

## Review Article



# COVID-19 vaccine injury compensation programs

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## ABSTRACT

Raising awareness about the urgency of using a coronavirus disease 2019 (COVID-19) vaccine that has not undergone sufficient clinical trials and safety that has not been secured due to this, and compensating for the responsibility of the state to inoculate the public with a COVID-19 vaccine that has not sufficiently verified safety After examining the medical limitations in proving the causal relationship between vaccination and the occurrence of harm in. I would like to point out the problem that the causal relationship must be recognized according to policy considerations such as budget or worsening public opinion, as the screening criteria for causality judgment can be decided at the discretion of the Minister of Disease Control. As a way to improve these problems, it is necessary to relax the screening standards so that people think that the government is sufficiently compensating for the damage to the people. We would like to replace the conclusion by suggesting a way for damage investigators to figure out the amount of compensation.

**Keywords:** COVID-19; AstraZeneca; Anaphylaxis; VACC; Vaccine; Pfizer vaccine

## INTRODUCTION

The Ministry of Food and Drug Safety approved the for Astra Vaccine as a medication that can be inoculated to Koreans, saying that it is effective and safe for the elderly over 65 years of age. On the same day, however, the Commissioner of the Korea Disease Control and Prevention Agency (KDCA) said that for the elderly over 65 years of age sufficient data to be considered safe and effective were not secured when data from the United Kingdom (UK) and the United States (US). So decided the vaccination would not be administered until early April.<sup>1</sup>

Coronavirus disease 2019 (COVID-19) is a new infectious disease that the world has never experienced, and clinical trials were not produced through normal procedures, but were rapidly progressing in a short period of time. Therefore, it became an uneasy situation of lack of information about who and how and when adverse reactions caused by vaccination would occur.

Meanwhile, ‘Special Measures Act for the Fighting Coronavirus Infectious Disease-19’ was submitted to the National Assembly, which includes a mandatory provision that all citizens

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should be vaccinated to prevent COVID-19. No one will disagree that vaccination of the entire nation is the best social barrier as the only way to end the corona virus.

However, the social stability of the recovery from compulsory vaccination is not guaranteed to be 100% safe, and if the victims of abnormal reactions lose their lives or suffer serious physical disabilities, the injury exceeds the limit for the society.

In this sense, the Korean government announced that the state will compensate a certain amount of money by applying the current “Infectious Disease Prevention Method” to the injury caused by the vaccination of COVID-19.<sup>2</sup> However, the decision to pay compensation is defined as the case recognized by the KDCA in the prevention of infectious diseases. If the standard for judgment of compensation is not published by law, the ratio of compensation payment by the former KDCA is not high at 57.2%, and if the current medical level is considered for reasons of rejection, the cause of abnormal reaction and injury is unclear, than the vaccine victims should file an administrative suit against the head of the KDCA, and proof of the causal relationship that the vaccination caused physical injury is solely borne by individuals who are victims of the vaccine.<sup>3</sup>

Eventually, the state declared the principle that the injury caused by vaccination will be compensated, but the compensation rate is not large in substance, and the compensation amount is not determined by considering the individual's injury, but a certain amount is paid. It is not a relatively legitimate compensation. As a result, there may be room to provide an excuse for the anti-vaccination movement, which may reduce the vaccination rate and make it impossible to guarantee the effectiveness of the vaccination.<sup>4</sup>

Therefore, review the current clinical results and vaccination cases of the COVID-19 vaccine in the US and the UK, find out how much injury can be caused, and see what steps countries are taking to compensate for the injury. Then, considering the specificity of the COVID-19 vaccination compulsion, it is suggested what is a legitimate compensation plan for vaccinated victims to achieve the purpose of vaccination.

## **THE URGENCY AND SAFETY OF COVID-19 VACCINE USE**

### **Emergency use authorization problem**

#### *Characteristics of the COVID-19 vaccine*

According to a press release from the KDCA (February 17, 2021), 20 million vaccinations were pre-purchased by the Covax Facility Agreement and 33 million Pfizer Vaccines, 20 million Nova Vax, and 20 million AstraZeneca.<sup>5</sup>

In general, scientists say that it takes about 10 years to develop a vaccine, but the above vaccine was developed in about a year, which means that there is absolutely no time to identify side effects. NovaVax vaccine is characterized by a synthetic antigen method applied to a number of vaccines such as influenza and hepatitis B, and the synthetic antigen vaccine combines antigen protein with an immune enhancer and administers it to the human body, which can be stored and distributed under refrigeration (2°C–8°C).

