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RESEARCH ARTICLE

THE URGENCY OF LEGAL PROTECTION FOR COVID-19 VACCINE QUALITY ASSURANCE DURING THE PANDEMIC IN INDONESIA

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ABSTRACT

Abstract: The implementation of vaccination has started in the first stage and will continue until the fourth stage, but in reality there are still many pros and cons that occur in the community. For people who are pro against the implementation of the COVID-19 vaccination, there are some people who accept that this vaccination is carried out as soon as possible in Indonesia because it is considered a solution in order to resolve the COVID-19 pandemic in Indonesia. As for the people who are against it, where some of these people refuse to carry out vaccinations because they think the vaccine is not necessarily safe for their bodies, and are worried about the side effects that arise after the implementation of the COVID-19 vaccination. Then there are also many questions that arise among the public regarding legal protection for them after getting the COVID-19 vaccine. So from research on legal protection if side effects occur after the implementation of COVID-19 vaccination for people in Indonesia, it is quite important, considering that the legal basis that guides the implementation of this vaccination is still new and is still being debated among the public. Where there are many regulations governing the implementation of this COVID-19 vaccination, even in every region in Indonesia, each region has the authority of regional government regulations.

Keywords: *Assurance; Vaccine Quality; Healthcare Law; Pandemic.*

INTRODUCTION

The spread of the COVID-19 pandemic to all corners of the world is undeniable. Due to its rapid spread, the Government is also seeking various ways to break the chain

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of the spread of COVID-19 infection.[1] In this case, health is vital, and the guarantee for this is even more enhanced. This cannot be separated from the fact that in the midst of the COVID-19 Pandemic, Health is one aspect of the welfare of vulnerable communities, as contained in Article 28H paragraph (1) of the 1945 Constitution of the Republic of Indonesia, which mandates that everyone has the right to live in prosperity, physically and mentally, to live, to have a good and healthy environment, and to have the right to health services. To improve and provide certainty for health insurance amid the COVID-19 Pandemic, the Government has made efforts by issuing various policies, including the socialization of the 5M movement (Wearing Masks, Keeping Distance, Washing Hands, Avoiding Crowds, and Reducing Mobility)[2], Social Restrictions on a Scale Large (PSBB), to the Enforcement of Restrictions on Micro-Based Community Activities (PPKM Mikro).

However, in reality, the implementation of these various policies is not enough in order to break the chain of the spread of COVID-19. Therefore, in order to accelerate the response to the COVID-19 pandemic, the Government uses a vaccine delivery strategy intending to increase the immune system of every citizen. The provision of this vaccine is one of the country's efforts to protect and fulfil the right to health insurance owned by every citizen during the COVID-19 pandemic. To support the implementation of COVID-19 vaccination, the Government issued Presidential Regulation Number 99 of 2020 concerning Vaccine Procurement and Vaccination Implementation in the Context of Combating the Corona Virus Disease 2019 (COVID-19) Pandemic, which is regulated in more detail by the Minister of Health Regulation Number 84 of 2020 concerning Implementation of Vaccination in the Context of the Corona Virus Disease 2019 (COVID-19) Pandemic. The two regulations contain provisions that regulate the standardization of planning, procurement, targets, implementation, to fines for people who refuse to be vaccinated. Whereas in a pandemic condition like this, as there is a principle in law, namely *salus populi suprema lex*, which prioritizing the safety of the people is the highest law for a country, the state is also obliged to fulfil the right to health for every citizen.[3]

The existence of vaccine does not mean COVID-19 would easily vanish. The transmission of this outbreak is still possible, however with the vaccine it can be slowed and eventually put an end to the pandemic. To achieve herd immunity against COVID-19, it is necessary to have around 60–80% of the entire population immune to this disease. This means that a minimum of 165 million people in Indonesia must get the COVID-19 vaccination. This is one of the reasons why the achievement of vaccination targets in Indonesia takes a long time. Therefore, continue to comply with health protocols by implementing physical distancing, wearing masks when outside the house, diligently washing hands, and always maintaining body resistance. Types of Covid-19

[1] Atmaezar H. Simanjutak and Rudy G. Erwinsyah, 'Kesejahteraan Petani Dan Ketahanan Pangan Pada Masa Pandemi COVID-19: Telaah Kritis Terhadap Rencana Megaproyek Lumbung Pangan Nasional Indonesia', *Jurnal Sosio Informa*, 6.2 (2020), 185.

