



# Legal Certainty and Benefits in Emergency Use Authorization of SINOVAC Vaccines as Halal Products During the Covid-19 Pandemic Outbreak in Indonesia

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**Abstract.** The World Health Organization (WHO) has declared COVID-19 as a Global Pandemic and the Government has declared a public health emergency of Corona Virus Disease 2019 (COVID-19) in Indonesia through Presidential Decree Number 11 of 2020 concerning the Determination of the Public Health Emergency of Corona Virus Disease 2019 (COVID-19). So that countermeasures must be carried out in accordance with the provisions of the legislation. Therefore, it is necessary to conduct an effective intervention to break the chain of disease transmission, namely through vaccination efforts. On January 11, 2021, BPOM gave approval for the Use of Sinovac Vaccine in Emergency Use Authorization.” The research used is empirical juridical research, which examines the applicable legal provisions and what happens in reality in society. Concluded the emergency use of Sinovac Vaccine as a Halal product has legal certainty and benefits.”

**Keywords:** Vaccines · Legal Certainty · Legal Benefits

## 1 Introduction

“*World Health Organization* (WHO) has declared COVID-19 as a Global Pandemic and the Government has declared a public health emergency of Corona Virus Disease 2019 (COVID-19) in Indonesia through Presidential Decree No. 11 of 2020 concerning the Determination of Public Health Emergency of Corona Virus Disease 2019 (COVID-19). so that countermeasures must be carried out in accordance with the provisions of the legislation.”

The determination of the COVID-19 public health emergency was carried out considering “the extraordinary spread of COVID-19 marked by the number of cases and/or the number of deaths that had increased and spread across regions and across countries and had an impact on political, economic, social, cultural, defense and security aspects., as well as the welfare of the people in Indonesia. In addition, considering that the spread of COVID-19 has an impact on increasing the number of victims and property losses, expanding the coverage of the affected area, as well as having implications for broad

socio-economic aspects in Indonesia, Presidential Decree No.” Corona Virus Disease 2019 (COVID-19) As a National Disaster.<sup>1</sup>

“As of October 29, 2021, more than 249 million people worldwide have been diagnosed with COVID-19, according to the WHO Dashboard. The pandemic has so far claimed more than 4.9 million lives. Vaccination has a major impact on case numbers and hospitalizations in a number of high-income countries, but limited global access to vaccines means that many populations remain vulnerable, even in vaccinated individuals, uncertainty remains about the duration of protection and efficacy of current vaccines against the SARS-CoV-2 variant. CoV-2 is emerging. Overall, there is still a need for more effective treatments for COVID-19. The COVID-19 pandemic and the explosion of research and misinformation have highlighted the need for reliable, accessible, and.”<sup>2</sup>

“Therefore, it is necessary to immediately intervene not only in terms of implementing health protocols but also other effective interventions to break the chain of disease transmission, namely through vaccination efforts. Efforts have been made by various countries, including Indonesia, to develop ideal vaccines for the prevention of SARS-CoV-2 infection with various platforms, namely inactivated virus vaccines, live attenuated virus vaccines, virus vector vaccines, nucleic acid vaccines, virus-like vaccines, and protein subunit vaccines.”

“The COVID-19 vaccination aims to reduce the transmission of COVID-19 transmission, reduce morbidity and mortality due to COVID-19, achieve group immunity in the community (herd immunity) and protect the community from COVID-19 in order to remain socially and economically productive. Herd immunity can only be formed if vaccination coverage is high and evenly distributed throughout the region. Prevention efforts through the provision of vaccination programs if assessed from an economic point of view, will be much more cost-effective, when compared to treatment efforts”.<sup>3</sup>

“Islam is very concerned about purity and halal (halalan thoyyiban). In order for humans to be healthy and intelligent emotionally, intellectually, morally and spiritually, everything that is consumed must meet the criteria of being holy, lawful, and good. This purity and halalness are the keys to the acceptance of one’s worship and open the door of His grace and pleasure. For this reason, in order to protect, maintain and be grateful for it, Islam has established a number of laws so that its existence can be maintained. Islam obliges to consume what is lawful and good, forbids what is unlawful and endangers health. Islam requires Muslims to maintain chastity and maintain health, and seek treatment when they are sick. Carry out prevention, immunization, eradication of disease.”

