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Government Liability to Adverse Event Following COVID-19 Vaccine Immunization in Indonesia
The Right Form of Access to Justice?

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ABSTRACT

The COVID-19 pandemic in Indonesia, which has been ongoing since March 2020, has had devastating consequences for economic, social and cultural aspects of the world. As an effort to overcome the pandemic, the Indonesian government has begun to promote the mass and mandatory administration of recently discovered COVID-19 vaccines. However, this government policy is still considered quite controversial with a large number of doubts from the public regarding COVID-19 vaccine safety. In regard to minimize doubts in the public, several regulations have been enacted such as Presidential Regulation Number 14 of 2021 and Regulation of the Minister of Health Number 10 of 2021, to which these regulations rule the government role and liability in handling AEFI that arise by the use of the COVID-19 Vaccine. These regulations established a system that resembled no-fault compensation scheme, a widely known scheme that has a purpose to give compensation for people who experience AEFI in the form of vaccine-related injury. Based on our research, it was found that the Indonesian scheme has the same essence as the common scheme. However, the current Indonesian scheme implementation has several elements that need to be improved regarding its problem of being governed under minister regulation, limited sources of funding, limited rules concerning elements of compensation, not-so-easy standard of proof, no guarantee to appeal, and restricted scope of vaccine eligibility.

Keywords: *COVID-19, Vaccine Injury, No-Fault, Compensation, Indonesia.*

1. INTRODUCTION

The pandemic of COVID-19 has created an unprecedented global health crisis in the modern times. In order to effectively stop the ongoing pandemic, the Indonesian government should have clear, comprehensive, and justified regulations in executing national-wide vaccination program for all of its citizens. This is due to the critical role that vaccinations programs have played in the past as government's intervention to effectively control and ultimately stop an ongoing pandemic, such as influenza [1]-[3]. It has been highly suggested that the vaccination program remains as one of the most viable solutions to finally stop the current COVID-19 pandemic, alongside other kinds of government responses [4], [5]-[6]. These regulations must also include provisions on how the government should be held liable for any physical injuries and their following implications that may be experienced by the vaccine recipients after the vaccines have been administered. These injuries are called Adverse Events Following Immunization (AEFI).

As of May 30, 2021 (16.27 GMT+7), there have been 1.816.041 confirmed COVID-19 cases and as a result, 50.404 people have died based on the data published by a group of independent Indonesian professionals and practitioners [7]. Since the first two confirmed cases of COVID-19 were publicly announced by the government of Indonesia on March 2, 2020 [8], the trend for the total number of confirmed cases each day has been increasing [9]. Last June, Indonesia just reported a surge in the number of COVID-19 cases and "entered the worst-case scenario in dealing with the COVID-19 pandemic" [10]-[11]. New variants of SARS-CoV-2 virus also entered Indonesia and started spreading rapidly [12].

Although the pandemic of COVID-19 has been declared as a national disaster on April 13, 2020 through the Presidential Decree Number 12 of 2020 regarding Determination of Non-Natural Disaster of the 2019 Virus Disease (COVID-19) Spread as a National Disaster, the government of Indonesia has been criticized concerning its slow and inadequate responses in dealing with the spread and impact of COVID-19 [13]. Several reasons may factor into this situation, including the lack of seriousness and scientific basis used by the public officials in addressing the threat of the pandemic resulted in minimal national response in early development [14], lack of adequate healthcare facility, protective equipment for health workers and people's weak compliance to health and hygiene protocols [15]-[16], ineffective top-down approach [17], and lack of coordination between governments in the national and provincial level [18].

With the high number of confirmed cases of COVID-19, increasing trend, and ineffective regulations, it has become a paramount importance for the government of Indonesia to conduct a safe and effective vaccination program to end the pandemic [19]. On January 13, 2021, the government of Indonesia began its national vaccination program [20]. This program is compulsory in accordance with Article 9 and 15 paragraphs (2) of the Law Number 6

of 2018 regarding Health Quarantine (Health Quarantine Law) which stipulates that every person is required to comply with health quarantine measures, including vaccination. Non-compliance might result in punishment with a maximum imprisonment of one year and/or a maximum fine of one hundred million rupiahs according to Article 93 of Health Quarantine Law.

A more contextual provision is used in Article 13A paragraph 2 of Presidential Regulation Number 14 of 2021 regarding the Amendment to Presidential Regulation Number 99 of 2020 on Vaccine Procurement and Vaccination to Overcome the Corona Virus Disease 2019 (COVID-19) Pandemic. It stipulates that every person who is determined as COVID-19 vaccine target recipient is obliged to participate in the COVID-19 vaccination program. According to paragraph 4, every person who doesn't comply with the provision may be subject to administrative sanctions: suspension or termination of social security or social assistance, suspension or termination of government administration services, and/or fine. The same provision can also be found in Article 14 of Regulation of Minister of Health of the Republic of Indonesia Number 10 of 2021 regarding Implementation of Vaccination in the Context of the Corona Virus Disease 2019 (Covid-19) Pandemic Management which stipulates that every person that is determined as COVID-19 vaccine target recipient must participate in the COVID-19 vaccination program in accordance with the provisions of laws and regulations. The legal obligation to participate in the vaccination program may be a factor in improving its coverage rates and overall effectiveness [21], although in the context of COVID-19 vaccination in Indonesia, the link hasn't been clearly established.