[2] Thafsin Alfarizi, *5M Dimasa Pandemi Covid-19 Di Indonesia* (Jakarta: Pusat Analisis Determinan Kesehatan Kementerian Kesehatan Republik Indonesia, 2021).

[3] Azis Andriansyah, 'Penerapan Asas Salus Populi Suprema Lex Pada Pelaksanaan Demokrasi Di Tengah Wabah Covid-19', *Jurnal Kajian Lembaga Ketahanan Nasional Republik Indonesia*, 8.2020 (2AD), 307.

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Vaccines Used in Indonesia 1. Sinovac Vaccine 2. Sinovac Vaccine made by PT Bio Farma 3. Novavax Vaccine 4. Oxford-AstraZeneca Vaccine 5. Pfizer-BioNTech Vaccine 6. Moderna Vaccine 7. Sinopharm Vaccine.

Therefore, as the right to health is fundamentally owned by every individual, the quality of health services has been guaranteed by the law. This, of course, also applies during the COVID-19 Pandemic, whose emergency status is declared by the issuance of Government Regulation in place of Law Number 1 of 2020 concerning State Financial Policy and Financial System Stability for Handling the 2019 Corona Virus Disease (COVID-19) Pandemic and/or in the Context of Facing Threats That Endanger the National Economy and/or Financial System Stability and Government Regulation Number 21 of 2020 concerning Large-Scale Social Restrictions in the Context of Accelerating Handling of Corona Virus Disease 2019 (COVID-19).

In this condition, health is the basis for recognizing the degree of humanity, as the definition of health itself is stated in Article 1 point 1 of Law Number 36 of 2009 concerning Health. Enable everyone to live socially and economically productive lives. Referring to this definition shows that without health, a person becomes conditionally unequal. Without health, a person will not be able to obtain other rights, thus causing health to be one measure of human status in addition to education and the economy, which is used to determine the quality of human resources (Human Development Index)[4]. Furthermore, the provisions related to vaccine quality assurance are only listed in Chapter III, Implementation of Immunization Program Attachment to the Regulation of the Minister of Health Number 12 of 2017 concerning Implementation of Immunization, and the guarantee has not been regulated in any statutory provisions.

It is understandable that the government has very urgent and even emergency interests regarding ending the pandemic, but the government can not cast aside its citizen rights. There are controversies regarding vaccination of COVID-19. Indonesian Survey Institute (LSI) reported through their survey. for the period 20-25 June 2021, that one of the reasons Indonesia citizen reject the vaccination program is fear of side effects of the Covid-19/unsafe vaccine. Thus, they claimed that someone has right to autonomy and decission making, means that the patients have the right to make decission concerning their own healthcare. It was also stated in Article 5 paragraph (3) Law Number 36 of 2009 concerning Health that "*Everyone has the right to independently and responsibly determine the health services needed for themselves*".

It means that as long as there is no assurance that COVID-19 vaccine is safe, this problem will be repeated in the future, especially if there will be another pandemic. It is reasonable for citizen to fear and doubt the quality of the vaccine, moreover there are many hoax and overlapping informations about the vaccines.

On the other side regarding COVID-19 Vaccine, the Goverment also need to ensure that the research and the experiements obey the Nuremberg Code, a set of ten ethical principles for human experimentation, or what would be called as 'good clinical research practice' today.[5] It also includes the right to benefit from scientific progress and right to information for the volunteers.

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[4] Dedi Afandi, 'Hak Atas Kesehatan Dalam Perspektif HAM', *Jurnal Ilmu Kedokteran*, 2.1 (2008), 2.

[5] Jarmusik N, 'The Nuremberg Code', *AVANIA*, 1947 <www.imarcresearch.com/blog/bid/359393/Nuremberg-Code-1947> [accessed 5 November 2022].

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However as what have stated before, COVID-19 pandemic is an urgent situation that pressing the Goverment to put an end to the pandemic as soon as possible through, one of the solution, vaccination program. Nonetheless, the Goverment shall obey the law and human rights. Therefore, this study will discuss about: (1) The urgency of legal protection to guarantee covid-19 vaccine quality; and (2) The state's obligation to guarantee the quality of vaccines during a pandemic.

