ORIGINAL ARTICLE

# AEFI: Government or Health Worker Liability?

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**ABSTRACT**

**Introduction:** In a large-scale immunization program, there are concerns that there will be errors in the immunization program by health workers, such as in terms of storage or at the time of injecting vaccines. This raises a problem regarding the occurrence of adverse events following immunization (AEFI) experienced by people after vaccination. Considering that the government is the party that organizes the immunization program and procures vaccines, technically, the party that administers or injects the vaccine is the health worker. **Methods**: This research is doctrinal legal research using a conceptual approach and a statute approach.. **Results:** AEFI is a medical event related to vaccine effects or effects, toxicity, side reactions, pharmacological or program errors, co-occurrence, injection reactions, or undetermined causal relationship. The increase in AEFI cases requires the government's role in handling efforts to reduce the number of AEFI cases. Monitoring and evaluation in the implementation of the immunization program is an infection necessary attempt to assess whether the activities have been carried out following applicable regulations. In addition, this activity must be able to identify aspects that cause cases of vaccine recipients experiencing AEFI. C**onclusions:** : Health workers can be personally responsible for their mistakes in administering vaccines. The government's responsibility is related to compensating people who suffer from AEFI as a form of government protection for their citizens.

**Keywords:** Adverse event following immunization, Liability, health worker, Government, Vaccines

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## INTRODUCTION

The emergence of various diseases encourages scientists to continue developing vaccines to prevent disease spread and find drugs to treat infections. One of the efforts made by governments in almost every country for a long time is to protect their citizens from all diseases by promoting immunization programs. Based on Article 1 point 1 of the Regulation of the Minister of Health of the Republic of Indonesia Number 12 of 2017 concerning the Implementation of Immunization (Permenkes 12/2017), immunization is one of the efforts to increase or increase a person's immunity to disease if one day a person exposed to the disease will only experience mild symptoms. Immunization is done by injecting the vaccine into the human body. According to Article 1 point 2, the definition of a vaccine is a biological product containing antigens in the form of live or dead microorganisms that are attenuated, still intact or in part, or in the condition of microorganism toxins that have been processed into toxoids or recombinant proteins added with other substances, so that when given to a person provides immunity against a disease. Immunization in Indonesia has been ongoing since 1956. The existence of the immunization program

positively impacted the efficiency and effectiveness of health services that freed Indonesians from smallpox in 1974. So that since 1977, the Indonesian government then expanded the immunization program into the Immunization Development Program to prevent the transmission of diseases such as diphtheria, polio, tetanus, pneumonia, and others (1).

Based on WHO, there are 5 (five) cycles in vaccine procurement, namely pre-qualifying sources for the vaccine, bid preparation, bidding, evaluation or adjudication, and contract stages. To ensure quality and availability, in the pre-qualifying stage, vaccines and suppliers will comply with the National Control Authority (NCA) criteria or the International competitive bidding (ICB) procedure. Furthermore, in the bid preparation stage, Limited International Bidding (LIB) must be prepared following standard drug procedures, including requirements for vaccines based on NCA or WHO standards. In vaccine procurement, competitive bidding is a method that is often used using LIB procedures to limit participation from pre-qualified sources so that bidding should be able to cover a full year's supply with stagged delivery. The next stage is evaluation or adjudication. The bids received at this stage must meet several conditions, such as product quantity, registration and certification, product packaging and delivery, delivery schedule, and product shelf life requirements. These things will later be stated in the contract according to the standard provisions set by the government (2).

Immunization is one of the preventive efforts that can be done in dealing with a disease. It is said to be a preventative measure if a vaccine is given to prevent a person's exposure to an infectious disease. The term immunization is not foreign and is not something that is done just because of a pandemic. However, it cannot be denied that until now, people have different understandings about immunization, resulting in uneven immunization. One of them is caused by people's fear of the effects felt after immunizing. This is also supposed to be during the current Covid-19 pandemic, which has lasted almost the last 2 (two) years. The government is currently promoting an active Covid-19 vaccination program. However, with the same concerns as previous immunizations, people are still skeptical of the effects that will occur after immunization which causes some people to be reluctant to vaccinate. In 2014, WHO's Global Advisory Committee on Vaccine Safety proposed 2 (two) assessment indicators for countries to monitor vaccine safety, namely having a national causality review committee and reporting more than 10 KPIs per 100,000 infants who survive each year.