The fact remains that the trend for the number of doses of COVID-19 vaccine administered daily in Indonesia is increasing [22]. As of May 30, 2021 (18.00 GMT+7) 16.304.700 people have been administered the first dose of COVID-19 vaccine (40,41% of the total targeted receivers of 40.349049 people) and 10.584.489 people have received their second dose (26,23% of the total targeted receivers of 40.349049 people) [22]. Despite this, a survey on COVID-10 vaccine acceptance in Indonesia conducted in November 2020 [23] showed that about 27% of respondents expressed hesitation and nearly 8% refused to receive COVID-19 vaccine. Common reasons for not accepting COVID-19 vaccine include concerns regarding vaccine safety and fear of side effects [23]. These concerns may relate to the existence of AEFI that are associated with the use of COVID-19 vaccine.

AEFI is generally defined as "any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine" [25]. WHO categorized AEFIs into five groups: vaccine product-related defect, vaccine quality defect-related reaction, immunization error-related reaction, immunization anxiety-related reaction, and coincidental event [25]. These reactions can range from common and minor, including pain, swelling, redness, fever, irritability, and malaise, to rare and severe, including fatal dissemination, prolonged crying and seizures, thrombocytopenia, and Anaphylaxis [25]. These reactions become serious if they cause death, significant disability, threaten life, and/or require prolonged intervention, such as inpatient hospitalization [25].

Thousands of cases of AEFIs after receiving COVID-19 vaccine have been reported in countries around the world [26]-[28]. Reported on May 20, 2021, the Indonesia's National Commission on AEFI (*Komisi Nasional Kejadian Ikutan Pasca Imunisasi*/*Komnas KIPI*) have received 229 reports of serious AEFI cases and 21.254 cases of minor AEFI [29]. Thirty people have been reported dead after receiving COVID-19 vaccine, although *Komnas KIPI* has stated that those deaths were unrelated to COVID-19 vaccine [30]. Following the death of a 21-year-old man from Jakarta after receiving AstraZeneca vaccine on May 10, 2021 [31] and recent development of its use in England [32], the Head of the Indonesian Medical Association (IDI)'s COVID-19 Task Force recommended that the use of AstraZeneca vaccine to not to be used for people under the age of 30 due to its potential to cause blood clotting and even death for its receivers [32].

As the number of AEFI cases are likely to rise in relation to the growing number of doses administered daily in Indonesia [33], it becomes increasingly relevant to discuss how the victims of AEFIs, especially the serious ones, should be compensated for the harm they experience. MacDonald *et al.* [34] concluded that an adequate compensation program for serious AEFIs is one of the reasons why mandatory vaccination conducted by the government can be ethically justifiable. In this context, the government has responsibility for those harmed as a result of the implementation of mandatory vaccination programs to protect public health and so the victims, based on the principle of distributive justice, are entitled to receive just compensation [35]. The existence of a compensation program for AEFI victims is also important because the traditional tort-based litigation may create difficulty for the victims to prove any negligence, deliberate harm, or causal relationship, and lead to an expensive and time-consuming process [35]-[36]. Based on this problem, countries around the world implemented a no-fault compensation mechanism for AEFI victims in which victims do not have the obligation to prove any fault against the injurers, be it government or the vaccine manufacturers, to receive compensation [35]. Effective AEFI victim's compensation programs may also contribute in maintaining the public trust in the national vaccination program and minimizing vaccine hesitancy [37]. The development of the program started in 1961 in Germany [36] and as of 2018, there were 25 countries that implemented a no-fault compensation program for vaccine injury [38].

In the context of COVID-19 pandemic, Indonesia has established its national compensation program for AEFI victims through Regulation of Minister of Health of the Republic of Indonesia Number 10 of 2021, specifically in Article 37-40. This is one step forward for the government

of Indonesia to ensure that the AEFI victims are able to receive compensation for the harm due to receiving mandatory COVID-19 vaccine. The regulation provides legal protection for the victims which is in line with the fulfillment of the constitutional right stated in Article 28D paragraph (1) of the Constitution of the State of the Republic of Indonesia of the Year 1945 (*Undang-Undang Dasar Negara Republik Indonesia Tahun 1945*/UUD 1945): "Every person shall be entitled to recognition, guaranty, protection, and equitable legal certainty as well as equal treatment before the law." In other hand, the benefit of AEFI victims compensation program to maintain vaccine safety and public trust is in line with the objective of the national vaccination program to end the COVID-19 pandemic in Indonesia and may help contribute to the fulfillment of the constitutional right to health which is stated in the Article 28H paragraph (1) of UUD 1945: "Every person is entitled to live prosperous physically and spiritually, to have a place to reside, and to acquire a good and healthy living environment as well as be entitled to obtain health care."

Considering the importance of AEFI victims compensation program to the overall effectiveness of the implementation of national vaccination program and to provide access to justice for the victims in Indonesia, this paper aims to examine how existing laws and regulations in Indonesia accommodate responsibility for people affected by AEFI after receiving COVID-19 vaccine and to evaluate those laws and regulations. Section 2 briefly explains the method used in this research. Section 3(a) with an overview of the no-fault compensation scheme for vaccine injury and how it differs from the traditional tort-based litigation. Section 3(b) then highlights and compares key elements of vaccine injury compensation programs from other countries. Section 3(c) examines the Indonesian laws and regulations regarding the general vaccine injury compensation program and specifically for the COVID-19 pandemic context. Section 3(d) discusses the ideal characteristics that should be implemented in Indonesia based on the lessons learned from other countries and the current understanding of existing compensation programs. Section 4 concludes the paper with suggested recommendations for improving the Indonesian compensation program for the AEFI victims of COVID-19 vaccines.

2. RESEARCH METHOD

The research used in this paper is normative legal research which heavily relies on qualitative data, especially secondary data [39]. Common in normative legal research, this paper uses statute approach to critically examine various laws and regulations as a focus of the research [40], especially this paper includes the findings of a comparative study regarding vaccine injury compensation program in Indonesia and other countries.