METHOD

This study is a socio-legal research where the Law, Legal Prescription, and Legal Definition are not assumpted or accepted as it is however problematically analysed and considered important to study further regarding its origin, articulation, and purposes.[6] The approach of study uses conceptual legal aprroach which the authors study the real concept in society. Another approach uses in this study is legal-sociology where the law in this case isn't designed as rules but as regularities of daily life or nature experiences. The data types used in this study is Primary Legal Instruments; International Legal Instruments; and citizen behaviour studies through previous studies.

RESULTS & DISCUSSION

I. The Urgency of Legal Protection to Guarantee COVID-19 Vaccine Quality

According to the Convention and International Law, healthcare is a fundamental right owned by every individual without exception. This is as stated in the preamble of the Constitution of the *World Health Organization* (WHO), "*The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic, or social condition*." The highest standard of healthcare can only be achieved if everyone can access their fundamental right to healthcare without discrimination against their background. Health itself cannot only be defined as free from disease but also as a state in which both physically, mentally, and socially a person is in good condition; as the WHO Constitution reads, "*Health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity*."

The COVID-19 pandemic that has hit the world since the end of 2019 has made almost everyone unable to access "health", both physically and mentally, and their social lives are sick and falling apart due to the pandemic. The SARS-CoV-2 virus spreads so quickly and infects many people regardless of state border or economic, cultural, and social background. Humanity's life was "*shut down*" when quarantines began to be imposed in many countries. Physical gatherings were restricted, economical movements were

[6] Manish Singh, 'Module IV: Socio-Legal Research' <http://www.bl.uk/reshelp/findhelpsubject/busmanlaw/legalstudies/soclegal/sociolegal.html>.

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slowed down, and chaos began to happen anywhere. According to a survey conducted by The Commonwealth Fund in 2020, as many as 33% of the population of the United States experienced mental health disorders due to the COVID-19 pandemic. Besides the United States, mental health disorder also affects 26% of the Canadian and British population.[7]

The first Covid-19 case in Indonesia was first recorded in March 2020 in Depok and then spread rapidly throughout the country. Two years of the pandemic have passed, and Indonesia has also experienced two high waves of COVID-19 cases. In order to reduce the growth rate of daily cases of COVID-19, the Indonesian Government carried out a package of policies to prevent and overcome the COVID-19 pandemic, including COVID-19 vaccination. COVID-19 vaccination has the primary purpose of reducing the transmission of COVID-19,[8] decreasing the infection and death rates due to COVID-19, gaining *herd immunity*, and protecting the public from the effects of the pandemic so that they remain socially and economically productive.

In Indonesia, the implementation of COVID-19 vaccination has been mandated and accommodated through various laws and regulations, such as Presidential Regulation Number 50 of 2021 concerning the Second Amendment to Presidential Regulation No.99 of 2020 concerning Vaccine Procurement and Vaccination Implementation in the Context of Overcoming the Covid-19 Pandemic, Minister of Health Regulation Number 19 of 2021 concerning the second amendment to the Regulation of the Minister of Health number 10 of 2021 concerning the Implementation of Vaccination in the Context of Overcoming the Covid-19 Pandemic, Regulation of the Minister of Health Number 19 of 2021 concerning the Second Amendment to the Regulation of the Minister of Health number 10 of 2021 concerning the Implementation of Vaccination to Overcome the Covid-19 Pandemic, Circular Letter Number HK.02.02/I/1727/2021 concerning Vaccination Phase 3 for vulnerable citizen, common citizen, and children aged 12-17 years old.

The implementation of COVID-19 vaccination nationwide as of July 15, 2022 has reached 201.74 million doses (96.82%) for first dose vaccination and 169.28 million doses (81.26%) for second (second) dose. As for the administration of the third dose of the COVID-19 vaccine, it has reached 52.747 million doses (25.25%).[9]

Unfortunately, there are some Indonesians who refuse the third dose vaccination program or what is more commonly known as the *booster* vaccine. According to the results of a survey conducted by Indonesian Political Indicators in January 2021, based on a sample of 1220 respondents, 54.8% of respondents disagreed with the plan to do booster vaccines. Meanwhile, until July 11, 2022, judging from the ratio of COVID-19 *booster* dose vaccinations in Southeast Asia, Indonesia is ranked 7th out of a total of 10 countries. There are several reasons for the low rate of COVID-19 *booster* vaccinations, such as it is

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[7] Yosepha Pusparisa, 'Pandemi Covid-19 Sebabkan Gangguan Kesehatan Mental Di Sejumlah Negara', *Databoks.Katadata.Com*, 2020, p. 1.