The immunization program generally held in each country is the National Immunization Program (NIP), organized by the government through the Ministry of Health to prevent disease, disability, and death from a disease (3). In implementing the immunization program, the government must be responsible for providing safe, effective, and quality vaccines to the community. So that all countries, in general, must form a National Regulatory Authority (NRA) to supervise drugs, including vaccines, used in a country. In Indonesia, The Indonesian Food and Drug Authority (Indonesian FDA/ BPOM) is the agency responsible for supervising drugs and vaccines. After the vaccine is given a distribution permit, it is the responsibility of the Indonesian FDA to deliver immunizations in the implementation of the immunization program in Indonesia, including detecting, investigating, and responding to AEFIs. In this case, the Indonesian FDA and vaccine manufacturers will provide guidelines on storing, preparing, and administering vaccines properly and correctly to health workers or trained immunization officers. However, in immunization programs which are generally carried out on a large scale, there are concerns that there will be mistakes in the immunization program by health workers, such as in terms of storage or at the time of injecting vaccines. This causes problems related to side effects after immunization (AEFI) experienced by the community. Considering that the government is the party that organizes the immunization program and procures vaccines, technically, the party that administers or injects the vaccine is the health worker. This study will conduct a more in-depth analysis of liability in the event of AEFI cases. The relevance of this research is related to the Covid-19 vaccination program carried out by almost all countries in the world and the case of AEFI, which has become an obstacle for some people to vaccinate.

## MATERIALS AND METHODS

This research is doctrinal legal research that employs a statute and conceptual approach. This study analyzes several laws and regulations related to the application program and AEFI obligations. The conceptual approach is generally used to define and analyze the concept of AEFI and liability carried out in this paper. This paper attempts to answer the issues of AEFI liability on the general immunization program and the ongoing Covid-19 vaccination program.

## ETHICAL CLEARANCE

This study was approved by the Research Development Unit, Community Service, and Scientific Publication (UP4I) Faculty of Law, Universitas Airlangga.

## RESULTS

### The Concept of AEFI

Every year more than 1.4 million people in the world die from various diseases that can be achieved by defeating them. Immunization is an effort to actively induce/ increase a person's immunity against a condition so that when one day he is faced with the disease, he will not get sick or will only experience a mild illness (4). To do the immunization require a vaccine following its

designation; this means that the type of vaccine must be by the particular disease you want to avoid. Vaccines are biological products containing antigens; when the vaccine is injected into a person, it will form a specific immunity against a particular disease. To carry out vaccine development which requires an expensive and time-consuming process.

Almost all over the world are administering and socializing the Covid-19 vaccine. The provision of the Covid-19 vaccine is prioritized, among others, to the community with the classification of the elderly, health workers, or public servants. But the end goal is that the Covid-19 vaccine will be given to the whole community, except for people who, for medical reasons, do not meet the category, can receive the Covid-19 vaccine. To create the Covid-19 immunization program a success, public awareness is needed regarding the importance of vaccines.

Immunization maturity is needed to achieve immunization goals. Several stages in the maturity of an immunization program, especially in the Covid-19 vaccine, include (5):

1. Pre-Vaccine Stage 1 is when the vaccine has not been introduced to the public, and a new disease is discovered, as is the case in the 2020-2021 timeframe, where Covid-19 has become a new disease for which, until now, the cause and proper treatment have not been known.
2. Stage 2 Increased coverage is the stage at which an effective vaccine has been deployed and is circulating in the market, thereby reducing the incidence of disease and the emergence of AEFI, which is of public concern.
3. Stage 3 Loss of trust is when public trust in immunization decreases because the mass media raises AEFI cases to reduce immunization coverage and may cause another outbreak. Like the thing in
4. Stage 4 The resumption of trust is the stage where people feel the need for immunization because of the increasing outbreak and accompanied by the availability of alternative vaccines that are more effective so that disease eradication can be carried out. In the case of Covid-19, several brands of vaccines are declared to have an immunity level of more than 90%. There are seven types of COVID-19 vaccines used in immunization activities in Indonesia. The seven vaccines are produced by Bio Farma, Astra Zeneca, Shinopharm, Moderna, Novavax Inc, Pfizer Inc, BioNTech, and Sinovac Biotech.
5. Stage 5 Eradication is where vaccine administration can be stopped because herd immunity has occurred. Herd immunity is when most people in a group have immunity to a particular disease, making it harder for it to spread. One way to achieve herd immunity is by immunizing.

