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INDONESIAN CONSUMER PROTECTION RELATED COVID-19 VACCINE THROUGH A PERMIT FROM THE DRUG AND FOOD SUPERVISORY AGENCY, INDONESIAN NATIONAL STANDARDS AND THE HALAL LABEL OF THE INDONESIAN ULAMA COUNCIL

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Abstract. Coronavirus is a disease that has shocked the world, including Indonesia. The emergency of the Covid-19 vaccine is not only related to efforts to prevent the covid-19 virus but also related to consumer protection as vaccine recipients that must be considered. This because the Covid-19 vaccine can be categorized as a type of goods so that it refers to article 8 paragraph 1 point an of law no.8 of 1999 on consumer protection. Then business actors are prohibited from producing and or trading goods and or services that do not meet or do not comply with the standards required by the provisions of laws and regulation. This means that in Indonesia, consumer goods must obtain a permit from The Good and Drug Supervisory Agency, Indonesia National Standards, and the Indonesian Ulama Council halal label. And the type of research is normative juridical research with the nature of research in the form of analytical descriptive, which discloses laws and regulations related to legal theories. This research was conducted by approaching, reviewing all laws and regulations related to the legal issues being handled. Data collection techniques are carried out by examining the existing document, namely with legal materials and information in the form of books, scientific essays, laws, and regulations, and other written materials related to the object of research. Data analysis that will be carried out qualitatively which can make it easier to analyze the problems to be discussed, interpret and then draw conclusion using logical thinking which is done deductively.

Keywords : Protection, Consumer, Vaccine Covid-19.

1. INTRODUCTION

Indonesia as one of the countries in the world today is experiencing the impact of the spread of the Covid-19 virus, so as a form of responsiveness to this, the President

of the Republic of Indonesia issued a regulation in the form of Presidential Decree (Keppres) No. 12 of 2020 concerning the Determination of Non-Natural Disasters for the Spread of Corona Virus Disease 2019 (Covid-19) as a National Disaster which was stipulated on April 13, 2020. Previously, the efforts made by the government were not only limited to these rules but there were several regulations that had been issued as Measures to prevent the spread of the Covid-19 virus include:

1. Presidential Decree No. 7 of 2020 concerning the Task Force for the Acceleration of Handling Corona Virus Disease 2019 (Covid-19);

2. Presidential Decree No. 9 of 2020 concerning Amendments to Presidential Decree No. 7 of 2020 concerning the Task Force for the Acceleration of Handling Corona Virus Disease 2019 (Covid-19) through Synergy between Ministries/Agencies and Local Governments.

The concern of the government of the Republic of Indonesia is not only limited to the formation of regulations to overcome the spread of the Covid-19 virus but also with the importation of various types of vaccines from abroad and vaccines made by the government of the Republic of Indonesia which aim to prevent and increase the immunity of the Indonesian people against the Covid virus. -19. These vaccines include:

1. Sinovac vaccine comes from the People's Republic of China (PRC);

2. The Oxford-AstraZeneca vaccine comes from the UK;

3. Sinopharm vaccine comes from the People's Republic of China (PRC);

4. Moderna vaccines come from the United States;

5. Pfizer-BioNTech vaccine comes from the United States of America;

6. Novavax vaccine comes from the United States;

7. The Red and White Vaccine by the Indonesian nation.

The existence or use of the vaccine for the Indonesian people certainly cannot be separated from the supervision of 3 (three) institutions or agencies in Indonesia. The three bodies or institutions are the Standardization Institute which issues the National Standard of the Republic of Indonesia (SNI) label, the Food and Drug Supervisory Agency (BPOM) and the Indonesian Ulema Council which issues the halal label. The existence of these institutions can provide legal protection to the Indonesian people who want to use the vaccines mentioned above. This means that the existence of these agencies/institutions guarantees the feasibility of using vaccines so that the Indonesian people can avoid news containing hoaxes.

The institution or agency will provide or guarantee the interests of the Indonesian people as consumers. Thus, this will prevent conflicts of interest between the public (consumers) as vaccine users and the government as vaccine providers (producers).