Pfizer vaccines, on the other hand, are a new platform that teaches cells how to generate protein fragments that induce our body's immune response without using live viruses. When

the COVID-19 mRNA vaccine is administered to a muscle, the vaccine instructs the cells to enter the immune cells and produce a harmless piece of protein called the “spike protein.” Spike proteins are the same but harmless proteins on the surface of the virus that cause COVID-19.<sup>6</sup> When the spike protein is made on the cell surface by the mRNA directive, the human immune system begins to make antibodies to remove the spike protein, and when the process is over, the US Food and Drug Administration (FDA) reportedly approved emergency use by meeting strict safety and efficacy standards.<sup>6</sup>

#### *Human challenge research*

Traditionally, the process of obtaining approval for use of new or improved substances as drugs or vaccines generally follows the same basic procedure in the US, Europe, Canada, Japan, and Korea, with only a very small difference, takes about 10 years to get approved and marketed.<sup>7</sup>

The first stage of this process<sup>8</sup> is a preclinical test, which animal experiments are conducted to evaluate the safety and effectiveness of the biological action of the compound against disease. The test takes an average of three and a half years, and the probability of success is one in 1,000. A company that has succeeded in preclinical trials submits an Investigational New Drug Application to the Ministry of Food and Drug Safety and conducts clinical trials in order to test drugs in adults. Tests of active compounds in the human body are conducted through stages 3 and 4 after approval, and phase 1 of clinical trials is conducted on 20 to 100 healthy volunteers for a year of safety profile.

The second phase of clinical trials takes about 2 years for 100 to 300 volunteers and studies safety and effectiveness. Phase 3 clinical trials are conducted on hundreds to thousands of people under certain conditions that the drug is trying to treat.

In phase 3 clinical trials, hundreds or thousands of volunteers are required to apply very thorough and strict criteria to determine whether the benefits of treatment through the tested compound outweigh the risks involved.

After passing all three phases of clinical trials, the company will apply for a New Drug Application (NDA) and, if the NDA is approved, the new drug will be included in the doctor’s prescription.

While following the usual vaccine research procedures above, millions of people could be infected and killed by COVID-19, so in emergency situations, we need to develop it as a shortening process for normal vaccine research. Human Challenge Studies has been proposed to test the efficacy of vaccines by infecting SARS-CoV-2 viruses directly from humans. This has accelerated effective vaccine release by replacing conventional three-phase tests.<sup>9</sup> However, in the UK’s Pfizer Vaccine Clinical 2/3 trial, 4 out of 19,067 participants had peripheral facial paralysis and 2 deaths.<sup>10</sup>

#### **Fair compensation that does not reflect reality**

##### *Unrealization of the compensation amount of the procedure*

According to the final analysis results published by Pfizer on November 18, 2020, 170 of the participants in the clinical trial showed 95% of the effect in preventing the onset seven days after the second vaccination.<sup>11</sup> On the other hand, 162 people in the placebo group were infected, eight people were vaccinated, nine cases of severe infection were in the placebo group and one were vaccinated, and the effect of the vaccine was more than 94% for adults aged 65 or older, regardless of age, gender, race, or ethnicity. Serious safety problems were

not recognized during abnormal reactions, and only 3.8% of abnormal responses were fatigue and 2.0% of headaches.

According to an interim analysis published by Moderna on November 9, 2020, the vaccine during clinical trials showed a 94.5% effect on the prevention of COVID-19 outbreak. Like Pfizer, there were no serious safety problems, and there were abnormal reactions of 9.7% fatigue after the second inoculation, 8.9% muscle pain, 5.2% joint pain, 4.5% headache, and 4.1% pain.

According to the AstraZeneca's interim analysis, published in November 23, 2020, showed an interim analysis of 131 new coronavirus infections among clinical trial participants, 90% of which were administered in half and 62% of those administered twice at one month's intervals. There was no serious abnormal reaction, so there was no safety problem.

#### *Criteria for compensation of single payment*

On February 19, 2021, according to a monthly monitoring report released by the Centers for Disease Control and Prevention, temporary use of the Pfizer-BionTech COVID-19 vaccine (December 11, 2020 approved) and Moderna COVID-19 vaccine (December 18, 2020 approved) in the US has been administered to medical staff and long-term care providers. It was 2.1% or 97.9%, of which 6,844 cases were reported by medical personnel unrelated to long-term care facilities.