Despite the many benefits of vaccines, it is essential to remember that vaccines consist of an active component (antigen) and additional components that often trigger hypersensitivity reactions. So that some people can experience a "reaction" after immunization, mild, such as fever, convulsions, and paralysis, in some cases, the cause can be a procedural error in administering the vaccine, the method of injection, or in the case of the vaccine storage process (6). Reaction after immunization, also known as AEFI, is often a reason for people to refuse immunization. For this reason, fast and accurate AEFI reporting followed by proper follow-up from the Government, Health Facilities, and Health Workers can help the implementation of the immunization program run more smoothly because the community will feel more secure (7).

AEFI are medical events related to immunization, either in the form of vaccine effects or side effects, sensitivity reactions, toxicity, pharmacological effects, coincidences, injection reactions, or causal relationships whose results cannot be determined (8). AEFI are all incidents of illness and death that occur quickly after immunization. In general, post-vaccine reactions are in the form of adverse events, other events, or other events as a direct result of the vaccine. Vaccine side effects include several side effects that are generally clinically difficult to distinguish from one another. Allergic reactions are one of the side effects that can occur due to vaccines.

Meanwhile, based on the World Health Organization (WHO), AEFI, a post-vaccine event, namely the presence of side effects, is defined as any unwanted medical events that occur after immunization and does not necessarily have a causal relationship with the use of the vaccine. Side effects can be unwanted signs, abnormal laboratory findings, symptoms, or disease. Vaccines cause AEFI due to one or more inherent properties of the vaccine product, either the active component or one of the other vaccine components (e.g., Preservatives, stabilizers, or adjuvants). If, by chance, the AEFI is caused by something other than the vaccine, an immunization error, or immunization anxiety (9). In fact, in this regard, to counter quickly, efficiently, and with scientific rigor to vaccine safety issues, WHO has formed the Global Advisory Committee on Vaccine Safety (10).

The effect caused by the provision of immunization is often a consideration for the community, especially ordinary people who are still unfamiliar with the term AEFI and lack education about it. The fear of the effects of immunization seems more frightening than the effects of the disease itself. Thus, providing education to the community will be maximized if there is good cooperation between the government and health workers. The government makes regulations to ensure the security and safety of the community, while health workers who are easier to reach the community can provide direct understanding. The right to good health services has also been stated in Article 28H Paragraph 1 of the 1945 Constitution of the Republic of

Indonesia, which states that "Everyone has the right to live in physical, to have a place to live, and a good and healthy environment, and has the rights to obtain health services".

From a legal point of view, according to Article 1, number 10 of the Regulation of the Minister of Health of the Republic of Indonesia Number 12 of 2017 concerning the Implementation of Immunization, AEFI is a medical event suspected to be related to immunization. Medical events can occur quickly or slowly and can be divided into symptoms, such as local symptoms, systemic, central nervous system reactions, and other reactions (11). Generally, the sooner the AEFI occurs, the sooner the symptoms appear.

Symptoms of AEFI are divided into 2, namely mild symptoms and severe symptoms. Symptoms can be further subdivided into local, systemic, and allergic acute settings. For the mechanism of allergic reactions caused by vaccines, among others (12):

