

Legal Protection of Consumer Rights Related to Misuse of Used Antigen Rapid Test Medical Devices Based on Law Number 8 of 1999 Concerning Consumer Protection

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ABSTRACT

The Indonesian government has an obligation to protect every citizen in any situation and condition. Protection from the government must be given to the community if there is an impact, not only to the community but also to an impact that occurs in the economy and politics on the government. Since March 2020 until now, Indonesia is facing a corona virus pandemic. Due to the virus, the government issued Government Regulation Number 21 of 2020 concerning Government Regulation (PP) concerning Large-Scale Social Restrictions in the Context of Accelerating Handling of CoronaVirus Disease 2019 (COVID-19). One of the policies is the rapid antigen test to prevent the spread of the virus and as a condition for traveling outside the city. In addition to being regulated by the Minister of Health, consumers are given protection according to Law Number 8 of 1999 concerning Consumer Protection. Consumers are given rights that are guaranteed and protected by the government in Article 4 of the consumer protection law. Despite having two regulations, it turns out that in the field there are still cases of misuse of medical devices by the perpetrators. One of the business actors who abused the rapid test medical device at Kualanamu Airport, North Sumatra. The formulation of the problem in this study is how the legal protection of consumer rights related to the misuse of used antigen rapid test medical devices is based on Law Number 8 of 1999 concerning Consumer Protection. The method is used; normative juridical, with the types and sources of secondary, primary, tertiary data. The results of the research are that consumer protection in medical devices for rapid tests is still lacking in supervision and guidance, resulting in violations of the law in the health sector and harming many consumers.

Keywords: *Consumer Rights, Consumer Protection, Rapid Antigen Test.*

1. INTRODUCTION

The world is currently being faced with the spread of a virus to almost all countries. This condition has been going on since November 2019. The virus is corona virus or better known as Covid-19. The virus was originally known to come from South China (Wuhan), according to the World Health Organization (WHO) where it is transmitted from bats to wildlife farm animals, thus eventually moving to humans.[1] The World Health Organization (WHO) states that it is one of the few dangerous viruses, whose rate of spread is very fast, and very difficult to control. One of the countries that feel the impact of this virus outbreak is our country the Republic of Indonesia, and at this time the outbreak of the covid-19 virus has spread throughout the country. The beginning of positive cases of Covid-19 in Indonesia is transmitted through human-to-human transmission, so the Indonesian government is

immediately on alert by making various efforts to handle the spread of this virus.

Indonesia is a country of law, where every society is always side by side with the rule of law to ensure legal certainty to every community. The rule of law is made to discipline the community in actions that can provide harm to others. The community is also given various rights as a form of legal certainty, to protect everyone in accordance with the applicable Law, one of which is the Consumer Protection Act and the Health Law. Consumer Protection Law is stipulated in the provisions No. 8 of 1999 concerning Consumer Protection made to protect the parties, namely, consumers and businesses in trading, consuming, and distribution of goods or services. The Health Law is stipulated in the provisions no. 36 of 2017 on Health aimed at protecting and regulating every public health that has good quality, healthy, and equitable evenly. In both laws are interrelated about pharmaceutical medical