“Vaccination is part of active immunization by providing antigens in vaccines. Vaccines that are inserted into the body contain viruses or bacteria that have been weakened so that the body is provoked to produce antibodies. In principle, Muslims do not need

<sup>1</sup> Keputusan Menteri Kesehatan Republik Indonesia No. Hk.01.07/Menkes/4638/2021 Tentang Petunjuk Teknis Pelaksanaan Vaksinasi dalam Rangka Penanggulangan Pandemi *Corona Virus Disease 2019* (COVID-19), Lampiran page.1

<sup>2</sup> WHO, 23 November 2021, “*Living Guidance for Clinical Management of Covid-19*”, hlm 9

<sup>3</sup> Keputusan Direktur Jenderal Pencegahan dan Pengendalian Penyakit No. Hk.02.02/4/ 423/2021 tentang Petunjuk Teknis Pelaksanaan Vaksinasi Dalam Rangka Penanggulangan Pandemi *Corona Virus Disease 2019* (COVID-19), Lampiran Page. 2

to refuse vaccination because it is not much different from immunization. Both have the same goal, namely to increase the body's resistance to certain diseases."<sup>4</sup>

"In its fatwa Number 2 of 2021, MUI confirms that the Covid-19 vaccine produced by Sinovac and Bio Farma meets the halal criteria and can be used for Muslims. Emergency Use Authorization (EUA) and assurance of safety, quality, and efficacy for the Covid-19 Vaccine produced by Sinovac Life Sciences Co. Ltd. China and PT. Bio Farma (Persero) which is one of the indicators"<sup>5</sup>

Formulation of the problem, Do you know whether the emergency use (Emergency Use Authorization) of the Covid-19 vaccine has legal certainty in Indonesia? And Do you know whether the emergency use (Emergency Use Authorization) of the Covid-19 vaccine has legal benefits in Indonesia?

## 2 Research Methods

"The type of research used is empirical juridical research, or what is called field research, which examines the applicable legal provisions and what happens in reality in society.<sup>6</sup> Empirical juridical research is legal research regarding the enactment or implementation of normative legal provisions in action on certain" "legal events that occur in society."<sup>7</sup> Or in other words is a research conducted on real situations or conditions that occur in the community with the intention of knowing and finding the facts and data needed, after the necessary data is collected then leads to the identification of problems which ultimately lead to on problem solving".<sup>8</sup>

## 3 Result and Discussion

"Islam is a way of life (ad-din) which has been considered a comprehensive way of life (kaffah) by its adherents. Following the concept of five missions and religious philosophy to be realized in human life, namely maintaining religion, preserving life, preserving reason, maintaining offspring, and maintaining property or commonly known as Al-Mashalih Ad Daruriyya Al-Khamsah"<sup>9</sup>.

For a Muslim, the halal status of a medicinal product and excipient as a substance used in pharmacy to mix drugs in order to obtain a form that is easier to use is an absolute

<sup>4</sup> Farhat Abdullah, "*Kontroversi Kehalalal Vaksin Sinovac Menurut Masyarakat Awam. (Sinovac Vaccine Halal Controllers According to lay Community)*" *Jurnal Pendidikan Islam Tahdzib Al-Akhlaq*, Vol 4 No. 1 (2021) page 1-15

<sup>5</sup> Fatwa Majelis Ulama Indonesia Nomor 02 Tahun 2021 Tentang Produk Vaksin Covid-19 dari Sinovac Life Sciences CO.LTD dan PT.Biofarma (Persero)

<sup>6</sup> Suharsini Arikunto, *Prosedur Penelitian: Pendekatan Praktis*, Jakarta: Rineka Cipta, 2012, page. 126

<sup>7</sup> Abdulkadir Muhammad, *Penelitian Hukum dan Hukum*, Bandung: Citra Aditya Bakti, 2004, page. 134

<sup>8</sup> Bambang W, *Penelitian Hukum dalam Praktek*, Jakarta: Sinar Grafika, 2002, page. 15

<sup>9</sup> M Asrorun Niam Sholeh, Muhammad Ishar Helmi "*The COVID-19 Vaccination: Realization on Halal Vaccines for Benefits*" *Jurnal Hukum Keluarga dan Hukum Islam* Volume 5 No. 1. January-June 2021 page 174-191

thing that must be fulfilled. Halal medicinal products must be free from pork and alcohol, both from the basic ingredients and the manufacturing process.<sup>10</sup>

Halal products guaranteed by law “are goods and/or services related to food, beverages, drugs, cosmetics, chemical products, biological products, genetically engineered products, as well as goods used, used, or utilized by the public” and are products which have been declared halal in accordance with Islamic law.<sup>11</sup>

“Along with the development of medical science and the number of cases of new diseases found, various types of vaccines were discovered and applied in the world of health. The vaccine itself is produced biologically, containing antigen in the form of an attenuated or completely killed microorganism. Vaccines can also be in the form of micro-organism toxins converted into toxoids or recombinant proteins combined with other elements.”