As mentioned, this paper mainly uses secondary data consist of primary legal materials, mainly laws and regulations regarding vaccine injury compensation program from Indonesia, the United States of America, Republic of Korea, New Zealand, and Vietnam which are used in the comparative study, and secondary legal materials, such as books, journals, online articles, reports, and other legal or non-legal documents related to the topic of this paper. The United States of America was selected to represent one of the most developed Western countries in the world. The Republic of Korea represents one of the most developed countries located in Asia. New Zealand was chosen as a country with one of the progressive healthcare systems in the world. Vietnam is analyzed as one of Southeast Asian countries which shares similar characteristics with Indonesia. The comparative study will be based on categorization by Evans [37] on six common elements that constantly present in vaccine compensation programs: administration and funding, eligibility, process and decision-making, standard of proof, elements of compensation, and litigation rights. The regulations of these programs used in this paper are relevant at least until May 2021.

The data collection was conducted through library research. Then, it was analyzed, interpreted, and presented in this paper through descriptive text to provide answers to the research problems mentioned in the Introduction.

3. FINDINGS AND DISCUSSION

3.1. No Fault Compensation for Vaccine Injury Scheme

No-fault vaccine injury compensation programmed are established in several countries on purpose to compensate individuals who experience adverse events following immunization in the form of vaccine-related injury, as long as there was probable cause between the problem and vaccination [38]. These programs do not require the claimant, their family or their legal representative to prove negligence or fault by any related parties that caused the injury, like the vaccine provider, health care system or the manufacturer [38]. A well implemented no-fault vaccine injury compensation scheme has been proven to be useful in ensuring justice for the injured party, also in actualizing social welfare through legal protection that helps vaccine procurement, so that the rates of vaccine-preventable diseases can be suppressed.

Before there was any formal no-fault compensation scheme, the only source for injured parties to get compensation was through courts, usually under the law of tort. In tort law, claimants were required to prove that there was any negligence or fault that happened to them [36]. Injuries from medical malpractice were covered under this tort law, as long it has been proven that there was negligence or fault that occurred. However, there are problems in the case of vaccination-caused injury, because there was often no clearly negligent party in vaccine injuries. Vaccine still may cause injury and its effects on particular individuals was very unpredictable, even though it may have already been manufactured and administered properly [37]. These problems made civil actions brought against manufacturers often proved unsuccessful, given the

difficulty in proving causation and negligence. In the other hand, there have been several cases in which some companies were held responsible for alleged vaccine-related injuries even when scientific evidence did not establish causation [41]. These particular cases have caused legal uncertainty in tort law enforcement regarding medical malpractice, specifically vaccine-related injury. Based on the previous explanation, it could be concluded that the original tort scheme did not provide legal certainty and it consequently affected both parties' fulfilment of justice.

Although it has been proven to be uncertain, in fact there were still so many claimants who filed lawsuits against vaccine manufacturers, and this had a very negative impact on the vaccine manufacturers. These manufacturers argue that those persistent lawsuits exceeded income they could earn from vaccines; therefore, they increase their vaccine price [42]. These particular circumstances negatively affect multidimensional aspects because it led to exponential price rises and a reduction in vaccine research [42]. Furthermore, several small vaccine manufacturers that faced difficulties competing in the market eventually left the market and it caused vaccine shortages [42]. Hence, the no-fault vaccine injury compensation programmed were enacted as a way to overcome problems related to legal uncertainty and also acts that were detrimental towards the manufacturers financial condition.

3.2. Indonesian No-Fault Compensation for Vaccine Injury Scheme

In Indonesia, the vaccine injury compensation system is enacted through the Minister of Health Regulation Number 10 of 2021, which is the implementing regulation of Presidential Decree Number 99 of 2020 and Number 14 of 2021 based on a no-fault principle. Those decrees not only regulate the system for vaccine injury compensation but also the vaccination program itself. From a regulatory framework perspective, Indonesia regulates the vaccine injury compensation differently from the previous countries explained, as Indonesia enacted laws specifically for COVID-19 vaccines and its compensation for vaccine injuries using previous laws regarding immunization as the legal basis. The regulation applies to everyone who receives COVID-19 vaccination in Indonesia and is not limited to Indonesian citizens [43].

Funding for the vaccine injury compensation in Indonesia is divided into two parts; one is for care and treatment given by health centers and the other is for the compensation itself. Both the national security insurance and the government's fund are used to fund the care and treatment given by health centers to treat people who suffer vaccine injuries. However, national security insurance can only be used by those who are a part of the national insurance program. If not, the expenses will be covered using the government's fund. On the other hand, the compensation for vaccine injuries are solely funded by the government's fund [43].

The compensation for vaccine injury can be accessed by people who suffer injuries following all official COVID-19 vaccinations by first filing a report regarding the injury to the corresponding health centers. Then, the health center will record the report and conduct a preliminary inspection to determine whether the claimants need to be given care and treatment. If so, the health centers will do so and the expenses will be covered by the government or social security insurance. Then, the process continues where the Regional Commission on AEFI conducts an etiological assessment and the National Commission on AEFI conducts a causality assessment between the injury and the vaccination. From this process, there can be two outcomes, one is where the assessment results in no causal relationship between the injury and vaccination and one is where the causal relationship is proven. If the causal relationship is not proven, the claim will simply be dismissed and the case will be recorded. On the other hand, if the causal relationship is proven, the claimants can file a claim to get compensation to the National Commission on AEFI while a follow-up process where the National Agency of Drug and Food Control will take place, which includes testing and sampling the claimants [43].