1. Type 1 Ig-E hypersensitivity reaction; reactions occur up to a few minutes to 4 hours after exposure, with common symptoms such as nasal congestion, urticaria, angioedema, cough, stridor, wheezing, shortness of breath, vomiting, abdominal pain, diarrhea, and hypotension. Anaphylaxis can also occur as a severe reaction but is very rarely a life-threatening reaction.
2. T cell-mediated hypersensitivity reaction Type IV. The onset usually begins 48 to 96 hours after vaccination with common symptoms like acute generalized exanthematous pustulosis, erythema multiforme, maculopapular exanthema, and eczema.
3. Immune complex-mediated hypersensitivity reaction Type III. The reactions are mediated by Ig-G, Ig-M, and protein complement. Vasculitis and myocarditis are the most common symptoms.
4. Autoimmune. The reactions create autoantibodies induced by the molecular similarity between vaccine antigen and endogenous epitope. Clinical manifestations are thrombocytopenia, macrophagic myofasciitis, bullous pemphigoid, vasculitis, polyradiculoneuritis, rheumatoid arthritis, Guillain-Barre syndrome, and polymyalgia.

In some countries, this AEFI is also quite observed in its effectiveness. According to the Australian Immunization Handbook, AEFI is any unwanted medical event after immunization. It doesn't necessarily have a causal relationship with the vaccine. AEFI is notifiable under the NSW Public Health Act. Most reactions include fever, pain, or redness at the injection site (13).

Meanwhile, according to the National Pharmaceutical Regulation Agency Ministry of Health Malaysia, AEFI is any adverse effects experienced after receiving a vaccine. The symptoms presented are also not much different from those described above, namely swelling or redness at the vaccine injection site. Fever, lethargy, or irritability after receiving the vaccine (14). In Singapore, AEFIs are also classified according to the reported reactions and time intervals.

The Covid-19 vaccination cannot be separated from the symptoms of AEFI. According to Article 1 point 7 of Law Number 10 of 2021 concerning the Implementation of Vaccination in the Context of Eradicating the Corona Virus Disease 2019 (Covid-19) Pandemic, AEFI is a medical event that is suspected to be related to the Covid-19 vaccination. The law's definition is more or less the same as the Regulation of the Minister of Health of the Republic of Indonesia Number 12 of 2017 concerning the Implementation of Immunization. It is necessary to know various aspects before and after receiving the vaccine. A person with a history of severe allergies and who are sick or currently exposed to Covid-19 should not receive the vaccine to avoid AEFI. After receiving the vaccine, of course, our immune system can wake up after that. However, severe AEFIs are very rare. The symptoms that arise are usually only mild to moderate and disappear in a few days (15).
The awareness of the Indonesian people to participate in the Covid-19 vaccine program can be said to be not high enough. Based on a survey conducted by the Ministry of Health of the Republic of Indonesia and supported by ITAGI, UNICEF, and WHO, at the end of 2020; around 65% of respondents stated that they were willing to receive the Covid-19 vaccine provided by the government for free, while another 8% refused the vaccine. The remaining 27% stated they had doubts about the Government's plan to distribute the Covid-19 vaccine. This group is essential to encourage the vaccination program's success. Based on this situation, it is necessary to understand carefully; The public may have a low confidence level in the Covid-19 vaccine, when it is available, and its safety profile.

## DISCUSSION

### Legal Protection for Vaccine Recipients from AEFI

To achieve optimal health status for everyone, it is necessary to have adequate health legal instruments for legal certainty and protection for health providers and the community as recipients of health services. In principle, health law rests on the right to health care as a fundamental social right (the right to health care) supported by the right to information and self-determination (16). In connection with the above, to balance the interests of immunization participants and health workers, immunization participants in implementing vaccine administration are entitled to informed consent. This has been regulated in Law No. 29 of 2004 concerning Medical Practice. Informed consent in the immunization program needs to be supported by regulations, so that vaccine recipients get protection for their health services (17). Implementing immunization is not only about planning before the vaccine is carried out. However, with the side effects that occur after the

vaccine, those responsible for this must make efforts to fulfill the right to obtain protection for vaccine recipients who experience AEFI.

In medical practice, the provision of health services involves the relationship between health workers and patients (18). Patients, including vaccine recipients, are consumers of a service provided by health workers in terms of a legal relationship based on the best possible effort and results (19). Therefore, Law Number 8 of 1999 concerning Consumer Protection is the principle and rule that can be a reference in Indonesia to regulate and protect the rights of vaccine recipients as product users with medical personnel or the government as providers in the relationship and problems of social life (20). According to Article 4 of the Consumer Protection Act, vaccine recipients have the following rights:

a. the right to comfort, security, and safety in consuming goods and/or services;
b. the right to correct, transparent and honest information regarding the condition and guarantee of goods and/or services;
c. the right to have their opinions and complaints heard on the goods and/or services used;
d. the right to obtain proper advocacy, protection, and efforts to resolve consumer protection disputes;
e. the right to be treated or served properly and honestly and not discriminatory;
f. the right to obtain compensation, compensation, and/or replacement if the goods and/or services received are not following the agreement or not as they should be.