This vaccine when given to someone, then he will have specific and active immunity against certain diseases. So vaccination is defined by the process of affixing a special vaccine given to generate active immunity to a disease in a person. This is done so that when he is exposed to the disease, he will not suffer from pain or at least only feel mild pain and not infect others.<sup>12</sup>

“The government has designated the Corona Virus Disease 2019 (COVID-19) pandemic as a non-natural disaster. Since the announcement of the first confirmed case in March 2020, within one month, all provinces have reported confirmed cases. The spread of COVID-19 has not only occurred in the Special Capital Region of Jakarta and other densely populated cities, but has spread to rural areas in remote areas. As of December 27, 2020, a total of 706,837 confirmed cases of COVID-19 have been reported in Indonesia and a total of 20,994 people have died..”

“The COVID-19 pandemic poses a major challenge in efforts to improve the health status of the Indonesian people and has an impact on the Indonesian health system as seen from the decline in performance in several health programs. This is due to the priority in dealing with the COVID-19 pandemic as well as the concerns of the public and officers regarding the transmission of COVID-19. In some areas, the COVID-19 pandemic situation has even resulted in temporary closures and/or delays of health services, especially at posyandu and puskesmas.”

“Therefore, it is necessary to immediately intervene not only in terms of implementing health protocols but also other effective interventions to break the chain of disease transmission, namely through vaccination efforts. Efforts have been made by various

<sup>10</sup> Deni hudaefi, Martin Roestamy, dan achmad Jaka santos adiwijaya; “Kepastian Hukum sertifikasi Halal pada Obat-Obatan dikaitkan dengan Jaminan produk halal” *Jurnal ilmiah Living Law*, Vol 13 No. 2 (2021) page 1-10

<sup>11</sup> Ketentuan Umum, Pasal 1 ayat 1 dan 2, Undang-Undang Republik Indonesia No. 33 tahun 2014 Tentang Jaminan Produk Halal

<sup>12</sup> Al-Mashlahah: Jurnal Hukum Islam dan Pranata Sosial Islam Vol 9, No 01 2021, “Kehalalan Vaksin Covid-19 Produksi SINOVA dalam Fatwa MUI dan Implementasi Vaksinasinya pada Tenaga Kesehatan di Puskesmas Tanjung Morawa, deli Serdang (Perspektif Qawaidh Fiqhiyyah)”.

countries, including Indonesia, to develop ideal vaccines for the prevention of SARS-CoV-2 infection with various platforms, namely inactivated virus vaccines, live attenuated virus vaccines, virus vector vaccines, nucleic acid vaccines., virus-like vaccines, and protein subunit vaccines.”

“The COVID-19 vaccination aims to reduce the transmission or transmission of COVID-19, reduce morbidity and mortality due to COVID-19, achieve herd immunity and protect the community from COVID-19 in order to remain socially and economically productive. Herd immunity can only be formed if vaccination coverage is high and evenly distributed throughout the region. Prevention efforts through the provision of vaccination programs if assessed from an economic point of view, will be much more cost-effective, when compared to treatment efforts”.<sup>13</sup>

### 3.1 Legal Certainty of Sinovac Vaccines as Halal Products

“Article 1 paragraph (3) of the 1945 Constitution of the Republic of Indonesia expressly states that “the State of Indonesia is a state of law”.<sup>14</sup> As a state of law, all aspects of society, nationality, and statehood, including government, must always be based on law”.

Frederich J. Stahl, put forward the concept of the rule of law which is characterized by four main elements, namely:

- a. Recognition and protection of human rights;
- b. The state is based on the political triad theory;
- c. Government is organized based on the law (*Wetmatig bestuur*); and
- d. There is a state administrative court tasked with handling cases of unlawful acts by the government (*onrechtmatige overheidsdaad*).

“Gustaf Radbruch, in the concept of “Baku Priority Teachings” suggests that there are three basic ideas of law or three legal objectives, namely justice, expediency and legal certainty. Justice is the main thing from the three things but that does not mean the other two elements can be ignored. A good law is a law that” “is able to synergize these three elements for the welfare and prosperity of the community. According to Radbruch: Justice in question is justice in a narrow sense, namely equal rights for all before the court. Expediency or finality describes the content of the law because the content of the law is indeed in accordance with the objectives to be achieved by the law, while legal certainty is interpreted as a condition in which the law can function as a regulation that must be obeyed”.<sup>15</sup>

Of the three basic ideas of Gustaf Radbruch’s law, legal certainty which requires that the law can function as a regulation that must be obeyed is of course not only about how the regulation is implemented, but also how the norms or content material in the regulation contains the basic principles of law. Legislation as a written norm (law), in

<sup>13</sup> Keputusan Direktur Jenderal Pencegahan dan Pengendalian penyakit No.HK.02.02/4/423/2021 Tentang Petunjuk Teknis Pelaksanaan Vaksin dalam Rangka Penanggulangan Pandemi Corona Virus Disease 2019 (COVID-19), Lampiran, page.2

<sup>14</sup> UUD 1945 dan Perubahannya, Pasal 1 Ayat 3.