devices, one of which is a rapid test of antigens. This fast antigen test is a medical device used to check for a virus exposed to the human body. Rapid test of antigens. At this time, it is suspected of misuse of used antigen rapid test medical devices at one of the airports in Indonesia. From the explanation above, the author is interested to raise the title on legal protection of consumer rights related to the misuse of used antigen rapid test medical devices. Given the portrait of the impact of the covid-19 problem in 2020, the many impacts given in various sectors include large poverty rates, declining income figures, and a decrease in the percentage of the business and business economy. The increase in the number of poverty lines continues to increase due to the pandemic, causing many economic activities to be hampered and decreased so that some people who lose their livelihoods. Data sources in the poverty line according to the Central Bureau of Statistics (BPS) noted that there is an increase in the number of poor people in Indonesia in 2020. In the first quarter of 2020 the percentage of poor people due to the pandemic rose to 9.78%, an increase of 0.37% compared to March 2019. In September 2020 the number of poor people increased by 0.97% or 2.76 million people. The total number of people who are classified as poor is 10.79% of the population of Indonesia or equivalent to 27.55 million people.[2] Then the impact of covid-19 in the income figures in Indonesia according to Price waterhouse Coopers (PwC) which launched the results of the survey namely Global Consumer Insight 2020 with the title "Before and After The Covid-19 Outbreak" household income in Indonesia experienced a decrease that exceeded the global average, with the number of 65% consumers in Indonesia while globally only 45%. The decrease in household income was also seen in the announcement of the Central Bureau of Statistics (BPS) on the level of public consumption. According to BPS, Indonesia's household consumption rate decreased by 5.51% in the second quarter of 2020. The decrease in income and consumption level that occurred in Indonesia is the impact of the pandemic resulting in termination of employment rights (layoffs) and an increase in household consumption.

Given the increasing number of impacts that occur due to national disasters in covid-19, the government is implementing policies that help suppress the rise in the number of covid-19, one of the policies is the government imposes a working or have an interest that is required to leave the region to wear masks and conduct rapid antigen tests to prevent the spread of the virus. This government policy leads to a need that must be obeyed by the community. As we know in March 2020, the demand for masks soared due to the need for the community. so the price of masks increases very far from the market price as usual and tends to be rarer or harder to obtain because of the number of people or businesses who actually take advantage of profit by selling the price of masks that are certainly not in accordance with the price marketed earlier[3] Similarly, the government also requires the public to visit clinics or hospitals (private or government), or airports that have been certified to conduct such tests. The benefit for the community who conduct rapid tests is

to make it easier for the public to check and know if the person is being exposed to the virus, in addition to the benefits of rapid test is to use mass transportation to get out of the area if there is a need or is a need that is very important. The government sets a price tariff for Rapid Test Antibodies Rp.150.000. Similarly, Rapid Test Antigen amounted to Rp.250.000,- for Java Island, and Rp.275.000,- for outside Java island and for swab PCR price of Rp.900.000,-.

Broadly speaking, people are in desperate need of rapid test checks to be an important requirement to travel using means of transportation of ships, trains, and aircraft. The need to conduct rapid test examinations makes people flock to conduct test tests, both in clinics, hospitals, drive-thru, and at airports that provide special facilities for rapid tests. It is suspected that this rapid test becomes a business ground for certain people who misuse the medical device to reap profits, thus making the public complain and complain. This shows that the government must understand and be firm with what is happening among consumers at the time of this pandemic. Unconsciously even with complaints from the public this means there is something wrong in consumer protection. We as well as consumers should understand the rights of consumers, but in fact there are still many people who do not or do not know about the rights of consumers themselves. Whereas as a society that has consumer rights, we should understand about legal protection in the use of medical devices rapid test is correct and clear. In the efforts to protect consumers, the government has also stipulated in Law No. 8 of 1999 on Consumer Protection With this law or regulation, the right of consumers can be fulfilled in accordance with Article 4 of the consumer protection laws, namely the "Right to correct, clear, and honest information regarding the conditions and guarantees of goods and/or services". Actions taken by businesspeople or certain persons who have misused rapid tests for personal gain is very detrimental to consumers. Many consumers who feel restless, upset, and complained about the events experienced for abuse by people who take advantage in this rapid test. The public is entitled to health rights, the right to fair facilities, and the right to correct, clear, and honest information. The existence of Consumer Protection Laws and the existence of Law No. 36 of 2009 on Health is expected to guarantee consumer rights and the right of equitable facilities for the entire community. Similarly, in this Consumer Protection Laws regulates business actors, which the interests of business actors are regulated in Article 6 and Article 7 Consumer Protection Laws for the rights and obligations of business actors and for Article 8 to Article 17 Consumer Protection Laws regulates the prohibited actions for business actors. This shows that the government must understand and be firm with what is happening among consumers in the current pandemic.