[8] Muh. Ali Masnun, Eny Sulistyowati, and Irfa Ronaboyd, 'Pelindungan Hukum Atas Vaksin Covid-19 Dan Tanggung Jawab Negara Pemenuhan Vaksin Dalam Mewujudukan Negara Kesejahteraan', *DiH: Jurnal Ilmu Hukum*, 17.1 (2021), 35–47 <https://doi.org/10.30996/dih.v17i1.4325>.

[9] The Ministry Of Heatlh of Indonesia, 'COVID-19 Vaccination in Indonesia', *The Ministry Og Health of Indonesia*, 2022, p. 1 <https://vaksin.kemkes.go.id/#/vaccines> [accessed 15 July 2022].

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not mandatory and the high level of public rejection.[10] Whereas as of July 15, 2022, Indonesia's weekly COVID-19 death rate is ranked 6th in Asia with 51 deaths in the last 7 (seven) days. On the other hand, daily cases of COVID-19 have also increased in recent weeks.[11] According to the COVID-19 Handling Task Force, as of July 15, 2022, there were 24,973 active cases. Among the causes of the increase in infection cases in Indonesia is the discovery of two new Omicron virus subvariants, namely BA.4 and BA.5.

Preventing the rise in active cases of COVID-19 infection cannot only stop with the implementation of Health Protocols and continuously impose the Implementation of Community Activity Restrictions (PPKM), considering that the international world currently has moved in the conditions of a new order. The implementation of vaccination must be increasingly carried out to accelerate and strengthen the formation of herd immunity among Indonesian citizens. Unfortunately, the biggest reason for the rejection of vaccines by the public is public trust. The public has lost confidence in the government and health care institutions regarding the safety and quality of the vaccines.

Meanwhile, data from the Indonesian Survey Institute (LSI) for the period 20-25 June 2021 said that around 82.6% of Indonesians had not been vaccinated. Among those who had not received the vaccination, approximately 36.4% said they were not willing to be vaccinated. The underlying reasons are fear of side effects of the Covid-19/unsafe vaccine (55.5%), ineffective vaccine (25.4%), not needing it/healthy body (19.0%), vaccines may not be halal (9.9%), unwillingness to pay to get the vaccine (8.7%), many people have been vaccinated so I do not need to be vaccinated (4.1%), vaccines are just the reason pharmaceutical companies are looking for profit (3.8%) and other reasons (9.3%). It can be concluded later that the reason people refuse vaccines is primarily because of doubts about the quality of the vaccines that are used.

Provisions regarding the quality of vaccines used in Indonesia to prevent the spread of COVID-19 outbreak are mentioned in Chapter III of the Implementation of Immunization Program Annex to the Regulation of the Minister of Health Number 12 of 2017 concerning the Implementation of Immunization. In the provisions of service implementation, it is stated that in the provision of Immunization, the vaccine quality must be considered, the use of syringes, and essential things when administering Immunization (dosage, method, and place of administration, intervals of administration, antiseptic measures and counter-indications).

Concerning the quality of vaccines, all vaccines that will be used in Immunization services must have met WHO standards and have a *Certificate of Release* (CoR) or even *an Emergency Use Authorization* (EUA) issued by the Food and Drug Administration. Standardization of vaccine regulation is divided into three stages of testing: 1) development, 2) licensing, and 3) post-licensing. The development stage consists of two

[10] Cindy Mutia Annur, 'Rasio Vaksinasi Booster Di Asia Tenggara, Indonesia Masih Tertinggal', *Databoks.Katadata.Com,* 2022, p. 1 <https://databoks.katadata.co.id/datapublish/2022/07/13/rasio-vaksinasi-booster-di-asia-tenggara-indonesia-masih-tertinggal> [accessed 14 July 2022].