<sup>15</sup> Theo Huijbers, *Filsafat Hukum Dalam Lintasan Sejarah*, Jakarta, Kanisius, 1982, page. 162

the context of the Indonesian legal state, becomes the basis for the administration of the state and as a guideline for administering the government. Every product of legislation, must be a reflection of Pancasila and the Constitution.<sup>16</sup>

According to Law Number 33 of 2014 concerning Halal Product Guarantee article 1 paragraph (1), “it says that halal products guaranteed by this law are goods and/or services related to food, beverages, drugs, cosmetics, chemical products, biological products, genetically engineered products, as well as goods used, used, or utilized by the public. Furthermore, in paragraph (2) it is stated that halal products are products that have been declared halal in accordance with Islamic law”. “Islamic Shari’a is intended to provide goodness, prosperity, and benefit for all humanity”.<sup>17</sup>

Halal guarantees on products, including medicines, are mandatory in this JPH Law, as Article 4 states that “products that enter, circulate, and are traded in Indonesian territory must be certified halal”. In article 10 paragraph 2 of Law No.33 of 2014 it is stated that the determination of product halalness is issued by the MUI in the form of a Decision on Determination of Halal Products.<sup>18</sup>

The Central MUI Fatwa Commission issued a halal fatwa and the sanctity of the corona virus disease 2019 (COVID-19) vaccine produced by Sinovac Lifescience Co Ltd., Jakarta on January 8, 2021. Of course this fatwa has passed various considerations, such as the Covid-19 outbreak which is still a health threat, and one of the efforts to prevent the spread of the epidemic is vaccination. The final decision is that Muslims may use the vaccine, provided that its safety is guaranteed according to credible and competent experts. This decision is stated in the MUI Fatwa No. 02 of 2021, where in the fatwa it is concluded as follows:

- a. Sinovac Life Sciences Co.’s Covid-19 vaccine Ltd. China and PT. Bio Farma (Persero) in the production process:
  - 1) not to use (intifa’) pigs or materials contaminated with pigs and their derivatives.
  - 2) do not use parts of the human body (juz’ minal insan).
  - 3) comes into contact with mutawassithah unclean goods, so that it is considered mutanajjis, but the purification has been carried out which has fulfilled the provisions of purification according to syar’i (tathhir syar’i).
  - 4) using production facilities that are sacred and only used for covid-19 vaccine products.

<sup>16</sup> R.Tony Prayogo, Penerapan Asas Kepastian Hukum dalam Peraturan Mahkamah Agung No. 1 Tahun 2011 Tentang Hak Uji Materiil dan dalam Peraturan Mahkamah Konstitusi No.06/PMK/2005 tentang Pedoman Beracara dalam Pengujian Undang-Undang. *Jurnal Legislasi Indonesia*, Vol. 13 No. 2 (2016), page 1-11

<sup>17</sup> Deni hudaefi, Martin Roestamy, dan achmad Jaka santos adiwijaya; “Kepastian Hukum sertifikasi Halal pada Obat-Obatan dikaitkan dengan Jaminan produk halal” *Jurnal Ilmiah Living Law*, Vol 13 No. 2 (2021) page 1-10

<sup>18</sup> Undang-Undang No.33 Tahun 2014 Tentang *Jaminan Produk Halal*, Pasal 4 dan 10.

- b. Equipment and cleaning in the vaccine production process at PT. Bio Farma (Persero) is deemed to have complied with the provisions of syar'i washing (tathhir syar'i).<sup>19</sup>

With the issuance of a halal fatwa from the MUI regarding the SINOVAC Vaccine, the COVID-19 vaccine has legal certainty as a halal product.