From the Consumer Protection Act perspective, the existence of AEFI cases has led to widespread demands for vaccine recipients who experience AEFIs on the way and work of health workers. However, this indicates the growing legal awareness of the community towards their rights if they are harmed in health services. The community has the right to obtain good service and compensation if health workers are proven to have violated the laws and regulations. Vaccine recipients, as consumers of health services, have the right to security, comfort, and safety and correct, transparent, and honest information. They have the right to claim compensation for the losses they have suffered.

In the implementation of immunization and the procurement of vaccination, immunization implementers are very worried about whether there is AEFI (21). Along with the high use of vaccines, there are unwanted side effects. The World Health Organization (WHO) states that an essential factor that must be considered in the manufacture of vaccines is the balance between the immunity of the vaccine recipient to be achieved and the reactions that may arise. In general, AEFI can be classified into reactions related to vaccine products, immunization procedural errors, responses related to quality defects, anxiety about immunization, and accidental events.

However, not all reactions that are felt after immunization are AEFIs, so there needs to be surveillance first by the government through the ministry of health. This is done to determine the effect or relationship with the vaccine reaction or another disease that has been suffered or is concurrent with co-morbidities sustained by the vaccine recipient (22). The World Health Organization (WHO) states that all AEFI must be reported according to their respective regions (23). The form of the report aims to be investigated further so that corrective and corrective actions can be taken. In addition, monitoring the provision of complete AEFI information is an integral part so that it can be quickly evaluated and analyzed to identify and respond to a problem in each area. For serious AEFIs, a tiered report will be carried out, and an investigation will be carried out for studies and recommendations by the Commission for the Assessment and Management of AEFIs in each country. A non-serious AEFI is a medical event that occurs after immunization that does not pose a potential risk to the health of the vaccine recipient. For serious AEFIs, a tiered report will be carried out, and an investigation will be carried out for studies and recommendations by the Commission for the Assessment and Management of AEFIs in each country. Cases of non-serious AEFIs are reported regularly every month, along with immunization results.

The increase in AEFI cases above requires the government's role in handling efforts to reduce the number of AEFI cases. Monitoring and evaluation in the immunization program implementation are necessary to assess whether the activities carried out have been carried out following applicable regulations. In addition, this activity must be able to identify aspects that cause cases of vaccine recipients experiencing AEFI. This monitoring and evaluation are carried out through reports or special studies of AEFI with laboratory confirmation. Vaccine recipients who have AEFIs have the right to express their complaints. In this case, the government's involvement in supervising the implementation of consumer protection must generally benefit consumers and ensure their interests of consumers (24). The government must provide facilities for reporting cases of AEFI.

WHO calls for monitoring of AEFI cases as stated in the 1996 WHO-SEARO friendship, which recommends that: (25)

1. The immunization development program (PPI) must have a detailed and targeted plan to provide an immediate response to the AEFI report.
2. A team of epidemiologists and professionals must examine every case of severe AEFI, and the findings must be disseminated through PII channels and the mass media.
3. The program must immediately respond quickly and accurately to the mass media regarding the AEFI case.

4. Reporting of certain AEFIs must be monitored to improve the correct injection method in the future.
5. The program must provide field officers with case report forms, clear definitions of AEFIs, and detailed instructions on reporting pathways.
6. The program needs to review the AEFI case reports from international experience to estimate the size of the AEFI cases it faces.