Based on the description above, a study will be carried out related to "Indonesian Consumer Protection Regarding the Covid-19 Vaccine Through Permits from the Food and Drug Supervisory Agency (BPOM), Indonesian National Standards (SNI) and the Halal Label of the Indonesian Ulema Council (MUI)".

2. LITERATURE REVIEW

Based on the above background and to provide limitations on the assessment, the problems are formulated as follows:

1. How are the regulations for the Licensing of the Food and Drug Supervisory Agency, the Indonesian National Standard and the Halal Label of the Indonesian Ulema Council for the Covid-19 vaccine?

2. What is the government's responsibility for the Covid-19 vaccine that does not comply with the Food and Drug Supervisory Agency Permit, Indonesian National Standards and the Halal Label of the Indonesian Ulema Council?

2.1 Research Objectives

This research aims, namely:

1. To find out and analyze the regulation of the mandatory BPOM Permit, SNI and MUI Halal Label for the covid-19 vaccine.

2. To find out and analyze the government's responsibility for the covid-19 vaccine that does not comply with the BPOM Permit, SNI and the MUI Halal Label.

3. RESEARCH METHODS/METHODOLOGY

The research method contains a description of the method or method used to obtain data or information. The type of research conducted in this research is normative legal research where this research is descriptive analytical with a statutory approach. The normative legal research data used is secondary data consisting of primary, secondary and tertiary legal materials. The data collection technique was carried out by means of library research with qualitative data analysis.

The theory used as a tool to conduct analysis in this research is the theory of legal certainty. In the concept of law according to H.L.A Hart, there are times when the words in a law and what it commands in a particular case can be very clear, but sometimes there may be doubts regarding its application. Such doubts can sometimes be resolved through interpretation of other legal provisions. According to H.L.A Hart, this is an uncertainty (legal uncertainty) in the provisions of the law.

A. Booth and P. Mc. Cawley quoted by Mahmul Siregar, said:

"Each regulation seems to give rise to another regulation, so that in the end, lower-level officials in regional and port offices feel free, and even have to make vague things by issuing their own regulations."

This opinion is related to legal uncertainty in the port area so that certain authorities can set vague regulations in trading activities.

Legal certainty in terms of substance must also be supported by legal substance in other fields of business law and also determine aspects of certainty in the structure of law enforcement. In this latter case, the application of the rule of law and legislation in concrete events through the decisions of the judiciary becomes a highlight factor for the existence of legal certainty. In this perspective, it is the judiciary that gives the image of legal certainty. What can make business actors or investors feel calm in doing business is if legal certainty is clear, because with legal certainty business actors or investors can make a number of predictions about the business plans they are doing. Whenever business actors enter into an agreement in business activities, the main consideration in this case is the governing legal issue, the aim is for legal certainty.

4. RESULTS AND DISCUSSION

1. Regulation of Obligations for BPOM, SNI and MUI Halal Labels for Covid-19 Vaccines

Legal protection for consumers is closely related to the existence of consumers as users of goods and business actors (producers) as producers of goods and services. This means that the existence of legal protection for consumers is not absolutely owned by consumers but also belongs to business actors. Consumers as part of consumer protection have protection, one of which is contained in Article 8 paragraph 1 letter a of Law no. 8 of 1999 concerning Consumer Protection where the article can be interpreted, namely that business actors are prohibited from producing or trading goods or services that do not meet the standards required by law. The regulation contains the sentence "standards required by law" where the sentence can be interpreted as protection through SNI, BPOM and the MUI halal label.

SNI regulation can be found in Law no. 20 of 2014 concerning Standardization and Conformity Assessment and Government Regulation no. 102 of 2000 concerning National Standardization. SNI is a standard set by the National Standardization Agency and applies nationally. Regulations related to SNI are first contained in Government Regulation no. 102 of 2000 concerning National Standardization. The existence of SNI as a standardization related to products in Indonesia is marked by the provision of a certificate and/or the affixing of an SNI mark. That is, as proof that a product has been declared to meet SNI, a certificate will be given which is a written guarantee given by an accredited institution/laboratory to state that the goods, services, processes, systems or personnel have met the required standards and are affixed with the SNI mark which is certification mark affixed to packaged goods or labels stating that the requirements of the Indonesian National Standard have been fulfilled.