Beside the coverage of care and treatment of claimants by the government, there are two types of compensation available for the claimants which is determined case by case. One is disability compensation and the other is death compensation. The disability compensation is awarded based on the severity of the disability which is classified into mild, moderate, and severe. Furthermore, the amount of compensation in each category is not strictly regulated, rather it is determined by the evaluation committees which will be forwarded to the Minister of Finance to be approved. Regarding the decision made, there is no regulation that allows any litigation process that can be done by the claimants regarding the compensation. However, it is regulated in the Minister of Health Regulation Number 10 of 2021 that the government will take over any legal responsibility from parties that supply and conduct COVID-19 vaccination [43]. Thus, litigation processes are actually possible under the Indonesian civil law.

3.3. Comparative Study

3.3.1. South Korea

South Korea has one main law that regulates the principles regarding compensation for vaccine injuries, which is the Infectious Disease and Prevention Act (IDPA). It is regulated that the state must give compensation to those who suffer injuries caused by certain vaccination based on a no-fault principle, which funds are given by Korea's Minister of Health and Welfare, which is derived from the national treasury of Korea. The compensation scheme is further regulated through multiple presidential decrees mentioned in the Enforcement Decree of the Infectious Disease and Prevention Act (EDIDPA).

Regarding eligibility, IDPA only facilitates compensation for injuries caused by vaccinations included in the National Immunization Program (NIP) [44]. As for injuries caused by the COVID-19 vaccination, even though the vaccine is not listed in the NIP, the Korea Disease Control and Prevention Agency has stated that the compensation scheme as regulated in IDPA and EDIDPA is also applicable for injuries caused by the COVID-19 vaccine [45]. Furthermore, the compensation claim should be filed within 5 years after the occurrence of the injury and the minimum cost of healthcare spent must be 300,000 Korean Won and above [46].

Claims regarding the compensation will be processed by the Korea Advisory Committee on Vaccine Injury Compensation (KACVIC). Their task is to assess and determine the causal relationship between the injury and the vaccination itself. The causality assessment done by KACVIC is based on the Korean's own criteria of standard of proof, which is based on the World Health Organization (WHO) causality assessment criteria [47]. Those criteria are (1) definitely related, (2) probably related, (3) possibly related, (4) probably not related, and (5) definitely not related. Full compensation is awarded only to cases that fall into the definitely related, probably related, and possibly related criteria. Other than those three categories, no compensation is awarded to the claimants [44].

There are three types of compensation that can be given to the claimant which is determined case by case, which are compensation for medical expenses along with nursing expenses, a lump-sum compensation, and compensation for funeral expenses. Medical expenses and nursing expenses are to be awarded to people who receive treatment for the injury that satisfies the eligibility terms. Secondly, the lump-sum compensation is awarded to people who suffer physical disability due to the vaccination and lastly, compensation for funeral expenses are awarded to the families and relatives of a deceased person in which his/her death is related to the vaccination.

Both IDPA and EDIDPA do not regulate any scheme that allows any litigation process regarding the compensation claim. However, claimants can submit an appeal to the KACVIC against the decision they made regarding the causality assessment of the claimant's injury to the vaccination. This system strengthens the claimant's access to compensation.

3.3.2. Vietnam

Vietnam is one of few countries in Southeast Asia that implement a no-fault compensation scheme in their healthcare system. In 2016, the Vietnamese Government enacted the Decree on Vaccine Activity Regulations in purpose to cope with vaccine-related injury problems [48]. Under this decree, the Vietnamese Government proclaims their responsibility to compensate victim that suffer disability or death because of vaccination [49]. Vietnam has organized funding for this compensation system through state budget, funding of organizations and individuals, the health insurance, and other legitimate revenues [49].

Compensation can only be granted if the damage is caused by national vaccination program or vaccination against epidemic that seriously affects the health and life of people that get vaccinated [49]. Other than that, the claimant must prove the fault behind the resulting damage. However, this system's eligibility actually has a broader coverage compared to some other countries. It can be said broader because several countries limit the type of vaccines that can be covered, for example the USA and United Kingdom schemes predominantly only cover childhood vaccines, adult influenza and vaccines given to the armed forces [36].

To get compensated, claimant (victim or relatives) firstly should submit the required documents (petition to determine the causes of injuries, bills, etc.) to the Department of Health Records [49]. Afterward, the Expert Advisory Council will review and determine the cause of injury and its relation to the vaccination [49]. Based on conclusion from the Expert Advisory Council, the Department of Health will decide claimant's compensation [49].

From the previous elucidation, it could be understood that the Vietnam no-fault compensation scheme appears to be rigid and implemented unilaterally according to the will of the State. There is no intermediary agency to assess and control a fair entitlement for claimant [48]. In case claimant isn't satisfied with the compensation, Claimant has no right to make an appeal because there is no provision that preserve such kind of right [48]. However, claimant may file a lawsuit to the court if they do not agree with the decision of the Department of Health [49].

Moreover, there is also a problem in the Vietnam scheme regarding the element of compensation. As stated under the government decree, the given compensation may encompass as follows [49]:

1. Compensation of base salary and the expenses for 30 months in case the damage caused by the vaccination resulting in disability
2. In the event that the vaccination leads to death, then the government must compensate:
    a. Expenses specified before death
    b. Funeral expenses, equal to 10 months of base salary ordered by the State
    c. Expenses to redeem mental suffering that the affected persons relatives must endure, as much as VND 100,000,000 (equal to IDR 62.750.000)
    d. Expenses due to lost or reduced incomes

Based on that stipulation, it is found that the compensation entitlement is actually quite limited. The Vietnam scheme only aims to partially recover some of the damage, especially in the case of disability from vaccine usage. The

scheme mainly can't be inferred to be intended to restore the claimant's damage to the previous condition [48].