However, the increasing number of vaccines must also consider many targets and available resources. Recently, the problem of AEFI in Indonesia with the COVID-19 pandemic has also increased. This is thought to be due to the reaction to the COVID-19 vaccine, administered for the body's immunity against COVID-19 transmission. Instead of motivating the public to vaccinate, it makes people afraid of being vaccinated because there are victims who experience AEFI after the vaccine is injected. Since the COVID-19 vaccination program started early vaccination until May 16, 2021, the number of AEFI cases based on the Covid-19 Task Force/KOMNAS AEFI data reached 229 reports of severe AEFIs and 10,627 reports of non-serious AEFIs.

Even though Indonesia has had the National Committee for the Study and Management of AEFIs (Komnas PP KIPI) and Regional Committees (Komda) PP KIPI since 1998, problems in handling AEFIs still occur. Based on the facts on the ground, taking the AEFI case reports has not been running optimally. The total reported AEFI cases are not proportional to the percentage of immunization coverage because AEFI surveillance officers have concurrent duties with other programs, making it very difficult to conduct a study by KOMDA and KOMNAS PP AEFI to determine the cause of AEFIs and provide feedback. This can lead to protests from immunization participants who feel disadvantaged because they are late in handling it so they will demand compensation for their losses.

The facts show that vaccine recipients who experience AEFI do not have their rights fulfilled. Various cases show that the legislation is only limited to the law as if it is used as a mere display without any implications in practice. Therefore, the aggrieved vaccine recipient may request an investigation by an authorized legal institution or file a lawsuit in court (26). In connection with these problems, it cannot be separated from the responsibility of health workers. In law, there are principles of responsibility, including:
a. The fundamental of liability based on fault
b. The fundamental responsibility for the presumption of liability
c. The entire responsibility for the inference of non-liability
d. The fundamental of absolute responsibility (strict liability)
e. The primary limitation of liability
One way to distinguish the principles of responsibility can be seen in terms of procedural law in the obligation to prove by looking at whether or not there is an obligation to verify and who has to prove in the process of proof in court. The first fundamental of responsibility is the fundamental of liability based on fault. Proving the defendant's guilt must be carried out by the plaintiff as the aggrieved party. In the principle of responsibility for the presumption of liability, the defendant is always considered guilty unless he can prove things that can free him from guilt. The principle of responsibility for the inference of non-liability is known in the limited scope of consumer transactions, and such restrictions are usually justified by common sense. Then the principle of absolute responsibility (strict liability) is that the defendant, as the party causing the loss, is always responsible regardless of whether or not there is an error. The last principle is the principle of limitation of liability based on the exoneration clause in the standard agreement he made.

According to the explanation above, legal liability by health workers is based on the principle of liability based on fault. This fundamental rests on the existence of unlawful acts (onrechtmatige daad). In this regard, vaccine recipients who experience AEFI as the plaintiff must prove that health workers as defendants may have made human errors or omissions (human error) that harm vaccine recipients who share AEFI. This responsibility principle is based on Article 1365 of the Civil Code (BW). The law states that any unlawful act that causes harm to another person obliges that person, because of his mistake to incur a loss, to compensate for the loss (27).

Cases of unlawful acts that occurred in the AEFI case have fulfilled the elements of the article, namely the existence of action from the perpetrator, in this case, a health worker; the act is a violation of the law which in the implementation of immunization carried out by health workers is not appropriate. Professional standards (standard operating procedure) health based on Article 58 paragraph 1 of Law Number 36 of 2014 concerning Health Workers (28). Errors or omissions in carrying out immunizations that are not following the SOP may be related to program problems and program errors, which include errors in the storage, management, and administration of vaccines that cause losses for vaccine recipients so that they will experience AEFI (29). This is a clear causal relationship between the act and the losses suffered by the vaccine recipient.

The provision of compensation rights is an effort to protect vaccine recipients from all consequences that arise, both physical and non-physical, due to errors or negligence of health workers. If proven guilty, the health worker or related agency is responsible for compensating for any losses arising from the adverse effects suffered by the vaccine recipient, not only providing compensation in terms of treatment and care. However, they must also

offer immaterial compensation to ease the burden of moral losses suffered by the families of AEFI sufferers. The compensation provided by health workers, which is only in the form of treatment and care, is also not following the orders regulated in Article 58 paragraph 1 of Law Number 36 the Year 2009 concerning Health. This article states that every person has the right to claim material or immaterial compensation following the amount of loss he has suffered from health workers who have caused losses due to errors or omissions in his health services.