The result of standardization and conformity assessment is the provision of certificate ownership and/or affixing of SNI marks and/or conformity marks. The nature of the application of SNI to goods, services, systems, processes, or personnel is voluntary and mandatory. SNI must be applied to goods, services, systems, processes, or personal with the category of interests of safety, security, health, or preservation of environmental functions and goods, services, systems, processes, or personal that do not fall into that category. volunteer. This is in accordance with Article 21 paragraph (1) and Article 24 paragraph (1) of Law no. 20 of 2014 concerning Standardization and Conformity Assessment. Furthermore, referring to the description above, the government should (in this case, distribute it through a company appointed as a distributor) which is a business actor. Carrying out SNI certification is because Article 24 paragraph (1) of Law no. 20 of 2014 concerning Standardization and Conformity Assessment requires products or goods in the health sector to register them not voluntarily.

BPOM is one of the institutions that carry out government duties to supervise the field of medicine and food. If you look at the task, BPOM is one of them to supervise the field of medicine. In drug settings, vaccines belong to the same biological product as drugs. This means that in the process of registering vaccines, specifically the COVID-19 vaccine and drugs, to the BPOM agency, it is carried out in the same way. The issuance of a distribution permit from BPOM in addition to meeting administrative requirements must also meet the requirements for good drug manufacture as regulated in BPOM Regulation No. 34 of 2018 concerning Guidelines for Good Medicine Manufacturing Practices.

Good Manufacturing Practices, hereinafter abbreviated as CPOB, is a method of manufacturing drugs and/or drug ingredients with the aim of ensuring that the quality of drugs and/or medicinal ingredients produced meets the requirements and intended use.

GMP guidelines must be a reference for the pharmaceutical industry and facilities that carry out drug manufacturing activities and drug ingredients. To protect the public against things that can harm health, it is necessary to prevent the circulation of vaccines that do not guarantee quality requirements. Quality control is part of GMP which includes sampling, specification and testing, and includes organization, which is required and relevant has been carried out. The pharmaceutical industry that does not follow the GMP reference will be subject to several administrative sanctions, namely:

a. Warning;

b. Strict Warning;

c. Temporary suspension of activities;

d. Freezing of GMP Certificate;

e. Revocation of GMP Certificate;

f. Recommendation for Revocation of Pharmaceutical Industry Permit.

The Covid-19 vaccine in Indonesia is known to come from abroad, in addition to complying with the above provisions, it must also comply with the regulations contained in BPOM Regulation No. 30 of 2017 concerning Supervision of the Importation of Drugs and Food into the Territory of Indonesia.

Furthermore, in addition to the SNI label and BPOM permit above, there is 1 (one) more thing that must be included in a covid-19 vaccine containing the halal label from the MUI. The meaning of the MUI halal label is a guarantee from the Government which has the responsibility to ensure the availability of halal drugs. In addition, manufacturers and scientists in the fields of pharmacy and medicine are also responsible, both legally and morally, to ensure that drugs that are circulated and used by the Muslim community are halal and holy. This is based on the mandate of laws and regulations that provide guarantees for halal products circulating in Indonesia, which contains the majority of the Muslim population. The mandate of the laws and regulations, namely:

a. Guarantee for freedom of worship in accordance with their respective religions and beliefs;

b. The existence of halal products basically aims to provide convenience, security, safety, and certainty of the availability of Halal Products for the public in consuming and using Products and increasing added value for Business Actors to produce and sell Halal Products;

c. To provide legal certainty and guarantee for the public on the halalness of Products that enter, circulate, and are traded in the territory of Indonesia.

Referring to the description above, it is clear that the covid-19 vaccine in circulation must have SNI, BPOM distribution permit and halal label as regulated in laws and regulations so as to guarantee legal certainty for the Indonesian population. If you look closely, only halal labeling has not confirmed that MUI is the only one that can issue the halal label.