3.3.3. New Zealand

New Zealand has a quite unique no-fault compensation scheme compared to the other country. It is unique because the no-fault compensation scheme in New Zealand, which is known as Accident Compensation Corporation (ACC) scheme, not only covers vaccination injury specifically. In general, it covers broader types of injury that have already been arranged under law regarding ACC schemes.

The foundation of ACC scheme is based on a report written in 1967 by a Royal Commission of Inquiry chaired by Sir Owen Woodhouse (The Woodhouse Report). The Woodhouse Report encompassed review over remedies given to victims of injuries, common-law claims, and social security. The Commission found that remedies given under those circumstances were quite lacking. Under Workers Compensation Act, compensation for injury is only given to employees injured at work, and therefore the application had been limited. Social security was considered inadequate because it did not compensate an injured person, it was means-tested, and it was provided at a flat rate. The Commission also found that the common-law claim system was inefficient, illogical, unpredictable, arbitrary, and presented a barrier to rehabilitation of the claimant. The problems uncovered by The Commission are mainly focused on the application of fault principle –A principle where the defendant must be proven to be the one who conducts a failure (negligently or intentionally). The rule of contributory negligence in the common law system also became a problem because it may reduce compensation that will be given if the injury is proven to be caused by the claimant. Therefore, the Commission recommended a solution by creating a system that provides "immediate compensation without proof of fault for every injured person, regardless of his or her fault, and whether the accident occurred in the factory, on the highway, or in the home [50]."

The Commission outlined five principles to be implemented through accident compensation schemes. The first principle was community responsibility, where the scheme should ensure the community's responsibility for injured persons [50]. The second principle was comprehensive entitlement, to which the scheme must cover all injury on the same method of assessment [50]. The next principle was complete rehabilitation, where compensation must be fully focused on the rehabilitation of the injured person [50]. Then, real compensation principle, which states that compensation must be given based on real economic and physical losses [50]. The fifth and final principle is about administrative efficiency, to which the scheme is enacted to avoid wasteful litigation spending [51]. In fact, not all of The Woodhouse Report's recommendations were implemented under the ACC scheme, so that this recommendation practically only serves as an unbinding guidance for the ACC scheme itself.

Most of the principle of Woodhouse Report is later manifested under the Accident Compensation Act 1972 that organized the first accident compensation scheme in New Zealand. It was later updated several times by the Accident Compensation Act 1982, Accident Rehabilitation Compensation and Insurance Act 1992, Accident Insurance Act 1998, and Accident Compensation Act 2001. Regarding the administrator of the no-fault compensation scheme in New Zealand, the responsibility is being held by the Accident Compensation Corporation, which is a statutory corporation that provides no-fault compensation for any personal injury and death caused by accident [36]. ACC is separated from the main public health system and responsible for its budget and spending [52].

As for funding, the ACC scheme in New Zealand is generated from several sources including general taxation, levies on employers, employees and motor vehicle owners, the cost of petrol, and government funding [53]. Then, the collected money is distributed into five ACC accounts that each cover a specific group of injuries [53]. Each group is funded by a different source of money. In case of treatment injury that includes vaccination-related injury, the funds are drawn from Earner Account and Non-Earner Account. The Earner Account is funded by levies paid by everyone in the workforce (personal income tax), while the Non-Earner Account is funded by money collected from general taxation by the Government [53]. The Earner Account funds are used to meet the treatment injury costs of people in employment and vice versa [53].

About eligibility, The Accident Compensation Act 2001 provides cover for any personal injury that has been determined to be compensated under that law. Personal injury itself can be defined as (1) the death of a person, (2) physical injuries suffered by a person, (3) mental injury suffered by a person because of physical injuries suffered by the person, (4) mental injury suffered by a person in the circumstances described in section 21, or (5) damage (other than wear and tear) to dentures or prostheses that replace a part of the human body [54]. Person in here is not restricted to certain groups of people, so person in here applies generally, even sometimes included foreign nationals that happened to get injured in New Zealand or get injured because of any act by a citizen or public official from New Zealand [55]. Then, the claimant has to prove that the injury was caused by an accident (exception for treatment injury), which is not defined to be fault-based under the New Zealand Law [50].

As to compensation for injury caused by COVID-19 Vaccination, it has already been covered by the Accident Compensation Act 2001, especially under provision which stated that personal injury also covers treatment injury suffered by a person [54]. Treatment injury could be determined as personal injury that is suffered by a person seeking or receiving treatment from 1 or more registered health professionals, and directly caused by the treatment [54]. The Law also stated that treatment injury compensation does not cover injury that is a necessary part, or ordinary consequence of the treatment, and personal

injury that is wholly or substantially caused by a person's underlying health condition [54]. Therefore, to determine whether treatment injury relating to COVID-19 vaccination has occurred or not, it has to be determined first whether there is causality between COVID-19 vaccination and the injury that happened later. The ACC scheme apply balance of probabilities as the standard of proof. Balance of probabilities is a civil standard of proof that is widely understood to require facts to be preponderance of evidence, or more evidence than not to suggest that an event occurred [56]. Thus, in relation to vaccine-caused injury, it has to meet the required standard of proof to determine that a vaccine caused an injury. It has to attain the balance of probabilities threshold, which is at least on the numbers of 51 percent.

Even though the eligibility criteria in ACC scheme have already been changed, the decision-making process itself remains much the same as before. If it can be compared to similar mechanisms implemented in other countries, the ACC scheme process could be considered as one of the simplest process in the world [57]. The process starts from initiation conducted by the healthcare worker, who will review the injury claim and then notify the ACC [36]. Claims are decided in the ACC's national claims unit, based on information gathered from the patients and providers, added with advice from independent clinical advisers as a consideration in decision making [57]. Overall, the ACC has 9 months to decide a claim. Claimants who are not satisfied with the decision may request a review of the decision [57].

