

Legal Protection for Vaccine Recipients in Indonesia

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Abstract

Since 2020 the world is hit by the Covid-19 pandemic. Indonesia has then declared a Covid-19 public health emergency based on Presidential Decree No. 11/2020 dated March 31, 2020. This pandemic does not have an impact on just the health sector but also on almost all aspects of life. One of the efforts to prevent the Covid-19 spread and its effects is through a vaccination program. In 2020 the President issued Presidential Decree Nr. 99/2020 concerning the Vaccine Procurement and the Vaccination Implementation in the Context of Combating the Covid-19 Pandemic. The target of vaccination is the entire population of Indonesia who meet the criteria and its implementation is carried out in stages. During the vaccination several incidents occurred which could be suspected as vaccination impacts. This paper aims to analyze legal protection for the vaccine recipients, particularly if there is any adverse impact. This is a normative study using secondary data which was analyzed qualitatively. Vaccine recipients, in the context of consumer protection law, can be categorized as consumers who receive vaccination services. They have basic rights that must be fulfilled by the service providers, in this case the State. The State must be responsible if the vaccine recipients experience losses, especially regarding post-immunization adverse events (KIPI). The responsibility is based on constitutional provisions and some other legislations.

Keywords: vaccination, consumer, state's responsibility

Introduction

Coronavirus is a cluster of viruses that can cause disease in animals or humans. Several types of the viruses are known to cause respiratory tract infection in human; ranging from coughs and colds to more serious ones as caused by Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The newest type of corona virus has caused a verily infectious disease named **Covid-19** standing for coronavirus disease of the year of 2019 . This new virus and the disease it causes were unknown before the outbreak began in Wuhan, China, in December 2019. Covid-19 is now a pandemic occurring in many countries around the world.¹

The World Health Organization (WHO) has announced that the coronavirus is categorized as a global pandemic. It was stated by the Director General Tedros Adhanom Ghebreyesus in a press conference that took place on March 11, 2020. According to WHO people will possibly catch Covid-19 from others having the virus. The virus spreads from person to person through tiny droplets from the nose or mouth when the carriers of the virus cough or exhale. These drops will land on objects and surfaces around them and others will then possibly catch Covid-19 by touching the

¹ <https://www.who.int/indonesia/news/novel-coronavirus/qa/qa-for-public>

objects or surfaces, particularly when they touch their eyes, nose, or mouth. They will also catch Covid-19 if they breathe in the droplets of the ones having Covid-19.²

The spread of Covid-19 is massively increasing almost all over the world. As reported to WHO there, globally, were 176,693,988 confirmed cases of Covid-19, covering 3,830,304 deaths in June 2021. Regional data are presented in the table below:

Table 1
Covid-19 Case Data³

| Region | Confirmed amount |
|-----------------------|------------------|
| America | 70.103.320 |
| Europe | 55.174.558 |
| South-East Asia | 33.774.368 |
| Eastern Mediterranean | 10.585.505 |
| Africa | 3.725.348 |
| Western Pacific | 3.330.125 |

Indonesia is one of the countries affected by Covid-19 pandemic. The first case of Covid-19 was announced by the Government on March 2, 2020. The website indonesia.go.id explained that 2 (two) Indonesian citizens domiciled in Depok were found to be positive for the SARS Cov-2 virus. They were reported to have interacted with the Japanese who were known having suffered from the disease.⁴ Since the emergence of this first case the spread of Covid-19 in Indonesia has been then increasingly widespread.

President responded the problem by issuing Presidential Decrees (Keppres) even up to 4 times in March 2020. First, Presidential Decree Nr. 7 of 2020 concerning the Task Force for the Acceleration of Handling Covid-19 as amended by Presidential Decree Nr. 9 of 2020. On March 31, 2020 the President again issued a decree Nr. 11 of 2020 concerning the Determination of the Corona Virus Disease 2019 (Covid-19) Public Health Emergency. This Presidential Decree was issued based on the consideration that the extraordinary spread of Covid-19 marked by the number of cases and/or the number of deaths had increased and spread across regions and across countries and had political, economic, social, cultural, defense and security impacts as well as the welfare of the Indonesia people. This Presidential Decree stipulates that Covid-19 was categorized as a disease

² <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/>

³ <https://covid19.who.int/>

⁴ ⁴ <https://indonesia.go.id/narasi/>

that causes a Public Health Emergency so that efforts should be made to overcome it in accordance with statutory provisions. Shortly after President issued Presidential Decree Nr. 12 of 2020 concerning the Determination of Non-Natural Disasters for the Spread of Covid-19 as a National Disaster.

