing to determine the body's response and potential side effects in humans. The

development and administration of the COVID-19 vaccine will result in a reduction in the number of positive cases and deaths caused by COVID-19, as well as the formation of herd immunity (Grech et al., 2020; Boodoosingh et al., 2020).

The immune system of the person being vaccinated will be ready to fight the bacteria or virus that causes the disease that enters so that infection does not occur. Even if an infection exists, the symptoms will be milder and the recovery will be quicker. As a result, the rate of disease transmission will naturally decrease. Vaccination offers promising safety and effectiveness in vaccine clinical trials in the midst of growing COVID-19 instances, thus several governments have advocated vaccination programs for their citizens. The greater the number of people who receive the vaccination, the less likely the disease will spread. Even though the vaccination has been administered, health regulations must still be followed (Kandel et al., 2020; Lim & Wang, 2009). The presence of a vaccine does not mean that it can immediately eliminate COVID-19. The potential for transmission of this disease remains, especially since vaccination in Indonesia is carried out in stages. To achieve herd immunity against COVID-19, it is necessary to have around 60–80% of the entire population immune to this disease. This means that a minimum of 165 million people in Indonesia must get the COVID-19 vaccination. This is one of the reasons why achieving the vaccination target in Indonesia takes a long time. The following are some criteria for recipients of the COVID-19 vaccine (Masnun et al., 2021):

- Not confirmed to have COVID-19 or have recovered from COVID-19 for at least 3 months;
- Normal body temperature, not more than 37.5°C;
- Blood pressure below 180/110 mmHg at screening before vaccination;
- Not pregnant. Breastfeeding mothers are still allowed to get vaccinated against COVID-19;
- Patients with diabetes mellitus can be vaccinated as long as there are no acute complications;
- People with HIV can be vaccinated against COVID-19 if their CD4 count is more than 200;
- Patients with lung diseases, such as asthma, COPD, or tuberculosis, can only be vaccinated if they have been controlled through medication (TB patients may be vaccinated after taking antituberculosis drugs regularly for more than 2 weeks);
- Have no symptoms of ARI in the last 7 days and do not have certain medical conditions, such as allergies to vaccines and autoimmune diseases, such as lupus, rheumatoid arthritis, or Sjogren's disease. Cancer survivors can get vaccinated. However, if there are special conditions or a history of serious illness, it is advisable to consult your doctor first before undergoing vaccination. The government will administer the COVID-19 vaccine in stages because there is not enough vaccine supply to be given to everyone at the same time. 2.2 Law NO. 8 the YEAR 1999.

In the procurement of the COVID-19 vaccine for the implementation of vaccination, an assignment was given to a State-Owned Enterprise where the BUMN showed PT Bio Farma in procuring the vaccine by purchasing the AstraZeneca vaccine. PT Bio Farma confirmed that direct purchase of AstraZeneca vaccine is regulated in Article 8 paragraphs (1), (2), (3) Regulation of the Minister of Health of the Republic of Indonesia No. 16 of 2021 concerning Implementation of Vaccine Procurement in the Context of Combating the Corona Virus Disease 2019 (COVID-19) Pandemic) which reads:

- Assignment to state-owned enterprises as referred to in article 7 paragraph (1) letter a is carried out by the Minister to PT Bio Farma (Persero);
- The assignment as referred to in paragraph (1) is determined by a Ministerial decision which includes determining the type and amount of the COVID-19 Vaccine;
- Vaccine procurement through assignment to PT Bio Farma (Persero) as referred to in paragraph (1) is the procurement of COVID-19 vaccine for the needs of implementing vaccination programs, either through vaccine production and/or import of vaccine products.

The receivers of the COVID-19 vaccine will continue to be consumers as the immunization program is implemented. These are general consumers rather than specific consumers. The rights of vaccination recipients as members of the general public are guaranteed by the 1954 Constitution, and the rights of vaccine recipients as general consumers are likewise guaranteed by Consumer Protection Law No. 8 of 1999. The

government does not recognize the AstraZeneca AEFI, where three citizens are said to have died after receiving the AstraZeneca vaccine during the COVID-19 vaccination. Trio Fauqi is one of the residents. In signing a purchase agreement for the COVID-19 vaccine with the UK-based pharmaceutical company AstraZeneca, PT Bio Farma (Persero) did not pay close attention to the quality, efficacy, and safety of the AstraZeneca vaccine, particularly the AstraZeneca batch CTMAV547. The Food and Drug Supervisory Agency (BPOM) granted the AstraZeneca vaccine an emergency use authorization (UAE).