Claimant cannot file claims regarding personal injury (including treatment injury that covers vaccination-related injury) through litigation process [54]. However, litigation process can be pursued in the event that the claimant files an appeal against the earlier ACC decision. Claimants have a right to appeal against the review decision or award of costs and expenses which has been determined in the decision [54].

If the filed claim is approved by the official, ACC scheme may provide several entitlements to the Claimant, comprising (1) *treatment and rehabilitation*, includes cost of pharmaceuticals, disability aids, child care, and home modifications; (2) *compensation for loss of earnings*, includes weekly compensation of 80 percent of the claimant's earnings at the time of injury, up to a set maximum; (3) *lump-sum compensation*, an additional payment to other ACC entitlements, can be given up to US$70,000 to compensate for permanent impairment resulted from injury; (4) *support for dependents* includes funeral grants, survivors grants, weekly compensation for the spouse or partner, children and other dependents of a deceased claimant, and child care payments [54], [57].

3.3.4. United States of America

In 1986, the government of the United States established the National Vaccine Injury Compensation Program (VICP) through the National Childhood Vaccine Injury Act (Public Law 99-660, 42 USC) based on the idea that the society, receiving public health benefit from vaccination program, had an obligation to compensate those who were harmed by the vaccines [42]. The program implements a no-fault compensation scheme in which petitioners (claimants) must first file in the process of VICP before undergoing legal action in state or federal civil courts [58]. The VICP is administered at the federal government level [39]; run jointly by the US Claims Court, Department of Health and Human Services, and Department of Justice [59]. The funding comes from the flat-rate excise tax of 0.75 USD on each dose of vaccine administered which is collected from the manufacturers into the Vaccine Injury Compensation Trust Fund which then can be drawn by the claimants [38], [59], [60].

To be granted compensation, claimants may show that the type of injury they experience after receiving certain types of vaccines within a specific timeframe is listed in the Vaccine Injury Table. The Table [61] contains seventeen categories of vaccine types covered by the VICP, ranging from vaccines containing tetanus toxoid to any new vaccine recommended by Centers for Disease Control and Prevention, alongside the injuries, disabilities, illnesses, conditions, and deaths caused by the vaccines and their time period "in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration", and provided with Qualifications and Aids to Interpretation (QAI) to help claimants, law enforcers, and relevant actors in further defining the injuries listed in the Table. This strategy has reduced liability for manufacturers as one of the incentives to ensure they continue innovating in the vaccine market while establishing a faster process in providing compensation for the victims [58], [60]. The high immunization rates and low rates of the majority of vaccine-preventable diseases in the US suggest that VICP has appeared to be successful [62].

If the vaccine type, injury type, and the time frame for its occurrence are all matched, the claimants may immediately be entitled to compensation as these injuries, based on the Table, are presumably to have been caused by the administration of the listed vaccine [59] If the conditions of the injury don't meet the criteria provided by the Table, the claimants can still justify their entitlement to compensation by proving the causation effect that the vaccine has caused the injury or prove that the vaccine worsen a preexisting condition that the claimants have by presenting adequate and necessary evidence from medical records to expert witnesses [38], [58]. Several other eligibilities include that the victims of the vaccine injury are qualified as petitioners according to Vaccine Act, they filed the petition within the statute of limitation, have not previously received any kind of compensation or settlement for their vaccine injury, the administration of the vaccine took place in the territory of the US of its trust territories, and the victims suffered the residual effects of the injury "for more than six months, died, or was

hospitalized and underwent surgical intervention." [61], [63].

Determining that the claimants are entitled to compensation for their vaccine injury falls under the jurisdiction of the US Claims Court and the US Claims Court special masters, appointed attorneys who are experts in medical and legal issues regarding vaccine injury [58], [63]. The decision is based on the medical expert review of the Department of Health and Human Services' Division of Vaccine Injury Compensation [58], [59]. After being found eligible, the actual amount of compensation is usually negotiated between the Department of Justice and the claimants, and if no final amount is agreed by both parties, it will be determined by the special master [58]. This compensation may cover actual and reasonable future non-reimbursable expenses resulting from the vaccine injury, impairment of earning capacity, lost earnings, pain and suffering, and reasonable attorneys' fees [63]. After the claimants accepted the compensation by the VICP, they lose their rights to undergo a civil claim [36], but if they choose to reject the decision or the compensation, they retain their right to file a lawsuit in civil court [58].

Although the VICP has been regarded successful in providing more preferred and effective mechanism to seek out compensation for the victims of vaccine injury [64] with a total of US$4.431.468.456 has been given from its establishment to 2020 [65], problems may arise when regulations instead bar the victims from undergoing the VICP process to receive compensation. Currently, victims of COVID-19 vaccine injury are unable to seek out compensation through VICP due to its status as public health emergency [66] based on the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, which was initiated on March 17, 2020, by the Secretary of Human and Health Services. As a consequence of this declaration, the victims are now required to seek out compensation only through the less-preferred Countermeasures Injury Compensation Program (CICP) established by the Public Readiness and Emergency Preparedness (PREP) Act as the COVID-19 vaccines act as countermeasures to deal with the ongoing public emergency [66].

