



Inquiring the Development of the Nusantara Vaccine and Legal Certainty in the Community

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Abstract. The Indonesian nation is a nation that has advantages in producing diverse and beneficial products for society. During the Covid-19 pandemic, the problem was regarding the existence of vaccines produced by the Indonesian people themselves. The purpose of this paper is the development of the Nusantara Vaccine as prevention of Covid-19 towards the independence of the nation and the legal position of the Memorandum of Understanding (MOU) for the community. The results of the research and discussion show that the Nusantara vaccine is a vaccine that has the potential to increase the nation's independence in the need for vaccines. The position of the Nusantara vaccine is as a service-based research platform and can be used individually by the community. The business agreement in the form of an MoU regarding vaccines as service-based research is still valid until another agreement is reached.

Keywords: Nusantara · Vaccine · Covid-19 · Legal Incertainty

1 Introduction

When the Indonesian nation has influenced the world, the Indonesian nation can be reactive in making contributions around the country and Indonesia's sovereignty will also be maintained. The main focus of the nation's independence is in the education sector but also weakens in other sectors, namely the economy, society, and culture. The form of weakening the nation's independence in the education sector is an orientation to findings or breakthroughs from other countries, although in the field of technology, the Indonesian people have created certain products that are also able to compete with foreign products. With the weakening of independence in the economic field, for example, the Indonesian people are increasingly consumptive and modern when using goods from abroad. Therefore, one way to improve the Indonesian economy is to love the products of the Indonesian people themselves. And the weakening of independence in the socio-cultural field is the culture of the Indonesian nation which is increasingly fading.

The way that can be applied in state life so that Indonesia becomes an independent person is to use domestic products. If the use of domestic products has been implemented, then the government is required to make regulations that limit foreign products and replace them with local products, such as food products, clothing, and technology. In

other words, domestic products can be produced if the government supports the education sector and also provides more opportunities for the Indonesian people to work, the underlying cause of the weakening of the Indonesian economy. The factor is government policies that are not appropriate, such as the government still does not understand the policies that have been passed. Some of these regulations do not support and adapt to the needs of the business world.

2 Methods

The purpose of this paper is to analyze the development of the Covid-19 vaccine as a domestic product in the direction of national independence while at the same time providing the position of the vaccine in the MOU as legal certainty for the community. The findings of this study are to show the existence of domestic products and to strengthen domestic products to obtain legal certainty. This writing use normative legal research with normative juridical approach. The normative juridical approach is an approach that refers to the applicable laws and regulations.

3 Discussion

The government is obliged to deal with the Covid-19 pandemic in various efforts to stop the spread and transmission of the Covid-19 virus. One of the efforts to make this happen is through efforts to procure a Covid-19 vaccine with procedures for procuring goods/services in handling emergencies. The implementation of the procurement of goods/services in handling emergencies has the principles of being effective, efficient and accountable, but on the other hand, community supervision has the potential to be reduced because of these principles. The procedure for implementing the procurement of the Covid-19 vaccine is guided by the procedures and rules for the implementation of the procurement of goods/services in handling emergencies as determined by LKPP Regulation Number 13 of 2018. Furthermore, in the implementation of the procurement of the Covid-19 vaccine, the community acts as an external supervisor in the implementation procurement of the Covid-19 vaccine [1].

Several COVID-19 vaccines that are 'recognized by the world' or included in the WHO's emergency use listing list are the Pfizer vaccine, Moderna vaccine, Sinopharm vaccine, Sinovac vaccine, AstraZeneca vaccine [2]. The Nusantara vaccine first appeared under the name 'Joglosemar' in December 2020. This vaccine was developed by PT Rama Emerald Multi Sukses (Rama Pharma) in collaboration with AIVITA Biomedical Inc, a US company as a supplier of dendritic technology. This is a claim of the same advantages, namely the use of the world's first dendritic cell base, which is a plus, can create antibodies for life. The Nusantara vaccine research is supported by funding from the Ministry of Health's Research and Development Agency (Litbangkes) (Health Research and Development).

The second vaccine after the Nusantara vaccine is Merah Putih vaccine. By Presidential Regulation Number 99 Year 2020 concerning Vaccine Procurement and Vaccination Implementation in the context of the COVID-19 Pandemic, the POM is assigned to approve use during an emergency (Emergency Use Authorization/EUA) or distribution

permitted COVID-19 vaccines. The COVID-19 vaccine developed in Indonesia is Merah Putih vaccine by several researchers and in collaboration with pharmaceutical industry partners.

One of Merah Putih vaccines is entering the production stage, namely the COVID-19 vaccine developed by Airlangga University Researchers (Cooperation and Public Relations, 2021) and in partnership with PT Biotis Pharmaceuticals Indonesia. To oversee the fulfillment of the standards and requirements for the production of Merah Putih vaccine, the POM Agency assists including the fulfillment of the application of Good Manufacturing Practices (CPOB) to PT Biotis Pharmaceuticals Indonesia as a full commitment to the POM Agency's support for the development of the domestic COVID-19 vaccine.

The analysis of domestic vaccines is full of debate and the manufacture of domestic vaccines certainly has a good goal, namely for the independence of the country's vaccination, the characteristics of vaccines that are specific to virus variants in Indonesia, and can help increase the number of vaccine doses available. Dahlan Iskan [3] ensured that this national vaccine was only related to the distribution permit issue.