[11] Agus Dwi Darmawan, 'Kematian Karena Covid-19 Mingguan, Indonesia Urutan Ke-6 Di Asia', *Databoks.Katadata.Com,* 2022, p. 1 <https://databoks.katadata.co.id/datapublish/2022/07/15/kematian-karena-covid-19-mingguan-indonesia-urutan-ke-6-di-asia> [accessed 15 July 2022].

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parts, pre-clinical research, and pre-clinical development and clinical research and development.

Regarding the process of manufacturing and testing the vaccine, even though a vaccine candidate has gone through a clinical trial process that has passed 3 phases (Phase 1 clinical trials will not be allowed if the developer does not show the efficacy and safety of the vaccine candidate in pre-clinical trials of experimental animals, as well as phase 2 clinical trials, it will not be allowed if phase 1 data does not show efficacy and safety, and so on) and using a large number of volunteers, the vaccines that are distributed do not have any guarantee that the quality of the vaccines is in good quality or even practical to ward off individuals who are injected with the vaccine from the disease that is currently spreading. This is due to the time it takes to be able to guarantee that the vaccines developed are of good quality and proven to be effective in warding off the disease outbreak.[12]

WHO, through *The International Clinical Trials Registry Platform (ICTRP),* there is a procedural standard for passing a vaccine, from production to distribution, and finally can be used by a wide range of people. In the vaccine development scheme under normal conditions, the first 1 (one) to 2 (two) years, the pre-clinical stage is carried out in the form of testing in the laboratory and on experimental animals, and phase 1 clinical trials involve dozens of volunteers. In phase 1 clinical trials, the dose level and safety of the vaccine were tested. This phase requires a minimum of 1 year, and not all vaccine candidates who complete phase 1 clinical trials can advance to clinical trial II. In Clinical trial 2, testing of the vaccine candidate involved more than hundreds of volunteers recruited to test the immunogenicity and safety of the vaccine candidate. Clinical Trial 3 is usually only conducted in the third year. In this phase, thousands of volunteers are recruited to test the safety and efficacy of the vaccine, and this phase usually takes years. Overall, under normal conditions, vaccine development can take about 10 (ten) years.

Discussing the national legal product that provides explicit guarantees to the public related to the quality of the vaccines given, so far, there has been no specific legal product that provides these guarantees. However, in response to the need for a COVID-19 vaccine in Indonesia is currently very urgent, the Food and Drug Supervisory Agency (BPOM) audits every lot or batch of vaccine production that has received an Emergency Use Authority (EUA) certificate to pay attention to aspects of efficacy, the content of vaccine or antigen base materials, safety, and purity with established criteria. Quality Control (QC) that occurs also includes the distribution and storage process from factories, central government warehouses, local governments, to hospitals or health centers implementing vaccinations.[13]

Meanwhile, during the COVID-19 pandemic, the flow of vaccine development accelerated. First, because SARS-CoV-2 is a coronavirus, it has similarities with SARS-CoV-1 and MERS-CoV. Therefore, the target antigen can be identified quickly and save

[12] National Center for Immunization Research and Survaillance, 'Phases of Clinical Trials', *Ncris.Org.Au*, 2020 <https://www.ncirs.org.au/phases-clinical-trials> [accessed 29 June 2022].

[13] Badan Pengawas Obat dan Makanan RI, *Badan POM Terbitkan EUA Vaksin Covovax Sebagai Vaksin Alternatif Ke-11 Dalam Penanganan Pandemi* (Jakarta, 2020) <https://www.pom.go.id/new/view/more/pers/629/Badan- POM-Terbitkan-EUA-Vaksin-Covovax-Sebagai-Vaksin-Alternatif-Ke-11-dalam-Penanganan-Pandemi.html>.

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pre-clinical time. Two months after the SARS-CoV-2 genome was sequenced and shared, phase 1 clinical trials began in March 2020. Phase 2 clinical trials begin before phase 1 clinical trials end. For many clinical trials of COVID-19 vaccines, phase 1 and phase 2 clinical trials are combined to help accelerate progress. However, the scientific design was not compromised as dosage, safety, and immunogenicity measures were evaluated. Phase 3 clinical trials also begin before the phase 3 clinical trials are completed. There are several experiments in which phase 2 and phase 3 are combined. Vaccine development, which used to take about 10 (ten) years under normal conditions, is now shortened to 1-2 years during the COVID-19 pandemic.[14]

The overlap and combined phases of clinical trials, the urgency of the need for safe and effective vaccines, international collaborative efforts, funding, and pre-planning in manufacturing have allowed the time frame of vaccine development to be compressed to about 10 (ten) months. COVID-19 vaccines are being rolled out for emergency use authorization in some countries. However, due to limited safety data, the complete registration of the vaccine will only be provided after comprehensive safety monitoring, which will take several years.