CICP provides legal protection towards the eligible persons who experience serious physical injuries or deaths which are directly caused by the administration of countermeasures, such as drugs, biological products, or devices, for diseases, conditions, or threats that are determined by the Secretary of Human and Health Services through issuing declarations [67]. Serious injuries are defined as injuries that are life-threatening, cause permanent impairment or damage to the body, or have to be handled through medical or surgical intervention [63]. Similar to the process in VICP, the requesters are presumably entitled to compensation after have successfully shown that their injuries meet all the requirements listed in the Countermeasure Injury Table, including the time periods between the administration of the vaccines and the occurring of injuries and the level of severity, and if not, the prove the causation that their injuries are directly caused by the administration of covered vaccines [67]. Compensations, or benefits, covered by CICP are medical benefits, including reimbursement for medical services or items used to diagnose and/or treat the injury, benefits for lost employment income, and survivor deaths benefits [67]. These compensations are funded from the emergency fund established by the Department of Treasury through Covered Countermeasures Process Fund [63]. The determination regarding the eligibility of the requester is decided by the Secretary of Human and Health Services [67].

The critics to the CICP are generally based on its less transparent process and limited types of compensation. The system of CICP provides "no guarantee of legal representation, a hearing, or a publicly available final decision" [68]. This results in lack of transparency in the process of determining the eligibility for compensation and overall difficulty for the victims to access their rights to justice. The process also may be more expensive as the compensation covered by CICP doesn't include attorney's fees, hindering the accessibility for the victims to ask for compensation. Furthermore, the compensation doesn't cover the adequate loss experienced by the victims like VICP, such as pain and suffering damages. Once the determination regarding the compensation is made, CICP doesn't allow for any judicial review of the determination to be conducted [69]. This further limits the ability of victims to seek out fair and adequate compensation for their loss due to the administration of vaccines.

3.4. Recommendation for the Current Indonesian Scheme

Based on review to the Indonesian No-Fault Compensation scheme provided to injury caused by COVID-19, along with theoretic and comparative study to No-Fault Compensation Scheme in several countries, it can be determined the recommendation for the current Indonesian scheme. First of all, it could be stated that it would be ideal if the scheme is governed in a national statute. As already mentioned before, the Indonesian scheme is only regulated under the regulation of the Minister of Health. There is a problem related to the latter because the no-fault compensation scheme for injury caused by COVID-19 vaccination regulation itself contains some vital provision respecting transfer of legal responsibility from vaccine manufacturer to the Indonesian government [43] and requirements to get compensation related to COVID-19 vaccine-caused injury, [43] where both restrict people to get fulfilment of their rights. Conceptually, restrictions on the people's rights must be governed under law that goes through stages of discussion, debate, and approval by the legislative members, as the legislatives themselves are their people's representative in the government [70]. Therefore, it should be mandatory to arrange these provisions under the national statute that passed by the people's representative.

Afterwards, there are some issues related to the element of compensation in Indonesian no-fault compensation scheme for injury related to COVID-19 vaccination. As already stated before, it is known that the form of compensation in the Indonesian scheme consists of disability pension and death pension [43]. However, the form of compensation in the Indonesian scheme regulation is not quite detailed compared to implementation in several countries. In terms of amount of compensation, it was obliged by the Health Minister Regulation Number 10 2021 that the Minister of Health should regulate the amount of those compensation [43], although the mentioned regulation is not yet been set on. From the explanation before and based on comparison to implementation in several countries, it could be concluded that the Indonesian regulations have not yet arranged the elements of compensation comprehensively. Thus, some consideration can be given regarding the ideal elements of compensation that should be included in the regulation draft. Based on comparison, the form of compensation in Indonesian scheme can be detailed and may include: lump-sum of money, monetary compensation calculated based on medical care costs and expenses, monetary compensation calculated based on non-monetary criteria, loss of earnings or earning capacity, emotional distress, permanent impairment, loss of function, disability pension, survival pension, death benefits, reasonable attorneys' fees, or etc. If a final decision has been reached, ideally the claimants should get compensated with either or a combination of those elements [38]. In relation to the amount of compensation, the choice is either to determine it based on the standardized amount or based on case by case [38].

To provide an adequate compensation, the scheme must have a strong source of funding. The existing sources of funding in Indonesia are quite risky, because funding for vaccination-caused injury compensation has so far been borne by the National Budget [43]. To minimize the government's burden, funding on this particular program should also attract sources from the private sector, quite similar to implementation in several countries [38]. If possible, it is necessary to optimize funding from the vaccine manufacturer company, of which these companies have a close relationship with the procurement of vaccines. Moreover, the possibility of obtaining funding from other sources different to the previously mentioned should not be closed either.

Regarding the system of proof, Indonesia has actually implemented a system as commonly applied in other countries, with a characteristic feature of proving causality between the use of the vaccine and the resulting injuries. However, the commonly applied causality system is considered to still make it difficult for claimants to get compensation. This is in line with the findings from a survey toward experts with in-depth knowledge of the no-fault scheme, where it was found that 40% of the respondents argued that the existing programs in several countries still face challenges related to the strict requirements for standards of proof [38]. For this reason, it should be realized that there is an urgency to reform the existing system of proof by simplifying the requirements for provision of compensation in vaccine-related injury cases. The most feasible reform effort is to implement the vaccine injury table system as in the United States. As well known, the vaccine injury table system has made it easier and faster to determine compensation in a case. This is because through this system, compensation can be given if the probability of causality has been satisfied by meeting the requirements written on the vaccine table, without any requirement to conduct any causality study between vaccine-usage and the injury effect [71]. Therefore, determining compensation based on the vaccine injury table system is easier than determining compensation based on the ordinary causality model that is generally applied in various countries. Thus, it may be considered to apply the vaccine injury table system together with the ordinary causality proving system, where the latter is needed if the vaccine table is not sufficient enough in certain cases.