One of the crimes that occurred was the practice of abuse rapid test antigen. An example of a case that occurred is at Kualanamu airport, North Sumatra. The case was revealed when The Police Crime Directorate of Sumatera Utara received information and many complaints from prospective passengers who found rapid antigen positive

results of COVID-19 within a period of approximately 1 week.[4]This antigen rapid test tool is recycled by the perpetrator by washing again using alcohol 75%. The case cost up to 1.8 M for the perpetrators but claimed nearly 30,000 victims. Judging from the case, it is still seen the lack of government supervision in businesses or certain persons in protecting consumer rights in Indonesia, especially during this pandemic.

Based on the description of the above problem, the author is interested to conduct further research and discussion in the form of thesis research entitled "LEGAL PROTECTION OF CONSUMER RIGHTS RELATED TO MISUSE OF USED ANTIGEN MEDICAL DEVICES BASED ON LAW NO. 8 OF 1999 ON CONSUMER PROTECTION"

1.1. Related Work

Based on the above information, the title of the study is titled: "Legal Protection of Consumer Rights Related to Misuse of Used Test Rapid Antigen Medical Devices Based on Law No. 8 of 1999 on Legal Protection

1.1.1. Legal protection of consumer rights related to the misuse of medical devices rapid antigen used tests under Law No. 8 of 1999 on Consumer Protection

Legal protection is a relationship given to the subject of law into the form of devices both preventive and repressive, both oral and written. The principle of legal certainty is intended so that both businesses and consumers obey the law and obtain justice in the organizers of consumer protection, as well as the state guarantees legal certainty.

Consumer protection efforts in the misuse of medical devices rapid test is very important for consumers. Consumer protection efforts to ensure legal certainty to consumers. In article 4 of the CONSUMER PROTECTION LAW on consumer rights explains that; the right to comfort, security, and safety in consuming goods and/or services; the right to choose goods and/or services and obtain such goods and/or services in accordance with the exchange rate and conditions and guarantees promised; the right to true, clear, and honest information regarding the conditions and warranties of goods and/or services; the right to be heard his opinions and complaints over the goods and/or services used; the right to appropriate advocacy, protection, and efforts to resolve consumer protection disputes; the right to coaching and consumer education; the right to be treated or served properly and honestly and non-discriminatory ; the right to compensation, indemnification and/or reimbursement, if the goods and/or services received are not in accordance with the agreement or not as.

1.2. Our Contributions

know and explain how the legal protection of consumer rights, related to the misuse of medical devices rapid test used antigens based on Law number 8 of 1999 on Consumer Protection

1.3. Paper Structure

The method of approach used in this study is the method of normative juridical approach, this research uses research specifications that are descriptive analytical, which in its operation describes or reviews a rule of law and doctrines that are connected. In this study was conducted to obtain primary data by collecting data from the literature.

2. BACKGROUND

2.1. Legal Protection for Consumers against Misuse of Used Antigen Rapid Test Medical Devices

The authors raised the issue of misuse of medical devices rapid test antigen because the problem is problematic at this time. Basically, a human being has a life in which the human being has human rights according to Law No. 39 of 1999 on Human Rights (HUMAN RIGHTS). Understanding Human Rights according to the Law that is Human Rights is a set of rights attached to the nature and existence of man as a creature of God Almighty and is His gift that must be respected, upheld and protected by the state, law, government, and everyone for the honor and protection of human dignity and dignity; One of the rights granted by the government is that everyone is entitled to a healthy life, or can be said to be entitled to have health. Health is something that is very important for every human being, because health is including the protection of human rights and one as an element of welfare that must be realized in accordance with the ideals of the Indonesian nation as intended in Pancasila and the 1945 Constitution and it is appropriate that the government and the state have an obligation to protect their citizens. Health Indonesia is regulated in the provisions of Law No. 36 of 2009 on Health, in practice this Law has been implemented well, can be seen from the progress of indicators in fulfilling the right to health where the government makes efforts and progressive efforts on the availability and affordable health care facilities for all citizens. The implementation of the right to health must meet the principles of availability, affordability, acceptance, and quality.