2. Government Accountability Against Covid-19 Vaccines That Do Not Comply With BPOM Permits, SNI And MUI Halal Labels

The validity of the COVID-19 vaccines in Indonesia is based on an emergency use authorization (EUA). In Indonesia, the government gives EUA to the pharmaceutical industry based on which if viewed from the regulation, the responsibility for the vaccines is transferred to the pharmaceutical industry. This can be seen from the responsibilities of the pharmaceutical industry, as follows:

a. Responsible for the quality of Drugs;

b. Conduct follow-up studies/clinical trials on drugs currently under clinical trial research in the world to ensure their effectiveness and safety;

c. Monitoring pharmacovigilance and reporting of drug side effects to the Head of the Agency in accordance with the provisions of the legislation; and

d. Report the realization of importation, production, and distribution of Drugs during the approval of emergency use to the Head of the Agency in accordance with the provisions of laws and regulations.

This means that the EUA approval granted by the BPOM agency to the pharmaceutical industry shifts all the conditions for distribution of vaccines that are part of a health product to the prevailing laws and regulations.

Vaccine distribution permit should include an SNI permit with the EUA approval granted by the BPOM, then SNI is not required to be included or the SNI standardization process is no longer needed. However, if viewed carefully, the SNI permit provides legal protection to consumers where if a health product does not include an SNI permit, it will be subject to sanctions as stated in Article 64, Article 65, Article 66 and Article 67 of Law no. 20 of 2014 concerning Standardization and Conformity Assessment. Furthermore, the BPOM distribution permit in which the issuance of the covid-19 vaccine must pass the test and administrative requirements, especially CPOB where if it does not pass these requirements it will not obtain a BPOM distribution permit and any health product or vaccine that does not have a distribution permit will be subject to Article 106 and Article 197 Law No. 36 of 2009 concerning Health.

Basically, the MUI halal label when referring to its institutions, constitutionally it does not have binding legal force, but religiously the institution is a representative or forum for scholars who are used as role models for Indonesian citizens who are Muslim to obtain instructions in daily activities or relationships. However, if you look closely at the laws and regulations, MUI is not the only absolute institution to issue halal certificates, but if business actors misuse the certificate, they can be held criminally responsible according to applicable laws and regulations, namely Articles 56 and 57 of the Law 11 of 2020 concerning Job Creation in conjunction with Law no. 33 of 2014 concerning Halal Product Guarantee. However, regarding the Covid-19 vaccine, the MUI has issued a fatwa related to its use which is listed in the MUI Fatwa No. 14 of 2021 concerning the Use of the Covid-19 Vaccine for Astrazeneca Products and MUI Fatwa No. 2 of 2021 Regarding Covid-19 Vaccine Products From Sinovac Life Sciences CO. LTD. China And PT. BIO Farma (Persero).

Furthermore, even though the EUA is in effect, it does not mean that the product cannot be held liable. It can be held accountable in accordance with Law no. 8 of 1999 concerning Consumer Protection. The emergence of consumer protection gave birth to product responsibility or product liability. The birth of product liability because there is an imbalance of responsibility between business actors and consumers. The application of product liability makes the marketing direction of business actors initially product oriented to become consumer oriented. This is because the application of product liability makes business actors have to be careful with their products because product liability adheres to strict liability.

Product liability when viewed from its scope is the legal responsibility of the person or entity that produces a product (producer, manufacture) or of a person or entity engaged in a process to produce a product (processor, assembler) or of a person or entity that sell or distribute (seller, distributor) the product. However, product liability is not only limited to that, it includes people/entities involved in commercial series regarding the preparation or distribution of products including workshop and

warehousing entrepreneurs. Thus, product liability is the responsibility of business actors. The regulation of the responsibilities of business actors contained in Law no. 8 of 1999 concerning Consumer Protection, as follows: Article 19, Article 20, Article 21, Article 22, Article 23, Article 24, Article 25, Article 26, Article 27 and Article 28 of Law no. 8 of 1999 concerning Consumer Protection.

The product liability above does not only contain strict liability but also contains an element of reverse proof. The reverse evidence adopted in consumer protection in Indonesia does not rule out the possibility for prosecutors to prove. This means that the negative evidence contained in the criminal procedure law is not lost. In addition, if the elements of a criminal act above are fulfilled, then for criminal liability if he is a human, it can be seen through the elements of criminal responsibility, namely:

a. Having the ability to be responsible

The ability to be responsible is related to 2 (two) important factors, namely:

1) The reason factor is to distinguish between permissible and prohibited acts or violating the law.