Komnas KIPI (Post Immunization Follow-Up) is tardy and does not respond swiftly to notifications from victims' families about Post-Immunization Incidents or AEFI when the autopsy process takes a lengthy time. The Fauqi Firdaus Trio is 21 years old. In contrast, Prof. Zubairi Djoeban, Head of the Task Force (Satgas) of the Indonesian Doctors Association (IDI), stated that the AstraZeneca vaccine should not be administered to those under the age of 30. Despite numerous complaints following immunization, the Ministry of Health is adamant about administering Astrazeneca to people under 30 years old.

Legal protection for vaccine recipients in Indonesia

Consumer legal protection consists of two components: preventative legal protection and repressive law. The government provides this type of preventive legal protection in the implementation of COVID-19 vaccination by establishing legislation that details the legal provisions in the implementation of vaccination in Indonesia to prevent problems in the community related to Post-Immunization Adverse Events (KIPI) of COVID-19 vaccination. The legislative provisions are outlined in Presidential Regulation Number 50 of 2021, which is the Second Amendment to Presidential Regulation Number 99 of 2020, which is concerned with Vaccine Procurement and Vaccination Implementation in the Context of Combating Corona Virus Disease 2019 (COVID 19) Pandemic. The Food and Drug Supervisory Agency (BPOM) also provides legal oversight ([Ayunda et al., 2021](#)).

Consumer Protection in essence has two key legal instruments that serve as the foundation for consumer protection measures in Indonesia. The first source of law in Indonesia is the 1945 Constitution, which demands that national development aspire to produce an equitable and affluent community ([Kusumo et al., 2022](#)). National development goals are fulfilled through a democratic economic development system to expand and build a world capable of producing commodities and services suited for community use. The second is Law no. 8 of 1999 concerning Consumer Protection (UUPK) ([Nasution, 1995](#)).

The enactment of this law provides hope for the Indonesian people to obtain protection for losses suffered by transactions of goods and services. UUPK guarantees legal certainty for consumers. Purpose of Consumer Protection Following Article 3 of the Consumer Protection Act as follows:

- Enhancing consumer awareness, ability, and independence to protect themselves;
- Elevating the dignity of consumers by avoiding the negative excesses of the use of goods and/or services;
- Increasing consumer empowerment in choosing, determining, and demanding their rights as consumers;
- Creating a consumer protection system that contains elements of legal certainty and information disclosure as well as access to information;
- Growing awareness of business actors regarding the importance of consumer protection so that an honest and responsible attitude grows in doing business;
- Improving the quality of goods and/or services that ensure the continuity of the business of producing goods and/or services, health, comfort, security, and safety of consumers.

Consumer Protection Principles:

- The benefit Principle; mandates that all efforts in the implementation of consumer protection must provide the maximum benefit for the interests of consumers and business actors as a whole;
- The Principle of Justice; participation of all people can be realized maximally and provide opportunities for consumers and business actors to obtain their rights and carry out their obligations fairly;
- Principle of Balance; provide a balance between the interests of consumers, business actors, and the

government in a material or spiritual sense;

- Principles of Consumer Security and Safety; provide guarantees for security and safety to consumers in the use, use, and utilization of goods and/or services that are consumed or used;
- The principle of legal certainty; both business actors and consumers obey the law and obtain justice in the implementation of consumer protection, and the state guarantees legal certainty.

Consumer Rights Following Article 5 of the Consumer Protection Act, Consumer Rights are:

- The right to consume products and/or services in comfort, security, and safety;
- The right to choose goods and/or services and to get such goods and/or services following the exchange rate and the promised conditions and guarantees;
- The right to correct, clear, and honest information about the conditions and guarantees of goods and/or services;
- The right to have their opinions and complaints about the goods and/or services used heard; and
- The right to appropriate advocacy, protection, and efforts to resolve consumer protection disputes.
- The right to consumer counseling and education;
- The right to be treated or served correctly, honestly, and without discrimination;
- The right to compensation, compensation/reimbursement, if the goods and/or services received are not following the agreement or are not provided properly;
- Rights governed by provisions of other laws and regulations.

Consumer Obligations based on Article 5 of the Consumer Protection Act are:

- Read or follow information instructions and procedures for the use or utilization of goods and/or services for the sake of security and safety;
- Have good faith when making transactions for the purchase of goods and/or services;
- Pay according to the agreed-upon exchange rate; and
- Follow the legal settlement of consumer protection disputes properly.