The issuance of 4 presidential decrees in a short time shows that the Covid-19 pandemic situation is very extraordinary and even it is categorized as a non-natural national disaster. The Covid-19 pandemic is factually not only a health issue but it is a multidimensional problem in which its impacts had penetrated almost every aspect of the people's life, namely social, economic, cultural and even national defense and security aspects. One of the impacts felt severely by the entire community is the economic impact and Indonesia's economic growth itself has fallen drastically, even getting minus growth. This condition triggered a wave of work termination and increased the number of unemployed which finally resulted in people's purchasing power decrease.

The government has made various efforts to prevent and overcome the Covid-19 pandemic impacts, among others, by closing the entrance and exit of the international flights, maintaining economic stability, socializing the prevention of the spread of Covid-19 through 5M activities (wear masks, keep distance, wash hands, avoid crowds, and reduce mobility). From the health aspect the government continues to carry out 3 Ts movement, namely tracing, testing and treatment.

All the government's efforts have not been able to stop the spread of Covid-19. Vaccination is considered as one of the urgent efforts that will stop the pandemic as long as the specific healing medicine has not been found. Health experts in various countries have conducted researches to find Covid-19 vaccines and several Covid-19 vaccines have been produced and worldly used for the time being.

The implementation of the Covid-19 vaccination in Indonesia is based on Presidential Regulation Nr. 99 of 2020 concerning the Procurement of Vaccines and the Implementation of Vaccinations in the Context of Combating the Corona Virus Disease-19 (Covid-19) Pandemic. This regulates the aspects of procurement, implementation and funding and facility support from government agencies/institutions.

The government, in this case the Minister of Health, determines the type and amount of Covid-19 vaccine and it takes into account the considerations of the Corona Virus Disease 2019 (Covid-19) Handling Committee and the National Economic Recovery. In the context of determining the type of Covid-19 Vaccine, the Head of the Food and Drug Supervisory Agency grants an emergency use authorization (EUA) or distribution permit.

Indonesia decides to use some vaccine brands, namely Sinovac, Pfizer/BioNTech, AstraZeneca, Moderna, and Sinopharm. The vaccination program is carried out in stages based on priority groups, namely health workers, public servants, the elderly, members of the army and police and others who meet the requirements to get the vaccine.

Sri Rejeki Hadinegoro, quoting Kassianos, stated that immunization is the most perfect prevention of an infectious disease and has an impact on improving public health. Therefore, the need for vaccines is increasing in line with the world's desire to prevent various diseases that can cause disability and death.⁵ Along with high immunization coverage the use of vaccines also increases so that possibly unwanted vaccination effects will also increase. The term of the possible effects which is commonly used is Post Immunization Adverse Events (AEFI) or KIPI in Indonesian. In the Regulation of the Minister of Health No. 12 of 2017 concerning the Implementation of Immunization AEFI is defined as a medical event that is suspected to be related to immunization.

From the consumer protection law perspective the vaccine recipients can be regarded as consumers. Normatively, consumers have the rights as regulated in the Act Nr. 8 of 1999 concerning Consumer Protection covering the rights to comfort, security and safety as well as the right to obtain compensation if harmed. Business actors or service providers, on the other hand, have obligations and responsibilities for losses suffered by the consumers as a result of consuming products or utilizing services provided by the business actors.

Research Question

How is the legal protection provided by the State to the Covid-19 vaccine recipients who experience AEFI?

Research methods

This is a conceptual study based on secondary data which were qualitatively analyzed.

Discussion

The word 'consumer' is very often used both in everyday conversation and in various texts. Other terms regarded as consumer are also used in Indonesian legislation, for example buyer, passenger, customers. Any term of consumer used in the laws and regulations, in principle, have the same purpose, namely a party who buys or receives or uses or utilizes goods or services provided by those who sell or provide the goods or services.