Another opinion is that collaborative efforts in the context of developing and manufacturing ensure equitable distribution of vaccines to all member countries of The Covid-19 Vaccines Global Access Facility (COVAC) initiative [4]. This leads to the legal aspect of the aim of distributing vaccines fairly. This is a legal goal for vaccine development.

The decision on the fate of the Nusantara vaccine is through an MoU (Memorandum of Understanding) between the Ministry of Health, the Indonesian Food and Drug Supervisory Agency (BPOM), and the Indonesian National Army (TNI AD) that research on Nusantara vaccines was previously on a 'vaccine research platform'. Under the supervision of BPOM, will be transferred to 'Service-Based Research' under the supervision of the Ministry of Health. Officers and research funding will be entirely the affairs of the Indonesian Army. And this vaccine cannot be mass-commercialized and no marketing authorization is required, research on dendritic cells to increase immunity to Covid-19 will start again from scratch. The research will not continue the Nusantara Vaccine project. The initial step will be to consolidate the research team from RSPAD, Vaccines Nusantara, Clinical Research Organizer (CRO), and also sponsors, namely PT Rama Emerald and AIVITA Indonesia regarding future development plans [5]. The above indicates that the Nusantara vaccine is a service-based research product and is not a product of service-based research. 2021 [6] and after the MOU of Dendritic Cells to Enhance Immunity Against the SARS-CoV-2 Virus' and this can be illustrated in the following chart at Table 1.

Table 1 shows that there are significant differences, especially in the research platform and the projection of the Indonesian vaccine. The research platform before the MOU was a research project under the supervision of BPOM. Implementation after the MOU is service-based research whose supervision is under the Ministry of Health [7].

Research with a research objective platform is that research output is a product resulting from research that can be classified based on the type of research output produced, then the commercialization of research results can be categorized into two, namely direct commercialization and indirect commercialization, and this research expects direct commercialization [8]. Meanwhile, the service-based research approach is a breakthrough

Table 1. Nusantara vaccine

	Before MOU (19 April 2022)	After MOU
Persons	Terawan Agus Putranto, Jonny Jonny, Enda Cindylosa Sitepu, Raoulian Irfon (Jonny et al., 2022).	The research team from RSPAD, Vaccines Nusantara, Clinical Research Organizer (CRO), and sponsors, (PT Rama Emerald and AIVITA Indonesia)
Research costs	PT Rama Emerald Multi Sukses (Rama Pharma), with AIVITA Biomedical Inc California	Officers and financing from TNI AD
Projection Vaccine	There is a clinical permit application and distribution and is connected to the care-protect application,	It cannot be commercialized in bulk and no marketing authorization is required. This reason is autologous or individual (Kemenkes, 2021)

effort to accelerate research with an orientation on the downstream side (the service side) [7].

Several officials and the public many elite officials in Indonesia announced that they had received an injection of the primary dose of corona virus vaccine (Covid-19) and a booster dose [8]. The projection of the archipelago after the MOU that the Nusantara vaccine is a vaccine that cannot be commercialized and does not need a distribution permit, then the people who want the Nusantara vaccine on their wish will be given an explanation of the benefits and side effects by the researchers. Then, when the prospective patient agrees, the Nusantara vaccine can be given with the patient's consent. This means that dendritic cells are autologous, meaning that they are made from materials used from and for ourselves, so they cannot be used for other people, so the product can only be used for the patient himself. In other words, the development of this vaccine is carried out using the autologous dendritic cell method, which means that the vaccine platform is taken from the individual cells themselves (Ramadhan, no date).

Legal certainty can be studied in the existence of an MOU made by the parties. MOU or understanding or Memorandum is an unofficial note/warning letter which is a form of communication that contains, among other things, suggestions, directions and information [9]. And Black's Law Dictionary, defines the memorandum is to serve as the basis of future formal contract [10]. Even the Memorandum of Understanding is the same as other agreements in various fields, such as trade, buying and selling, agreements between countries and investment [11]. Meanwhile, European countries are more familiar with Head Agreements, Cooperation Agreements, and Gentlement Agreements [12].

There are no special arrangements regarding the MoU but it can be stated that the MoU is nothing but a preliminary agreement, then the arrangement is subject to the provisions of the agreement contained in Book III of the Civil Code, as long as the preparation of the MoU fulfills the legal requirements of an agreement as stated in

Article 1320 of the Civil Code, so it can be stated that currently the business agreement in the form of an MOU is still valid until another agreement is reached.

4 Conclusion

The Nusantara vaccine is a vaccine that has the potential to increase the nation's independence in the need for vaccines. The position of the Nusantara vaccine is as a service-based research platform and can be used individually by the community. The business agreement in the form of an MoU regarding vaccines as service-based research is still valid until another agreement is reached.

Acknowledgments. We thank to Universitas Negeri Surabaya as a donor for this research publication.

Authors' Contributions. Emmilia Rusdiana arranged all the article writing. Arinto Nugroho compile of the article writing framework. Eny Sulistyowati arranged based on the template writing. Muh. Ali Masnun had an idea of the theme of article writing.

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