Among them, 6,326 cases (92.4%), of which 1,564 cases of headaches (22.4%), 1,149 cases of dizziness (16.8%) and 1,147 cases of fatigue (16.8%) were reported.<sup>12</sup>

A total of 113 people were reported to Vaccine Adverse Event Reporting System, including 78 (65%) and 35 (35%) non-residents of LTCF residents, with 640 cases reported in serious conditions, or 9.2% of cases of anaphylaxis. The age of the dead was 25 to 91, of which 15 (42.9%) were women. It is usually three days from vaccination to death, and it also occurred after 20 days. Sixteen of the dead are believed to be the cause of death, including heart disease, cancer, stroke, pre-clogging, and other weak health, and an additional 19 are under investigation is underway.

The Novavax vaccine and AstraZene vaccine are produced according to the manufacturing method of the viral vaccine, which is the method used to manufacture the existing influenza vaccine. The Pfizer vaccine is said to have been developed in an existing mRNA method.

The Pfizer vaccine, mRNA vaccine, was inoculated to 270,000 people and 6 people were reported to be allergic to symptoms, with a frequency of 22 people per million.

This is slightly higher than the 1.35 cases per million cases of the influenza vaccine in Japan. In addition, comparing the monthly vaccination and severe abnormalities of the COVID-19 vaccine in Germany, Canada, and France, it seems to be significantly higher, with 141 people, 95 people, and 265 people per million, respectively. If so, it is also meaningful to review the frequency of deaths among the cases of deaths caused by side effects of influenza vaccines in Korea and those inoculated in the US for the first month (**Table 1**).

As you can see in the table above, the number of deaths from influenza side effects in Korea is about 10 times as high as the number of deaths from COVID-19 vaccinations in the first

**Table 1.** Comparison of COVID-19 vaccination status by countries

Characteristics	Korea	US	UK	Germany	Canada	France
Publication date	Influenza	2021.1.13	2021.1.31	2021.1.31	2021.2.5	2021.2.4
Inoculator	9,421,806	13,794,904	9,262,367	2,467,918	1,042,171	1,772,000
Report an adverse reaction	-	6,994	32,067	2,846	651	2,180
Severe adverse reactions	-	640	-	349	99	466
Severe adverse reactions (per 1 million people)	-	46	-	141	95	263
Anaphylaxis	-	62	160	70	-	51
Facial paralysis	-	-	114	10	-	12
Dead	36	113	233	113	6	85
Mortality rate (per million people)	3.82	8.19	25.16	45.79	5.76	47.97
Death rate comparison (Korea = 1.00)	1.00	2.14	6.58	11.98	1.51	12.55
The deceased	5	78	-	-	-	-
Causal mortality rate (per million people)	0.53	5.65	-	-	-	-
Causal and mortality comparison (times)	1.00	10.65	-	-	-	-

month in the US. In the case of unidentified deaths, when Korea is based on 1, at a minimum, Canada has far more deaths than Korea's existing influenza vaccinated deaths, ranging from 1.51 times to about 12 times that of France.

Assuming that our population is estimated at 50 million, there are about 26 deaths from influenza vaccinations. The number of deaths from the COVID-19 vaccination accident is likely to be at least twice or ten times higher. The number of deaths from the COVID-19 vaccination accident is expected to occur at least twice to ten times higher. In addition, there are 2,300 to 13,000 people who have severe abnormalities to compensate for the injury.

From the results of such a simple comparison, it seems that the government will have to take measures to compensate the victims.

## PROBLEM OF COMPENSATION FOR COVID-19 VACCINATION INJURY

### Limitations of proof of human relationship

#### *Problems in the operation of the no-fault compensation system*

Being vaccinated is a protection not only for the recipients but also for others, so getting vaccinated will result in protecting others and society. For this reason, if injury occurred due to an accident caused by vaccination on the subject, the society that benefited should compensate the victim for the injury.

However, if injuries are generally recognized only when the person who has suffered the other person's intention or negligence proves them, victims have to prove manufacturer defects or medical staff's negligence, which is almost impossible. Therefore, the government operates a fault-free compensation system on a policy level that increases the vaccination rate administratively rather than civil injuries.<sup>13</sup>

The World Health Organization Vaccine Injury Compensation Program is a fruitless system established to compensate individuals who have experienced vaccine-related injuries due to inherent risks of vaccination. Such a program does not require the party or its legal representative to prove any negligence or negligence of the vaccine provider, medical system or manufacturer prior to compensation.