Pandemic situations do urge the world to immediately find a vaccine that can prevent the spread of the outbreak more widely and form people's immunity. However, it is natural for the public to doubt then the quality of the vaccines that are injected, given the large number of procedures carried out in an overlapping manner. Especially in Indonesia, there are no laws and regulations that can guarantee the quality of vaccines given to the community in the midst of the tense COVID-19 pandemic. In addition, public tolerance for receiving risk from administering vaccines is lower than other pharmaceutical products, given that the majority of vaccine recipients are those who are initially healthy, including infants and children. Therefore, vaccine-related risk management is not only limited to the vaccine development industry but also regulations related to vaccines and quality assurance.

Health care is one of the most fundamental human rights and elements of life whose scopes are very complex. The existence of legal protection related to testing standards for vaccine products will provide a guarantee from the State regarding the quality of a vaccine that is distributed as a "drug" to overcome particular outbreaks. The problem arising from the legal vacuum is the distrust of some groups of people over the results of clinical trials of a vaccine product that will be used to overcome outbreaks of certain diseases.

The distrust that's fostered by the legal vacuum of legal quality assurance could put Indonesia in a new wave of COVID-19 infection cases. The SARS-CoV-2 virus continues to mutate rapidly, creating new variants and subvariants. Looking at the track record of COVID-19 infection in Indonesia, the country is often overwhelmed with each new variant and subvariant that appears and begins to infect. Herd immunity must be formed immediately if we do not want to continue to be slumped due to the pandemic.

In addition, the case of vaccine jockeys should also be a concern for the GovernmentGovernment. In South Sulawesi, for example, a vaccine jockey has even received 17 doses of vaccine by utilizing mass vaccinations. The South Sulawesi Legal and

[14] Jiao Feng and Qin LI, 'How to Ensure Vaccine Safety: An Evaluation of China's Vaccine Regulation System', *Vaccine*, 39.37 (2021), 5285–94 <https://doi.org/10.1016/j.vaccine.2021.07.081>.

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Rights Research Information System Team explained that this practice of jockeying could occur due to a person's reluctance to be vaccinated. Unfortunately, this case is not only in South Sulawesi but also in other regions of Indonesia.[15] That way, there is a possibility of data mismatch between the vaccine doses that have been given and the actual number of people who have received the vaccine doses. This is undoubtedly a new homework for the GovernmentGovernment and the threat of weakening herd immunity due to public distrust of the State in ensuring the quality of COVID-19 vaccines.

II. The State's Obligation to Guarantee The Quality of Vaccines During A Pandemic

The WHO constitution preamble states that "*Governments have a rensponsbility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures*." This means that the State, through the Government, must be responsible for the health of its people. Therefore, the right to one's health must be guaranteed its implementation by the State, without exception.

Furthermore, referring to Article 1 Number 1 of Law Number 36 of 2009 concerning Health, what is meant by health is a healthy state, both physically, mentally, spiritually, and socially that allows everyone to live a productive life socially and economically. Health is a fundamental thing where if a person does not have "health" they cannot access their human rights or their freedoms.

According to Karamishev, the most prominent objective factor in the low level of public health, including also the efficiency of the industry and the quality of health care, is the lack of public awareness regarding the opportunities available in their health systems and the emerging threats.[16] People often have a low level of interest in state-run health facilities, which is often fostered by the lack of role of the State in ensuring the quality standards of their health care facilities.