2) Feelings or will factors that determine his will by adjusting his behavior with full awareness.

b. Having a form of error in the form of intentional (dolus/opzet) or negligence (culpa)

c. No error eraser reason

There is no excuse for forgiveness is that there is an ability to be responsible, the form of intention is intentionally or negligent, without being erased from the mistake or there is no excuse for forgiveness, is included in the definition of error (schuld). There is no justification for the existence of an unlawful nature in which a person is not in a state of emergency, forced defense, carrying out laws and regulations and carrying out office orders where as if the business actor is an artificial legal subject in this case a corporation, then the criminal liability can refer to the opinion of Mardjono Reksodiputro who put forward a model of corporate criminal responsibility, as follows:

a. Corporate management as responsible corporate makers and administrators.

b. Corporations as producers and administrators are responsible.

c. Corporations as producers and also responsible corporations.

The existence of EUA further emphasizes the government's responsibility in this case BPOM. EUA is based on BPOM Regulation No. 27 of 2020 concerning the Second Amendment to the Regulation of the Head of BPOM No. 24 of 2017 Regarding the Criteria and Procedure for Drug Registration, BPOM and the Decree of the Head of BPOM No. HK.02.02.1.2.11.20.1126 of 2020 concerning Technical Guidelines for the Implementation of Emergency Use Authorization. If the existence of the regulation is considered detrimental to the community, especially regarding the cutting of several regulations, the community in this case can file a lawsuit against the law against the government, namely a Citizen Lawsuit (CLS) lawsuit. CLS is one of the lawsuit models that has often been filed in Indonesia, although there is no direct legal basis. CLS as a model for a lawsuit against PMH carried out by the authorities is a dispute resolution originating from countries adhering to the Anglo Saxon system or the common law system. CLS gives citizens the power to sue certain (private) that violate the law in addition to the power to citizens to sue the State and (federal) institutions that violate the law or fail to fulfill their obligations in implementing the law.

Furthermore, the current COVID-19 vaccines are based on the EUA whose regulations and distribution of the vaccine are the responsibility of BPOM, if there is a use or effect that is not in accordance with the analysis and assessment that has been carried out, it is the responsibility of BPOM nor is it absolutely the responsibility of BPOM. the pharmaceutical company replied. This responsibility is where BPOM is considered not to carry out its authority properly because BPOM should know about its duties but it is not carried out properly, therefore parties who feel aggrieved by BPOM's supervision can sue BPOM on the basis of Article 1365 of the Civil Code which is said to be an act. violate the law by filing a civil suit in the competent district court.

5. CONCLUSION

1. The regulation of the obligation for BPOM Permits, SNI and MUI Halal Labels for the covid-19 vaccine is basically referring to the implementation of the SNI obligations listed in Article 24 paragraph (1) of Law no. 20 of 2014 concerning Standardization and Conformity Assessment, BPOM distribution permit refers to BPOM Regulation No. 34 of 2018 concerning Guidelines for Good Manufacturing Practices and MUI halal labels refer to Law Number 33 of 2014 concerning Guaranteed Halal Products in conjunction with Law Number 11 of 2020 concerning Job Creation, the permits of which are from Article 8 paragraph (1) letter a Law no. 8 of 1999 concerning Consumer Protection.

2. The government's responsibility for the covid-19 vaccine that does not comply with the BPOM Permit, SNI and the MUI Halal Label is basically related to the covid-19 vaccine that has been implemented by the EUA so that there is no obligation to apply SNI permits, BPOM distribution permits in general or the MUI halal label eliminate government responsibility. Government responsibilities can be held jointly and severally through civil lawsuits and Citizen Lawsuits.

REFERENCES

Book

Hart, H.L.A, The Concept of Law, (New York: Clarendon Press-Oxford, 1997) translated by M. Khozim, Legal Concepts, Bandung: Nusamedia, 2010.

Kanter, E.Y. & S.R. Sianturi, Principles of Criminal Law in Indonesia and Its Application, Jakarta: Storia Graphic, 2002.

Kristiyanti, Celina Tri Siwi, Consumer Protection Law, Jakarta: Sinar Graphic, 2009.