However, unlike the purpose of this no-fault compensation system, the compensation process is not easy. In Korea, 210 cases were reported in 2010, when the number of applications for compensation for vaccination accidents was the highest, and the last 10 years, there have been 70 to 120 cases. However, Article 21 of the Enforcement Decree of the Prevention of Infectious Diseases Act<sup>14</sup> stipulates that the current injury investigation team of the KDCA consists of less than 10 people. It would not be enough to investigate at least 10 times the number of applications for compensation for furthermore, it seems difficult to trust their report on the runaway application when the causal relationship to the abnormal response of the new COVID-19 vaccine has not been verified.

The current Infectious Disease Prevention and Control Act Article 71 (2) stipulates that “injury caused by the relevant vaccination’ can be compensated regardless of whether the vaccination drug is abnormal or not, or whether he vaccination agent, preventive or treatment drug administrator, etc. are guilty. Article 71 (3) of the Act requires the Minister of Health and Welfare to decide whether it is “injury caused by the relevant vaccination” by listening to the opinions of the Committee. Thus, based on the reports of the victims’ investigation team, the committee specializing in injury compensation under Article 31 (3) of the Enforcement Decree of the Prevention of Infectious Diseases will present its opinion on compensation. This expert committee is not a specialized committee for COVID-19, so their opinions may not seem reasonable and reasonable. Therefore, it seems necessary to organize a specialized professional committee.

Meanwhile, the KDCA recognized and compensated only 675 cases, or 57.2% of the 1,180 applications for compensation for vaccination injury (Table 2).<sup>15</sup>

However, this is significantly lower than the 80% compensation rate in the US. By 2018, only about 16.25% of the cases that applied for compensation for vaccination injury in the US were compensated by HHS’s decision to pay, and 4.61% were recognized by the court’s ruling. What’s unusual is that about 50% of cases were agreed in the mediation process before the court ruled. Meanwhile, the refusal to pay compensation for applications will be about 20%.<sup>16</sup>

In the case of Korea, it is difficult to compensate because it is not easy to prove causality. This is one of the reasons why the vaccination rate may be lowered and the prevention effect may be reduced.

#### *Discretion of the screening criteria*

Considering the cases paid in preparation for the compensation application, the opinions of the injury investigation team and the vaccination injury compensation committee do not seem to be easy to acknowledge the causal relationship.<sup>17</sup>

**Table 2.** Decisions on compensation and payment results for compensation applications from January 1, 2006 to December 31, 2019 for vaccination in the United States

Characteristics	Value
Inoculator	3,761,744,351
Claim for compensation	7,633 (0.0002)
Payment decision	1,240 (16.25)
Court decision	352 (4.61)
Mediation agreement	3,757 (49.22)
Total compensation	5,351 (70.10)
Refusal of compensation	2,282 (20.90)

Values are presented as number (%).

The COVID-19 vaccination accident also reported 8 deaths as of March 8, 2021, but the injury investigation team's investigation announced that there was no causal relationship.

The court ruled that the KDCA's decision was discretionary. Accordingly, if the KDCA refuses to acknowledge the relationship, the court will only examine the KDCA chief's abuse of discretion, even if the victim files a lawsuit. The way for the victim to be compensated for the injury by the lawsuit has become not easy.

The criteria for determining causality currently operated by the government shall be in accordance with the five-stage screening criteria prepared by the Committee for Compensation for Vaccination.

The 5 steps are paid if it falls under 1), 2) and 3). The 5 steps are following: 1) Relevance The obvious case (Definitely related, definite); 2) If there is a possibility of relevance (probably related, possible); 3) If there is a possibility of relevance (possibly related, possible); 4) Relevant to be acknowledged difficult cases (probable not related, unlike); 5) Clear the relevance is not the case (definitely not related).

The problem is that even if this screening standard is followed, the boundary between 3) and 4) is ambiguous, so it is bound to comply with the payment decision of the Vaccination injury Compensation Committee. Anyone who disagrees with this must file an administrative lawsuit against the Director of the KDCA (Table 3).