About decision making, it is very important to guarantee that the entire decision-making process is carried out on the basis of transparency. A transparent decision-making process is the key to the success of the no-fault compensation program in several countries, such as the United States and New Zealand. The form of transparency in those two countries is by opening up opportunities for hearings and making the final decision accessible. Both of these things are deemed insecure in the existing regulations in Indonesia, therefore it needs to be improved.

Furthermore, regarding the possibility of opening a litigation process for claimants who want to seek justice, this really depends on the nation's needs. Opening a litigation process for claimants is quite possible to guarantee a proper access to justice with relatively easy compensation for claimant [72]. Meanwhile, the impossibility of the ordinary litigation process in adjudicating vaccination-caused injury cases is also a reasonable choice, namely in order to protect the vaccine manufacturer company from a series of lawsuits that could harm the company financially and the society in general [72]. Hence, the choice between these two matters is closely related to the nation's perspective regarding the vaccination policy to be implemented.

However, it is surely necessary to open the possibility for a claimant to file an appeal against the decision of the National Committee for the Assessment and Prevention of AEFI. Appeal should be able to be filed in line with the philosophy of legal effort in court, where legal effort is a series of attempt made possible for justice seekers to oppose a judge's decision which is considered detrimental and does not quite fulfill the sense of justice of either party, because judges themselves is a human being who can make errors in decision making [73]. This can be matched and applicable in the context of decision making by the National Committee for the Study and Prevention of AEFI, where it is possible if the committee is mistaken in making decision, so that it is necessary to open up efforts to conduct a review against that particular decisions in order to fulfill the sense of justice of claimants.

Consequently, in regard to application for compensation system, it is necessary to integrate the administration-based system with the appeal system through legal effort within court. In the event that the committee has already decide the compensation and the claimant is not satisfied with the decision, it should be made wide open for claimant to request an appeal to that particular decision. Claimant should be given a right to appeal if the committee in their decision rejects the compensation request or gives an inadequate award of costs and expenses to the claimant. This appeal mechanism may take inspiration from the objection scheme in the Law No. 8 of 1999 on Consumer Protection, where in this law objections can be filed in District Court [74]. In this regard, if the court decision with sufficient grounds is deemed not satisfactory to the claimant, then the possibility of filing an appeal to the Supreme Court should be opened [74].

Those previous explanations are things that can be considered to improve the existing no-fault compensation scheme for vaccine injury. Indonesia, like several countries, has not yet established an adequate compensation scheme for claimants. Moreover, there are still many governments that have not yet implemented the no-fault compensation scheme in their countries. This may be driven by the voluntary nature of the vaccination programs in these countries, giving rise to impression that the no-fault compensation scheme for vaccine injury is only a form of government social responsibility that is not binding for the government to implement. This will apply differently if the government vaccination program in that country is mandatorily carried out, as in the implementation in Indonesia. In the event that vaccination is applied mandatory, then the government's responsibility should be even greater. This is in line with the emergence of ethical problems related to claimant's fulfillment of fairness when vaccination is mandatory. The party who are harmed by the exercise of coercive power in the form of mandatory vaccination should be offered a suitable restitution by the government [72]. More specifically, Mello [72] stated that the government should take whatever steps are practically available to minimize vaccine's intrusion on the claimant. Therefore, the government's responsibility to provide the most adequate compensation will escalate along with the implementation of the mandatory vaccination policy in that country. Consequently, the still-problematic Indonesian system should be reformed in the very best way.

The implementation of the no-fault compensation scheme for COVID-19 Vaccine injury by the government as an effort to make the vaccination policy successful and at the same time upholding the rights of affected parties is a strategic step that should be appreciated. The application of a no-fault compensation scheme in Indonesia, which has so far only included the use of the COVID-19 vaccine, can be an initial consideration to review the expansion of the scope of vaccine types in the future. In addition, the implementation of the existing no-fault compensation scheme can also be taken into consideration in order to implement a no-fault compensation scheme for injuries in general, as part of the Universal Healthcare goals that have been successfully implemented by various developed countries and are being pursued in the Indonesian National Health System for the foreseeable future.

4. CONCLUSION

With regards to the high number and increasing trend of COVID-19 cases alongside the emergence of many new variants of COVID-19, the topic of compensation for vaccine injuries becomes more relevant. Based on the findings and discussions above, it can be concluded that there is a need for reform in the laws and regulations of Indonesia regarding the establishment of compensation scheme for the AEFI victims due to the mandatory administration of COVID-19 vaccine. Different from international practice which regulates compensation programs for general vaccine use, the compensation system related to AEFI is only comprehensively established for the COVID-19 vaccine through the Regulation of Minister of Health of the Republic of Indonesia Number 10 of 2021. Several improvements can be made. First, the compensation program should be regulated through national statute to strengthen the legal basis of its establishment. Second, the types of compensation covered can be broadened to ensure adequate compensation for the victims. Third, open up options for several forms of funding to guarantee that the compensation can actually be given to the eligible victims and reduce burden on the national budget. Fourth, establish a comprehensive vaccine injury table similar to the US to make the compensation program more accessible to the victims. Fifth, the regulatory framework should provide a clear legal basis for the victims to appeal the decision regarding the eligibility and the total number of compensations received to ensure fair compensation for the victims. Sixth, the compensation program should effectively integrate between the administration and judicial process to maximize the benefits of the program. Furthermore, these lessons learned can also be implemented for a national compensation program which covers all necessary vaccines administered in Indonesia.

AUTHORS' CONTRIBUTIONS

The corresponding author conceptualized the study. All authors contributed equally to collect data, perform analysis, write, and edit the manuscript. All authors have reviewed the results and approved the final version of the manuscript.

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