Mertokusumo, Sudikno, Introduction to Law, Yogyakarta: Liberty, 2003.

Reza, Aulia Ali, Corporate Accountability in the Draft Criminal Code, Jakarta: Institute for Criminal Justice Reform & the National Alliance for Criminal Code Reform, 2015.

Sahetapy, J.E. & Agustinus Pohan (ed), Criminal Law, Bandung: PT. Image of Aditya Bakti, 2007.

Saleh, Roeslan, Criminal Acts and Criminal Liability, Jakarta: New Script, 1983.

Siregar, Mahmul, Legal Certainty in International Business Transactions and Its Implications for Investment Activities in Indonesia, Medan: USU Faculty of Law, undated.

Soekanto, Soerjono and Sri Mamudji, Normative Legal Research: A Brief Overview, Jakarta: PT. Raja Grafindo Persada, 2001.

Subagyo, A Simple Book Understanding the Principles of Consumer Protection, Surabaya: Without Publishers, 2010.

Tarigan, Muhammad Iqbal, Lecture Material on Consumer Protection Law (Business Actors) Graha Kirana College of Law, Medan: Without Publisher, 2015.

Tongat, Fundamentals of Indonesian Criminal Law in Renewal Perspective, Malang: UMM Press, 2004.

Constitution

1945 Constitution of the Republic of Indonesia

Law No. 20 of 2014 concerning Standardization and Conformity Assessment

Law No. 33 of 2014 concerning Halal Product Guarantee

Law Number 11 of 2020 concerning Job Creation

Government Regulation No. 102 of 2000 concerning National Standards

Government Regulation No. 39 of 2021 concerning the Implementation of the Halal Product Assurance Sector

Presidential Regulation No. 80 of 2017 concerning the Food and Drug Supervisory Agency

Regulation of the Head of BPOM No. 24 of 2017 concerning Criteria and Procedure for Drug Registration

BPOM Regulation No. 30 of 2017 concerning Supervision of the Importation of Drugs and Food into Indonesian Territory

BPOM Regulation No. 34 of 2018 concerning Guidelines for Good Medicine Manufacturing

BPOM Regulation No. 27 of 2020 concerning the Second Amendment to the Regulation of the Head of BPOM No. 24 of 2017 concerning Criteria and Procedure for Drug Registration

Decision of the Head of BPOM No. HK.02.02.1.2.11.20.1126 of 2020 concerning Technical Guidelines for the Implementation of Emergency Use Authorization (Emergency Use Authorization).

Journal

Bolendea, Anastasia Isabelle Regina, “Consumer Protection Against the Circulation of Traditional Medicines Made from Medicinal Chemicals According to Law Number 8 of 1999 concerning Consumer Protection”, In Lex Privatum Journal Vol. VII/No. 2/Feb/2019, 2019, Manado: Unsrat.

Purba, Simon et.al, “The Judge's Considerations in Sentencing the Plaintiff's Lawsuit Decision Was Completely Rejected Against Citizen Lawsuit In Lubukpakam District Court Decision No. 24/Pdt.G/2017/PN.Lbp”, In Mutiara Hukum Journal Vol. 3 No. 1, 2020, Medan: Sari Mutiara University of Indonesia.

Rufaidah, Ani, "Responsibility of the Food and Drug Supervisory Agency Against the Circulation of Ranitidine", In the Journal of Jurist-Diction Vol. 3(6), 2020, Surabaya: Airlangga University.

Sholeh, Asrorun Ni'am, “Halal Guarantee in Medicinal Products: A Study of MUI Fatwa and Its Absorption in the Law on Halal Product Assurance”, In Sharia Journal 3, November 2015, South Tangerang: UIN Syarif Hidayatullah Jakarta.

Website

https://www.alodokter.com/kenali-beda-vaksin-vaksin-covid-19-yang-akan-digunakan-di-indonesia, accessed 15 July 2021

https://health.detik.com/berita-detikhealth/d-5319253/jangan-jaringan-kera-ini-kandungan-vaksin-covid-19-sinovac-actually, accessed July 15, 2021

https://kesehatan.kontan.co.id/news/like-ini-beda-di-antara-eul-dan-eua-untuk-vaksin-covid-19?page=all, accessed 18 July 2021