⁵ Sri Rejeki Hadinegoro, *Kejadian Ikutan Pasca Imunisasi*, Jurnal Sari Pediatri Vol. 2 No. 1, Juni 2020, p. 2

The term consumer or *consument/konsument* (Dutch) as opposed to producer literally means everyone who uses goods and/or services. The purpose of using the goods and/or services will determine in which group of the consumers or the user belongs to.⁶ Ross Cranston mentions more broadly that the term of consumer is virtually equal with term of citizen.⁷ This statement is very reasonable because in fact all people (citizens) are consumers. Consumer transactions described by David Epstein are very broad, including credit, goods, property transactions and services for individuals, families and other household interests.⁸

The definition of consumers regulated in state laws differs from one another. Lauren Krohn explains that *basically, a consumer is anyone who buys or uses a product or service...for the purposes of many laws affecting users of goods and services* this broad definition may be modified.⁹ Further, Krohn says laws under some consumer protection laws, the user of product and service must be natural, living person to qualify as a consumer. Under such laws, businesses, corporations or other merely legal entities are not protected.⁹ Similarly, Black's Law Dictionary describes consumers as those who consume, individuals who purchase, use, maintain, and dispose of products and services, users of the final product.... Consumers are to be distinguished from manufacturers (who produce goods), and wholesalers or retailers (who sell goods). and/or services available in the community, both for the benefit of oneself, one's family, other people, and other living creatures and are not for trade.¹⁰ According to Article 1 paragraph (2) of the Act on Consumer Protection (UUPK), consumers are they who use goods and/or services available in the community, both for the benefit of themselves, their families, other people, and other living creatures and not for trade.

Based on the consumers meaning described above, they who receive vaccines can be categorized as consumers. Consumers receive services as well as goods in the form of vaccines that are injected into their bodies. Normatively, they are protected by UUPK, as an umbrella act, which integrates and strengthens enforcement law in the field of consumer protection. This means that consumer protection is not limited to UUPK beside some other relevant laws and regulations.

Article 28H of the Indonesian Constitution states that "everyone has the right to live in physical and spiritual prosperity, to live, and to have a good and healthy living environment and the right to health services". Articles 4 and 5 of the Act Nr. 36 of 2009 concerning Health (Health

⁶ Az. Nasution, 2014, *Hukum Perlindungan Konsumen Suatu Pengantar*, Jakarta: Diadit Media, p. 21

⁷ Ross Cranston, 1978, *Consumer and the Law*, London: Weidenfeld and Nicolson, p. 9

⁸ David G. Epstein, Steve H. Nickles, 1982, *Consumer Law*, St. Paul Minnesota: West Publishing Company, p. 1

⁹ Lauren Krohn, 1995, *Consumer Protection and the Law A Dictionary*, California: ABC-CLIO, p. 50-51

¹⁰ Henry Campbell Black, 1991, *Black's Law Dictionary Abridged Sixth Edition*, St. Paul Minn: West Publishing, p. 219

Law) states that everyone has the right to health and the right to obtain safe, quality, and affordable health services.

Important elements in consumer protection include the consumers' rights fulfillment and the implementation of the obligations and responsibilities of the business actors (service providers). Consumers have rights as regarded as 4 basic consumer rights referring to President Kennedy's 1962 Consumer's Bill of Rights, namely:

- a. The right to safety
- b. The right to choose
- c. The right to be informed
- d. The right to be heard¹¹

UUPK regulates consumer rights in Article 4 covering:

- a. The right to comfort, security and safety in consuming goods and/or services.
- b. The right to choose goods and/or services and to obtain such goods and/or services in accordance with the exchange rate and the promised conditions and guarantees.
- c. The right to correct, clear, and honest information regarding the condition and guarantee of goods/or services.
- d. The right to have their opinions and complaints heard on the goods and/or services used.
- e. The right to get advocacy, protection and efforts to resolve consumer protection disputes properly.
- f. The right to obtain consumer guidance and education.
- g. The right to be treated or served correctly and honestly and not discriminatory.
- h. The right to obtain compensation, redressal and/or replacement, if the goods and/or services received are not in accordance with the agreement or not as they should be.
- i. The rights regulated in the provisions of other laws and regulations.