Whether the vaccination is categorized as a process of buying and selling goods and services can be explained further. Vaccine recipients in this case are consumers, while buyers and users, as well as vaccine givers, are sellers. This means that both of them are subject to the articles of the Consumer Protection Act (UU No. 8 of 1999 concerning Consumer Protection). If in the mechanism of sellers and buyers or providers of goods and services; then the buyer of goods and services as consumers can sue the seller if what he buys is not following the quality, is damaged, and so on. However, of course, the vaccination is not like that. Vaccination is not just required if there is money, especially in cases involving COVID-19. Vaccination (anti) COVID-19 cannot be referred to as broad purchasing and selling. Vaccination is required (international and national society) to slow or even eliminate the COVID-19 Pandemic. It requires worldwide cooperation. Based on these things, the Indonesian people need to get clarity about all of the procedures in vaccination.

Therefore, especially legal practitioners and law enforcement officials should provide some kind of public education, so that the recipients of the COVID-19 vaccine have a sense of security and protection as consumers. Consumers are people or someone who buys (receive, uses, applies) goods or services; the goods and services he or they use for the benefit of themselves, their families, others, and so on; however, there is no compulsion for someone to buy (receive, use, use) these goods and services. Generally, consumers buy (receive, use, and apply) these goods and services because of usability, necessity, quality, according to ability, or purchasing power. Vaccination recipients are individuals or groups who receive a vaccination (through drip or injection) to develop immunity (immunity) to particular diseases (or diseases). Vaccination is performed (recognized) as a requirement (and obligation) to achieve community and community immunity, whether for free or paid (paid).

To combat the COVID-19 pandemic, the government has decided to launch a vaccination campaign. This immunization effort is planned to last 15 months, with health personnel receiving priority among the 1.3 million people scattered across 34 regions. However, the population continues to oppose the government's

immunization effort. Several public people have refused to inject vaccines since the results of the third stage of the vaccine test are unknown. As beneficiaries of the COVID 19 vaccination, the public has the right to question the government's guarantee of protection. In this regard, it is also important to emphasize that the government must pay attention to consumer rights concerning the COVID 19 vaccination program, such as providing vaccine safety information, disseminating an opinion-complaint information system, and accepting legal responsibility for the COVID-19 vaccine's side effects. Henny further stated that in the event of issues or losses caused by the use of vaccines, compensation as an absolute obligation of the state (Strict Liability) (Qc, 2019) is highly crucial and important for the Indonesian people as consumers.

If the government violates the COVID-19 vaccination implementation criteria, the public can sue the government in civil court if the community has evidence that the implementation of the COVID-19 immunization does not satisfy the standards, resulting in community losses. Civil lawsuits can be initiated against illegal conduct that results in financial losses. This is governed by Article 1365 of the Civil Code ("Civil Code"), which states: "Every conduct that breaches the law and causes harm to others requires the person who caused the loss due to his mistake to compensate for the loss." A person must be held accountable not just for his actions, but also for his inaction (Fahrudin et al., 2020). This is addressed in Civil Code Article 1366, which states: "Everyone is accountable, not only for damages caused by actions but also for losses caused by negligence or carelessness." A person will also be held accountable for the acts of persons under his care or items under his control. "A person is not only accountable for damages produced by his conduct, but also for losses caused by the actions of others who are his dependents or caused by objects under his control," according to Civil Code Article 1367.

4 Conclusion

In terms of consumer protection in Indonesia, the recipients of the COVID-19 vaccination are general consumers, hence general consumers are protected. Consumer protection is divided into two categories: preventive and repressive. Preventive legal protection takes the form of law that details the legal provisions governing the government's implementation of vaccines in Indonesia. Meanwhile, the government allocates the Ministry of Health and the Food and Drug Supervisory Agency, along with the Provincial and Regency/City Governments, to monitor and deal with follow-up occurrences following the COVID-19 vaccination.

Vaccines do not ensure the end of the COVID-19 outbreak in Indonesia. Vaccines are a type of medical intervention used to boost people's immunity during a pandemic. Vaccination program must be followed by public awareness and discipline on health protocol. Without discipline on health protocol, then the effort of overcoming pandemic would be difficult to be done. In the constitution Number 8 Year 1999 about Consumer Protection and the constitution Number 36 Year 2009 about health say that the community has right to obtain fair health right and health facility. In the constitution Number 36 Year 2009 also clearly stated in Article 14 and Article 16 that the government is responsible in organizing health for community evenly and affordably.

Based on the provision above, the government has responsibility to guarantee the citizen rights on health, until when it is violated and cause disadvantage then the government has carried out an act against the law then they must be responsible in accordance with what is stated in Article 1365, 1366, and 1367 of Code of Civil Law (KUHPerduta). Then more intensive coordination and collaboration is necessary between the government and the community through organized approach to reach maximal result, in vaccination implementation the government must give clear information to the community so that they do not become afraid of participating in the vaccination. The government must give clear explanation to the community that after being vaccinated, they must still apply health protocol for the sake of altogether security.




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