The COVID-19 pandemic has brought the world health care order into a new chapter quickly and often makes many countries' health systems feel unprepared and falling apart, including Indonesia. Almost all aspects of health are required to adapt soon, including the process of developing a COVID-19 vaccine which must be given to the community immediately. This then makes the public also question the quality of the vaccines, given the safety and efficiency of the vaccines given. Vaccines are actually pharmaceutical products that are given to healthy people to form immunity to the possibility of viruses attacking and infecting the body.[17] However, suppose later it turns out that the vaccine that has been given actually causes a negative reaction to life-

[15] Kantor Wilayah Sulawesi Selatan, *Tim SIPKUMHAM Kumham Sulsel Kaji Kasus Joki Vaksin Di Pinrang* (Sulawesi Selatan, 2022) <https://sulsel.kemenkumham.go.id/berita-kanwil/berita-utama/7346-tim-sipkumham-kumham-sulsel-kaji-kasus-joki-vaksin-di-pinrang>.

[16] Olena Artemenko and others, 'The Importance of the State Ensuring the Right of Citizens To Quality Medical Care in the Context of the Vaccination of Covid-19', *Baltic Journal of Economic Studies*, 7.5 (2021), 260–67 <https://doi.org/10.30525/2256-0742/2021-7-5-260-267>.

[17] World Health Organization, *Vaccine Safety Basic Learning* (Washington DC: World Health Organization, 2013).

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threatening cases, worsening with the fake news of pseudoscience that develops in the community, it is not surprising that then the community refuses to accept the vaccine.

People who do not want to get and even refuse the vaccine claimed that their refusal is protected by human rights and law. Those people claimed that everyone have right to autonomy and decision-making where patients have the right to make their own healthcare decisions.[18] Additionally, Article 5 paragraph (3) Law Number 36 of 2009 concerning Health that "*Everyone has the right to independently and responsibly determine the health services needed for themselves*".

However, we should underline the word of "patient" in this statement. Cambridge Dictionary define patient as "a person who is receiving medical care, or who is cared for by a particular doctor or dentist when necessary". Then Merriam-Webster state that "patient" means an individual awaiting or under medical care and treatment. Thus, it can be concluded that patient is someone who recieve and has medical care by healthcare worker. It means, to become a patient, someone need to be sick or has illness first. Yet, a vaccine only be given to healthy person to build immunity toward any possibility of virus contamination.

Furthermore, in an emergency state such as this pandemic, apply the principle of Lex populi Suprema Les Esto, which states that the safety of the people is the highest law, as well as the principle of Lex Specialist Derogat Lex Generali, which states that two laws and regulations have the same position hierarchically, but the scope of the content of the two laws and regulations is not the same, namely one is a special arrangement of the other. Lex Generalis refers to Law No. 36 of 2009, while Lex Specialis refers to Law No. 4 of 1984 and Law No. 6 of 2018 on Health Quarantine.Regarding the implementation of vaccinations, indeed everyone has the right to choose health services, but in a pandemic condition, the safety of citizens in general is prioritized over personal rights, because every person infected with the Covid-19 virus is very likely to infect other people and can be dangerous. and threaten the life of the person.

According to Indonesian laws and regulations, the State, through its legal products, can "force" the distribution of vaccines to the public during the COVID-19 pandemic, which Indonesia itself has declared this pandemic as an emergency period. This means that people who refuse to vaccinate against COVID-19 can be restricted in their movements and rights and get administrative sanctions. For example, through Article 13A paragraph (4) of Presidential Regulation Number 14 of 2021, the Goverment may provide administrative sanctions in the form of: a) delay or termination of the provision of social security or social assistance; b) delay or termination of government administrative services; c) a fine, if a person who has been designated as a target recipient of the COVID-19 vaccine does not participate in the vaccination. It left the citizens no other choice than to accept the vaccines. However, on the other hand, people also have the right to get guarantees for the quality of the vaccines given.

The legal vacuum in providing quality assurance for the COVID-19 Vaccine will undoubtedly provide a big question mark regarding the standards of the Indonesian Government and the legal umbrella for a vaccine product that exists and circulates in Indonesia. This is certainly contrary to the content of the provisions of Article 28 H

[18] Global Library of Women's Medicine (GLOWM), 'Women's Rights, Health and Empowerment', *Integrated Competencies for Medical Practice,* 2016.

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paragraph (1) of the 1945 Constitution of the Republic of Indonesia, which states "Everyone has the right to live a prosperous life born and mentally, to live, and to get a good and healthy living environment and the right to obtain health services."