However, as the injury compensation committee decided that there was no relationship. If the head of the KDCA refuses to make a decision to pay compensation, the victim should argue in a lawsuit whether there is a causal relationship. The court should assume that the causal relationship required as a premise to receive compensation for vaccination accidents should not be clearly proved medically and scientifically, but that there is evidence if it is assumed that there is a causal relationship to consider indirect facts. In other words, in order to estimate causality, there is a time-space close relationship between vaccination and disability, the disability of the victim is not impossible from the vaccination, and evidence that the disorder is unknown or not caused by the vaccination.<sup>18</sup>

For example, in the case of Gilbert syndrome, an adverse reaction due to competition between vaccination, influenza vaccine and gastrointestinal tract infection, which is a leading cause, the KDCA and the court of first instance can regard the plaintiff's injury as a symptom caused by gastrointestinal infection. Vaccination compensation was not paid because the possibility of the vaccine was unclear and the relevance to vaccination was difficult to recognize.

**Table 3.** Criteria for causal relationship review by the Vaccination injury Compensation Committee

1. Relevance The obvious case (definitely related, definite)	If there is clear evidence of vaccination, there is proximity to the chronological sequence in which abnormal reactions have emerged, and, for any other reason, causality by vaccination is recognized, and it is recognized as a known vaccine response.
2. If there is a possibility of relevance (probably related, probable)	If there is clear evidence of vaccination, there is proximity to the chronological sequence in which abnormal reactions have emerged, and the causality of the vaccine is recognized more than for any other reason.
3. If there is a possibility of relevance (possibly related, possible)	If there is clear evidence of vaccination and there is proximity to the chronological order in which abnormal reactions have emerged, but the occurrence of results for other reasons is also recognized as the same level of probability as vaccination.
4. Relevant to be acknowledged difficult cases (probably not related, unlike)	In the case that there is clear evidence of vaccination, and the time sequence in which the abnormal reaction occurred is less close, and the possibility of the vaccine is unclear.
5. Clear the relevance is not the case (definitely not related)	If there is no clear evidence of vaccination, if there is no close proximity of the chronological order in which the adverse reaction has emerged, or if any other obvious cause has been identified.

However, unlike the judgment of the Second Trial High Court, there is a temporal closeness between vaccination in this case and the onset of symptoms in this case, and it is not impossible by medical theory or empirical rule to infer that the symptoms in this case occurred from vaccination in this case. The Supreme Court acknowledged the causal relationship between the vaccination of the case and the symptoms of the case, as there can be evidence that the symptoms are unknown or not caused by other causes than vaccination. In other words, it seems that the Vaccination Injury Compensation Committee should ease the recognition of the causal relationship between vaccination and injury. In other words, if the occurrence of injury caused by underlying diseases other than vaccination is not clearly proven, it should be recognized as injury caused by vaccination.

Such a standard of judgment is the same in Japan as in the case of the Korean court. In the Supreme Court's ruling (H18-6-16, etc.), between vaccination, symptoms, and outbreaks 1) Medical rationality; 2) Time closeness, if there are no other causes, causal relationships shall be recognized. In addition, the purpose of Japan's fault-free compensation system in Japan's Supreme Court's ruling S50, October 24, requires proof of causality, and the side effects of vaccination vary depending on the type of vaccination, and it is often virtually impossible to require complete medical proof of the causal relationship with the inoculation. So the judgment of causality is that it is sufficient to prove the probability of predicting the outcome of a particular fact, and the extent of the proof is enough for ordinary people to not doubt it. In other words, the principle of compensation is established that the burden of proof is on the victim, but if it is suspicious by lowering the level of proof, it will be saved.

Therefore, it is necessary to ease the review criteria of the KDCA only for compensation for injury to the COVID-19 vaccination. We should seek ways to gain public trust in the direction of focusing on people's lives rather than making policy judgments such as the budget.

### Compensation for injury that does not reflect reality

#### *Realization of compensation items and amounts*

In order to strengthen the state's responsibility for adverse reactions to the COVID-19 vaccination, the KDCA has expanded the application criteria for the national compensation system for vaccination only for the 2021 COVID-19 vaccination from 300,000 won or more to the full amount. It has been announced that it plans to expand and operate the scope of injury compensation under the national compensation system for vaccination injury.

Based on Article 71 of the Act on the Prevention and Management of Infectious Diseases, Korea currently operates a national compensation system for vaccination victims of abnormal reactions inevitably occurring after vaccination. The injury compensation covers the following sources of money sources as shown in the following table (Table 4).