Based on the nine points of consumer rights above it can be seen that the issue of security, comfort and consumer safety are the most basic and prioritized things in consumer protection. Goods and/or services which do not provide comfort, especially those that are not safe or endanger the safety of consumers are clearly not fit to be circulated in the community. Therefore, if there are adverse deviations, consumers have the rights to be heard, obtain advocacy, guidance, fair treatment, compensation and redressal.

¹¹ Shidarta, 2006, *Hukum Perlindungan Konsumen Indonesia*, Jakarta: Grasindo, p. 19-20

Article 10 of the Act Nr. 4 of 1984 concerning Outbreak of Infectious Diseases stipulates that the Government is responsible for carrying out efforts to control the outbreak. In the context of Covid-19 pandemic, the provision of vaccines and the implementation of vaccinations are then to be the State's responsibility. This is in accordance with the Preamble of the Indonesian Constitution which mandates the responsibility of the State to protect the entire nation and the entire homeland of Indonesia. Article 19 of the Health Law stipulates that the Government is responsible for the availability of all forms of qualified, safe, efficient and affordable health efforts.

In particular, the Covid-19 vaccination program is regulated by Presidential Regulation Nr. 99 of 2020. This regulation stipulates that in the context of accelerating the prevention of the Corona Virus Disease 2019 (Covid-19) pandemic, the Government accelerates the procurement of Covid-19 vaccines and the implementation of Covid-19 vaccinations covering:

- a. procurement of the Covid-19 vaccine;
- b. implementation of the Covid-19 vaccination;
- c. funding for Covid-19 vaccine procurement and implementation of Covid-19 vaccination; and
- d. support and facilities of ministries, institutions, and local governments.

The process of providing immunization as regulated in the Regulation of Health Minister (*Permenkes*) Nr. 12/2017 concerning the Implementation of Immunization, must pay attention to:

- a. safety, quality, and efficacy of the vaccines used;
- b. safety injection so that there is no disease transmission to health workers who carry out the immunization and the community and to avoid the occurrence of AEFI.

Prior to the immunization program the health workers must provide an information on immunization covering the type of vaccine to be given, benefits, consequences if not immunized, the possibility of AEFI and the efforts to be made, as well as the schedule for the next immunization.

In the context of monitoring and overcoming AEFI, the Minister establishes National Commission of AEFI (Komnas PP KIPI) and the Governors establish Provincial Commission of AEFI (Komda PP KIPI). AEFI monitoring and controlling must be carried out through the following activities:

- a. AEFI surveillance and vaccine safety website;
- b. Treatment and care of AEFI patients; and
- c. AEFI research and development.

People who are aware of the alleged occurrence of AEFI must immediately report to the health service facility that carries out immunization services or the local health office. The health service facilities that carry out immunization services or the local health office receiving the report must carry out an investigation. The results of the investigation must be reported in stages to the head of the district/city health office and then to the head of the provincial health office.

Patients who experience health problems suspected of being caused by AEFI are given treatment and care during the investigation and assessment of the causality of AEFI. In the event that a health disorder is determined as a health disorder due to AEFI, the patients will receive treatment and care. Funding for the investigations and case studies is charged to the Central Government, Provincial Governments, District or Municipal Governments, as well as other funding sources in accordance with the prevailing laws and regulations. Financing for treatment, care, and referral for someone who has a health disorder suspected of AEFI or as a result of AEFI is charged to the regional income budget or other financing sources in accordance with the provisions of the legislation.

Various legislations and regulations governing the administration of vaccinations and the actions that must be taken due to AEFI show that the State exists to protect the consumers who receive vaccines. The consumers are normatively guaranteed their rights, including the rights to get compensation and treatment when experiencing illness that is medically caused by Covid-19 vaccination.

Conclusion

The Covid-19 pandemic has emerged tremendous impacts on various aspects of the people's life such as health, economic, social and cultural. One of the efforts made by the government is to carry out a covid-19 vaccination program for the people in order to create herd immunity. The vaccination program could possibly emerge side effects that will be experienced by the recipients.

People who receive the Covid-19 vaccine can be regarded as consumers who receive services and products (vaccines). They have rights that must be fulfilled by the service and product provider, namely the State. These consumer's rights have been regulated in various laws. Through legal instruments it can be seen that the State has responsibility for the vaccination implementation and the handling of the possible side effects emerging. This legal instrument has factually provided legal protection to the consumers, namely the Covid-19 vaccine recipients.

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