Therefore, in order to realize the implementation of public health rights, especially for vaccine quality assurance during the COVID-19 pandemic, the State needs to be present through laws and regulations and institutional mechanisms to provide a sense of security to the community. The State must be able to ensure the safety of the vaccine development process at each stage, including during clinical trials until it is finally distributed to the public. This includes the safety of vaccine clinical trial volunteers.

The State must also establish a risk management system for vaccines through the legal system regarding vaccines in Indonesia. This risk management contains the establishment of a system of quality retrospective analysis and risk reporting, as well as an annual report on vaccine production, circulation, and post-marketing research. In addition, the supervision of Adverse Events Following Immunization (AEFI) is also an essential part of risk management after the vaccine is marketed. With the risk management of vaccines guaranteed by laws and regulations, the Government can provide guarantees to the public regarding the vaccines to be given and also all aspects when the vaccine has been distributed along with side effects.

Concerning COVID-19 vaccine research, the state must supervise how the research was conducted. A clinical research shall obey the Nuremberg Code, the ethic code of clinical research practice[19]:

1. There should be voluntary consent;
2. The experiment should produce results that are beneficial to society and cannot be obtained through other methods or means;
3. The experiment should be planned and based on the findings of animal testing;
4. The experiment should be carried out in such a way that unnecessary physical and mental suffering or injury is avoided;
5. No experiment should be carried out if there is a reasonable expectation of death or disability;
6. The degree of risk should never be greater than the humanitarian significance of the problem to be solved by the experiment;
7. If something goes wrong, proper preparations should be made and an adequate facility should be available to protect the subject from injury or harm;
8. Only people with scientific backgrounds should conduct the experiment;
9. The human subject should be free to leave at any time during the experiment;
10. If there is reason to believe that continuing the experiment will cause harm to the subject, the scientist in charge is responsible for stopping the experiment or withdrawing the subject and terminating the experiment at any stage.

Clinical research that involving human as experiment object in Indonesia was regulated through The Decree of Health Minister (KMK) No. 1333/MENKES/SK/X/2002 about Approval of Human Health Research. This regulation regulate the consent of the volunteer as the object of research which is considered valid by law and the rights of the volunteer.

[19] S Arulkumaran, 'Health and Human Rights', *Singapore Medical Journal*, 58.1 (2017), 4–13 <https://doi.org/10.11622/smedj.2017003>.

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Implementing phase 1 to 3 clinical trials necessitates a large number of subjects, potentially thousands of people or volunteers. Health insurance for volunteers is critical, particularly legal regulations that can provide an umbrella to protect from conducting clinical trials of drugs or vaccines. The current situation is inversely proportional to the fact that there is no specific legal framework in place to protect volunteers participating in clinical trials of the Covid-19 vaccine, even the legal rules that are used as guidelines in the prevention and control of Covid-19, the Decree of the Minister of Health of the Republic of Indonesia Number Hk.01.07/Menkes/413/2020 concerning Guidelines for the Prevention and Control of Corona Virus Disease 2019 (COVID-19). There were also no regulations governing the testing of the COVID-19 vaccine in the Ministry of Health's preamble.

CONCLUSION

Recovery of people's lives during the COVID-19 pandemic can only be achieved if public health is fulfilled by the state, in this case, the implementation of the COVID-19 vaccination. However, the COVID-19 vaccination in Indonesia is constrained by public distrust of the quality of the vaccines given, considering that in the process of developing a COVID-19 vaccine, clinical trial phases overlap. In addition, getting a guarantee for the quality of the vaccines given is also part of the right to health, whose sustainability is guaranteed by law and the state. Therefore, the state is obliged to provide certainty to the public regarding the quality of the COVID-19 vaccine distributed through laws and regulations. Countries are also considered necessary to establish risk mitigation in dealing with vaccine production and distribution as well as Adverse Events Following Immunization (AEFI).

Legal protection for COVID-19 Vaccine quality shall not only limited to ensure everyone can access the vaccine but also ensure that whole process of vaccination does not violate any law no human rights. The goverment also need to consider in formulating regulation regarding legal protection of vaccine quality during pandemic. It is because when the pandemic hit humankind, everything is rushed and often has no regard toward human rights. However, if a state already has prepares legal formulation to face the pandemic, goverment can control the damages.

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