**Table 4.** The standard for vaccination damage compensation in Korea

Division	Temporary compensation (KRW)	Criteria for calculating payment	Application deadline
Temporary death compensation (KRW)	437,395,200	Minimum monthly wage <sup>a</sup> × 240 mon	Within 5 yrs from the date of death
Temporary disability compensation (KRW; severe <sup>b</sup> )	437,395,200	100% of death compensation	Within 5 yrs from the date of diagnosis of disability
Temporary disability compensation (KRW; mild <sup>b</sup> )	240,567,360	55% of death compensation	Within 5 yrs from the date of diagnosis of disability
Flat-rate nursing expenses	50,000 per day	-	Within 5 yrs from the date of vaccination injury
Funeral	300,000	-	Within 5 yrs from the date of death

<sup>a</sup>Based on the Minimum Wage Act announced by the Ministry of Employment and Labor, the monthly minimum wage in 2021 is calculated as KRW 1,822,480.

<sup>b</sup>In the case of receiving temporary compensation for disability, no further medical expenses are paid.

**Table 5.** The standard for vaccination damage compensation in Japan

Division	COVID-19 payment (yen)
Medical expenses	Self-pay amount excluding health insurance
Medical allowance	> 3 days out of hospital (per month) 35,000 ≤ 3 days out of hospital (per month) 37,000 > 8 days of hospitalization (per month) 35,000 Hospitalization for more than 8 days (per month) 37,000 Same month admission (per month) 37,000
Disabled child support pension	Level 1 (annual) 1,581,600 Level 2 (annual) 1,266,000
Disability pension	Level 1 (annual) 5,056,800 Level 2 (annual) 4,045,200 Level 3 (annual) 3,034,800
Temporary compensation for death	44,200,000
Funeral	209,000
Nursing care fee	Level 1 (annual) 844,300 Level 2 (annual) 562,900

In the case of Japan, similar to Korea, it is said that it will pay 44.2 million yen (₩460,029,180) lump-sum for death (Table 5).

In the US, medical expenses up to \$50,000 per year are provided, and death compensation is \$370,376 (₩418,154,504).

Meanwhile, the UK is not operating as a compensation system, but is currently paying £120,000 (₩1,876,172,400) as a one-time tax-free lump sum. In the case of the COVID-19 vaccine, the amount of compensation for other vaccinations has been reduced, and in the case of Australia, vaccination is strongly reduced. It is supported, but it is not obligatory for all citizens, so the national compensation system is not introduced.

If so, it seems necessary to specify items by reflecting the reality for injuries that occur other than death accidents.

*A lump sum payment method that does not take into account personal circumstances*  
National Vaccine Injury Compensation announced by the KDCA is a system that provides financial compensation for any special sacrifice to personal property due to public power lawfully exercised in accordance with public needs. The principle of compensation for special sacrifices is applied to the purpose of allowing the members of the community to bear the special sacrifices of a specific individual arising from them on an equal basis. Therefore, compensation for administrative losses can be paid within the scope of the budget without a separate legal basis according to the legitimate compensation of Article 23, Paragraph 3 of the Constitution, and it is said that the target and scale are different from financial support determined by policy judgment.

In accordance with this policy judgment, the government seems to be setting the standard for lump sum compensation. Regardless of the age of the victim of the accident, the limitation of the lump sum compensation standard is that it cannot be said that this is not fair compensation if the compensation is paid in a lump sum equivalent to 240 months at the time of death based on the minimum wage.

For the convenience of administration, lump-sum compensation may be convenient, but in the current system, a detailed investigation is conducted through a injury investigator for

each individual injury case, and the compensation is determined by deliberation for each case. Can be calculated. If so, it seems that the system should be improved so that substantial compensation, not administrative convenience, can be paid.

It would be nice if the people took the risk of the COVID-19 vaccine and actively responded to the national vaccination policy, but in a situation where there is opposition such as resistance movements, a carrot policy is also needed.

## IMPROVEMENT MEASURES FOR COMPENSATION FOR COVID-19 VACCINATION ACCIDENTS

### Fast and fair injury compensation

*Unconditional payment in case of death or accident within 24 hours after vaccination*

In accordance with the current Infectious Disease Prevention Act Article, the decision to pay compensation for injuries has not been determined by the Commissioner of the KDCA.