### 3.2 Legal Benefits of Sinovac Vaccines as Halal Products

In a legal regulation, there are legal principles that form the basis for its formation. Satjipto Rahardjo said that legal principles can be interpreted as the "heart" of legal regulations, because they are the broadest basis for the birth of a legal regulation. Because legal principles contain ethical demands, legal principles are a bridge between legal regulations and ideals. social and ethical views of society.<sup>20</sup>

In the formation of the rule of law, the main principle is built in order to create a clarity of legal regulations. The idea of principle was introduced by Gustav Radbruch in his book entitled "einführung in die rechtswissenschaften". Radbruch wrote that in the law there are 3 (three) basic values, namely:

- a. Justice (Gerechtigkeit);
- b. Benefit (Zweckmassigkeit); and
- c. Legal Certainty (Rechtssicherheit).<sup>21</sup>

Legal benefits is the principle that accompanies the principles of justice and legal certainty. In implementing the principle of legal certainty and the principle of justice, the principle of expediency should be considered. The community expects benefits in the implementation or enforcement of the law. Law is for humans, so the implementation of law or law enforcement must provide benefits or uses for the community.

On January 11, 2021, BPOM gave approval for the Use of Drugs for Sinovac Vaccines in Emergency Conditions (Emergency Use Authorization) with the EUA approval number being EUA2057300143A1. The POM Agency took into account the following matters:

- a. The emergency situation of the COVID-19 pandemic outbreak and the limited evidence of the usefulness and
- b. the safety of the above-mentioned drugs for the treatment of COVID-19,
- c. Decree of the President of the Republic of Indonesia Number 11 of 2020 concerning Stipulation
- d. Corona Virus Disease 2019 (COVID-19) Public Health Emergency
- e. The results of the evaluation of aspects of efficacy, safety and quality.<sup>22</sup>

Today, Monday 11 January 2021, BPOM gave approval for emergency use authorization to Sinovac," said Penny Lukito in a digital press conference:Based on interim

<sup>19</sup> "Fatwa Majelis Ulama Indonesia Nomor: 02 Tahun 2021 Tentang Produk Vaksin Covid-19 Dari Sinovac Life Sciences Co. Ltd dan PT. Bio Farma (Persero)."

<sup>20</sup> Satjipto Rahardjo, *Ilmu Hukum*, Citra Aditya Bakti: Bandung, 2012, page. 45

<sup>21</sup> Satjipto Rahardjo, *Op.Cit.*, page. 19

<sup>22</sup> Surat Keputusan Badan POM No.T-RG.01.03.32.322.01.21.00089/NE Tentang Persetujuan Penggunaan Obat dalam Kondisi Darurat (*Emergency Use Authorization*)

data from the Sinovac clinical trial in Bandung, the efficacy level of CoronaVac reached 65.3% while in Brazil it reached 78%. Both of these data are above the efficacy requirement above 50%. In addition, interim data from clinical trials in Bandung also showed the immunogenicity of Sinovac vaccine reached 99.23%. This vaccine is able to stimulate the formation of antibodies in the body to kill and neutralize viruses up to 99.23%.

Head of BPOM Penny Lukito said the emergency use authorization policy was in line with WHO guidelines. An emergency use permit can be assigned according to five criteria.

- a. First, the government has declared a public health emergency.
- b. Second, there is sufficient scientific evidence regarding the safety and efficacy of drugs and vaccines to prevent, diagnose, or treat serious and life-threatening conditions.
- c. Third, said Penny, having quality that meets applicable standards and with good medicine manufacturing methods.
- d. Fourth, it has a greater benefit than risk, based on a study of non-clinical and clinical drug data for the proposed indication.
- e. Fifth, there is no alternative treatment that is adequate and approved for the diagnosis of prevention or treatment of disease, the cause of public emergency conditions.<sup>23</sup>

## 4 Conclusion

- “The Emergency Use Authorization of the Sinovac Vaccine as a Halal product has legal certainty with the issuance of the Central MUI Fatwa on Halal and the Sanctity of the Corona Virus Disease (COVID19) Vaccine produced by Sinovac Co Ltd, Jakarta on January 8, 2021. So that the Indonesian people do not need to worry about Halal sinovac vaccine.”
- “The Emergency Use Authorization Sinovac Vaccine as a Halal product has legal benefits where interim data from the Sinovac clinical trial in Bandung the efficacy level of CoronaVac reaches 65.3% while in Brazil it reaches 78%. Both of these data are above the efficacy requirement above 50%. In addition, interim data from clinical trials in Bandung also showed the immunogenicity of Sinovac vaccine reached 99.23%. This vaccine is able to stimulate the formation of antibodies in the body to kill and neutralize viruses up to 99.23%.”

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<sup>23</sup> BPOM Restui Vaksin Sinovac & Vaksinasi Mulai 13 Januari (cnbcindonesia.com) diakses tgl 20 Februari 2022 Pukul 03:24 WIB



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