From the point of view of criminal law and administrative law, the professional staff for their mistakes can be held accountable (30). In terms of criminal law, health workers can be subject to threats based on Article 351 of the Criminal Code (KUHP). According to the article, it is stated that a person, including a health worker who causes a vaccine recipient who experiences AEFI to become disabled or even die, is subject to a maximum threat of 5 years due to his negligence. The responsibility of health workers in administrative law is in the form of sanctions for the revocation of practice permits. This can be imposed if health workers have neglected their obligations, taken actions that should have been prohibited and neglected something that should have been done, and violated a provision according to or based on the law.

However, in the case of AEFI, civil claims will often be used because civil liability aims to obtain compensation for losses suffered by vaccine recipients who suffer from AEFI. However, legal protection for doctors and patients is objective and balanced, so in the concept of liability based on the fault where the burden of proof is on the claimant, it will be difficult for the patient as claimant to prove the fault of health workers (31). Suppose the responsibility of the AEFI case is seen as an unlawful act. In that case, the legal subject of product responsibility is also the same as the subject of the unlawful act (32). The government is a legal subject that is always involved in the implementation of immunization and has a great interest in the supervision and protection of both parties in the relationship between health workers and vaccine recipients. Therefore, the government will always be considered responsible for providing compensation until it is proven that the disease suffered by the patient is not an AEFI affected by the vaccine product.

In connection with the government's role as the organizer of the immunization program, the Indonesian government is fully responsible for all rights related to public health. It is accountable for guarantees from socialization and implementation to compensation to vaccine participants who experience AEFI. The liability given by the order is a form of fundamental infallible responsibility (strict liability), as it is stated that the responsibility for providing compensation is granted without the need for an error in vaccination. This protects to fulfill the right to health under Article 9 of the Law. Health Law states that the government is responsible for improving the health status of the community.

To realize legal protection for vaccine recipients who experience AEFI, the Indonesian government has prepared regulations related to AEFI in the vaccination program. The regulation is regulated in the Regulation of the Minister of Health of the Republic of Indonesia Number 12 of 2017 concerning the Implementation of Immunization. According to Article 42 paragraph (4) of the Minister of Health 12/2017, it is stated that the government is responsible for financing treatment, care, and referral for vaccine recipients who experience AEFI or as a result of AEFI, which is charged to the revenue budget or other cost sources following the provisions of the legislation. In addition to these regulations, in connection with the losses suffered by vaccine recipients against Covid-19 vaccination, the Indonesian government announced the cost of treatment for AEFI cases through Minister of Health Regulation Number 10 of 2021, which was amended by Regulation of the Minister of Health Number 18 of 2021 concerning Implementation of Vaccinations in the Context Handling the Corona Virus Disease 2019 (Covid-19) Pandemic.

## CONCLUSION

Almost all over the world are conducting socialization and activities to provide Covid-19 vaccines. Based on the World Health Organization (WHO), AEFI is defined as any unwanted medical event that occurs after immunization and does not necessarily have a causal relationship with the use of the vaccine. Vaccine side effects include pharmacological effects, drug interactions, tolerance, side effects, and allergic reactions, which are generally clinically hard to distinguish from one another. From the Consumer Protection Act perspective, the existence of AEFI cases has led to widespread demands for vaccine recipients who experience AEFIs on the way and work of health workers. Legal responsibility by health workers is based on the principle of liability based on fault. This principle rests on the existence of unlawful acts (*onrechtmatige daad*). From the point of view of criminal law and administrative law, professional staff can be held accountable for their mistakes. However, in the case of AEFI, civil claims will often be used because civil liability aims to obtain compensation for losses suffered by vaccine recipients who suffer from AEFI. In connection with the government's role as the organizer of the immunization program, the Indonesian government is fully responsible for all health-related rights. The community is accountable for guarantees from socialization and implementation to compensation to vaccine participants who experience AEFI. The responsibility given by the order is a form of absolute fundamental responsibility (strict liability). Health workers can be personally responsible for their mistakes in administering vaccines. At the same time, the

government's commitment is related to compensating people who suffer from AEFI as a form of government protection for their citizens.

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