Since adverse reactions that may occur due to the new vaccine cannot be referenced in existing cases, compensation will be difficult according to the existing screening criteria. Therefore, if a person who has been vaccinated dies after developing anaphylaxis within 24 hours, it is better for the state to compensate unconditionally. In the case of other vaccinations, the occurrence of anaphylaxis is required for 24 hours after vaccination, and anaphylaxis is said to be seen before death due to a severe allergic reaction. Therefore, it seems that there was a symptom of anaphylaxis, and it seems reasonable to pay unconditionally if there is a doctor's opinion.

On the other hand, even in the case of disability sequelae, if an adverse reaction has occurred, it seems reasonable that the state will preferentially compensate.

### *Operation of the Dispute Mediation Committee*

For victims who are denied compensation because the causal relationship recognized by the Commissioner of the KDCA is not proven, it is necessary to enact a law so that the Dispute Mediation Committee can handle it rather than the administrative litigation procedure. If vaccination has been implemented by the state, it is the responsibility of the state to prove that the cause of the injury is not vaccination, so a prompt settlement agreement is needed rather than a long-term lawsuit.

In the case of the US, this mediation agreement system was activated, and about 50% of the injury compensation cases were made through mediation agreements.

### The need for legislation to respond to the COVID-19 crisis

*Disclaimer of vaccine manufacturers and medical staff*

COVID-19 vaccine developers have demanded that the Korean government as well as the countries that sign supply contracts include a disclaimer clause. Accordingly, the US granted immunity to COVID-19 vaccines approved for use by the FDA in accordance with the Public Readiness and Emergency Preparedness Act.

Japan, UK and Canada also recognized the manufacturer's immunity in case of side effects of the COVID-19 vaccine.

It is known that Korea also entered a disclaimer when signing contracts with AstraZeneca, Pfizer, and Moderna.

On the other hand, in the partial amendment of the infectious disease prevention method submitted to the National Assembly, a law proposal was proposed to establish a legal basis for contracts including manufacturer's immunity, and the KDCA and the Ministry of Strategy and Finance have announced their intention to accept it, so it is expected that the law will be amended.

However, since the details of the contract between the government and the vaccine development company are non-public, the disclaimer is not disclosed, so the exact details are not known, but the inoculated person cannot file a lawsuit for injuries against the manufacturer according to the Product Liability Act or file a lawsuit. Even so, it seems difficult to receive compensation for injuries based on the disclaimer.

The Korean Medical Association is held on January 26, 2021. Despite the controversy and concerns about the safety and effectiveness in the press release, the Korean Medical Association supports the vaccination, assuming that the vaccine is a reliable means for ending COVID-19, but there may be side effects or unforeseen accidents due to vaccination, so it is related to vaccination. Since there is much room for accidents and medical disputes, the government needs to provide flexible and comprehensive compensation, and medical staff and medical institutions are demanded to protect them with immunity.

#### *National liability compensation*

Such a series of indemnification claims states that manufacturers or medical staff will not be held responsible for side effects caused by urgent vaccine development. As a country that must block the COVID-19 infection and return the people to their daily lives, the spread of infectious diseases is not the risk of such injury compensation. With the policy judgment that prevention is more for the public good, some countries, including Korea, US, Japan, and Canada, introduced a system in which the state compensates for the injuries of vaccination at a lump sum.

In the case of the US, compensation is provided according to the National Vaccine Injury Compensation Program, February 20, 2021 announced.

In accordance with this trend, it is necessary to stipulate the state's no-fault liability compensation in law so that the state compensates, but the compensation is justified. To this end, it is necessary to declare that all injuries occurred within 24 hours after vaccination are compensated by the national government so as not to require proof of causal relationship.

## **CONCLUSION**

### **Proposal of Special Measures Act on Relief, etc. for Health injury due to COVID-19 Vaccination**

#### *Chapter 1: General provisions*

##### Article 1 (Purpose)

This Act takes special measures for remedy for health injury caused by the COVID-19 vaccination conducted by the Commissioner of the KDCA, and compensates for injuries related to health injury caused by the use of the COVID-19 vaccine, etc. The purpose of this

is to promote the smooth implementation of the COVID-19 vaccination by compensating the government for losses incurred by the COVID-19 vaccine manufacturer and seller, etc.

#### Article 2 (Definition)

- ① In this Act, the term “COVID-19” refers to what has been declared as a first-class infectious disease by the Commissioner of the KDCA in accordance with Article 2, No. 2 of the Infectious Disease Prevention and Management Act.
- ② In this law, “COVID vaccine” refers to a vaccine against COVID-19 infectious diseases.
- ③ In this law, “COVID-19 vaccination” refers to injecting or inoculating the human body with the COVID-19 vaccine in order to obtain the effect of immunity against COVID-19.
- ④ A person due to the act of implementing vaccination by a health care professional (including those who are permitted to do so pursuant to the proviso to Article 27 (1) of the Medical Act or the proviso to Article 23 (1) of the Pharmaceutical Affairs Act) referred to as “COVID-19 vaccination accident.” It refers to a case in which injury has occurred to the life or body of a person.
- ⑤ “Vaccination injury compensation dispute” refers to a dispute caused by a vaccination accident.
- ④ In this Act, “special case approval COVID-19 vaccine manufacturer and seller” refers to a person who has obtained approval for the manufacture and sale of pharmaceuticals under Article Paragraph Article of the Pharmaceutical Affairs Act, and who has obtained approval of Article 2 of the same Act for the manufacture and sale of the COVID-19 vaccine (to obtain such approval. Including the narrator).

#### *Chapter 2: Compensation for those who died from the COVID-19 vaccination*

In the event of the death of a victim within 24 hours after the COVID-19 vaccination, the state pays 200 million won.

#### Article 3 (Payment of compensation for relief of health injury caused by the COVID-19 vaccination)

- ① If a person who received the COVID-19 vaccination conducted by the Commissioner of the KDCA has acquired a disease and has become in a state of disability. If there is proximity and it is not clear that the result of the injury is due to another cause, payment shall be made in accordance with Articles 4 and 5.
- ② In recognition of Paragraph 1, the Commissioner of the KDCA may form a Specialized Committee for Compensation for COVID-19 Vaccination to hear opinions.

#### Article 4 (Scope of compensation money)

The compensation money pursuant to Article 3, Paragraph 1 shall be as prescribed in each of the following subparagraphs, and shall be paid to persons designated in each subparagraph.

1. Medical expenses and medical allowances: Those who have received treatment for diseases caused by corona vaccine vaccination.
2. Parenting pension for children with disabilities: Those who raise a child under the age of 18 who suffered a disability due to the corona vaccine vaccination.
3. Disability pension: persons 18 years of age or older who suffered disability due to corona vaccine vaccination.
4. Survivor’s pension: Survivors of those who died after receiving the COVID-19 vaccination.
5. Funeral expenses: Those who perform the funeral of a person who died after receiving the COVID-19 vaccination.

Article 5 (Compensation amount and payment procedure)

- ① The decision on the payment of compensation is made by the Commissioner of the KDCA with the opinion of the Vaccination Injury Compensation Committee.
- ② If you disagree with the decision to pay compensation, you can apply for mediation to the Dispute Mediation Committee.

Article 6 (Adjustment with compensation for injuries)

- ① The Commissioner of the KDCA may not pay the compensation within the limit of the value if a person who is required to receive compensation is compensated for injuries for the same reason.
- ② If the person who received the compensation is compensated for the same reason, the Commissioner of the KDCA may order an amount equivalent to the amount of compensation received within the limit of the value.

Article 7 (Collection of unfair benefits)

- ① If there is a person who has received compensation through false or other illegal means, the Commissioner of the KDCA may collect all or part of the amount equivalent to the amount of benefits received from the person according to the example of national tax collection.
- ② The priority of the right to acquire the collection money pursuant to Paragraph 1 shall be after national and local taxes.

Article 8 (Protection of right to receive benefits)

The right to receive compensation is non-transferable and cannot be provided as collateral or foreclosure.

Article 9 (Prohibition of public affairs)

Taxes and other public affairs cannot be exceeded based on the amount paid as compensation.

Article 10 (Promotion of health and welfare projects)

The State shall provide consultations with the family regarding medical care, nursing care, etc. of a person who has received home care as a person concerned with the payment of compensations listed in Article 4 (1) through (3). Promote responsive projects and other health and welfare programs.

*Chapter 3: Approval of special cases compensation contract with COVID-19 vaccine manufacturing and sales business*

Article 11 (Conclusion of compensation contract)

It is possible to conclude a contract that promises to compensate the government for losses incurred to the other party and related parties by responding to claims made for the corona vaccine in relation to compensation for injuries related to health injury and other related purchase contracts.

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