As we know Indonesia is experiencing a pandemic corona virus outbreak that started in Wuhan, China. Indonesia reported the first case of Covid-19 on March 2, 2020, that infected mothers and children living in Depok, West Java. The two men had contact with Japanese citizens who had previously been positive about Covid-19. The Japanese

citizen has only been detected by Covid-19 in Malaysia, after leaving Indonesia. With the corona virus, the government cooperates from various sectors to emphasize the spread of the impact of corona virus.

Then in terms of cooperation, the government has an obligation that needs to protect its citizens from corona virus. The form of measures taken by the government to prevent the spread of corona virus is to implement various public health measures including Large-Scale Social Restrictions (PSBB) in accordance with Regulation of the Minister of Health No. 9 of 2020 on Guidelines for Large-Scale Social Restrictions (PSBB) in order to Accelerate the Handling of Corona virus Disease 2019 (Covid-19) such as school and business closures, restrictions on displacement or mobilization of residents, and restrictions on national and international travel.

During the current pandemic, Indonesian people or consumers need antigen rapid test medical devices to check for covid-19 virus, and for travel conditions out of the city, especially through air transportation or airplanes. Many health care facilities are provided and facilitated by the government to check for the virus, one example is at the airport.

Based on the results of research conducted by the author, the misuse of used antigen rapid test medical devices that occurred at Kualanamu Airport, North Sumatra, according to the Chairman of BPKN this policy violates the right of Indonesian people as consumers to obtain safety, safety in utilizing rapid antigen test services [5][5]. Medical devices that existed during the current pandemic turned out to be misused by officers who worked at PT. Kimia Farma Diagnostika, which is part of BUMN. The actions taken by these people are very detrimental to many people in order to reap personal benefits.

2.2. Consumer Protection

According to Article 1 number 1 mentioned:

"Consumer Protection is all efforts that ensure the existence of legal certainty to provide protection to consumers".

From Article CONSUMER PROTECTION ACT can be stated that consumer protection means to question what is guaranteed or how certainty about the fulfillment of consumer rights. In the Consumer Protection Act be used as an umbrella act or as a basis for other legislation aimed at protecting consumers, both existing and future. This law is also an integration of legislation to strengthen law enforcement in the field of consumer protection. Speaking of consumer rights in the legal sense, generally what is meant by rights is the importance of the law that is twisted by law, while interest is a demand that is expected to be met. The interest in its nature contains powers that are guaranteed and protected by the law in carrying it out. Consumer rights itself are regulated in Article 4. In the Consumer Protection Law is used foundation for umbrella actor as a basis for other legislation aimed at protecting consumers, both existing and still to be made later. This

law is also an integration of legislation to strengthen law enforcement in the field of consumer protection.

Investigators found that every day there were 250 prospective passengers on board the plane who checked themselves in the lab. The data found approximately 37,500 consumers were victimized. The use of used antigen rapid test medical devices by officers, lacking supervision and guidance from the government, which has not been firm despite the existing regulations imposed. In addition, this act of abuse is caused by low consumer knowledge related to the use of medical devices rapid antigen tests. Consumers are too indifferent to the use of medical devices. So that the person can violate the law, because of the lack of adequate information. Smart consumers must know their rights, namely the right to get correct, clear, and honest information related to goods and /or services provided by businesses. With the correct, clear, and honest information and strict supervision on the use of medical devices rapid test antigens, consumers will avoid losses caused by officers. The importance of true, clear, and honest information for consumers related to a product can prevent consumers from misuse or unlawful acts committed by officers or businesses against a product. The delivery of information to consumers is better in relevant ways, such as direct socialization to the public about the importance of knowing the use of medical devices rapid test antigens, giving warnings through news, sms, social media, or through instructions.

2.3. Violation of law

In general, violations of the law are divided into 2 aspects, namely in terms of civil law and criminal law:

Civil Aspects In terms of civil violations of the law according to Article 1365 of the Book of Indonesian Civil Law, then what is meant by unlawful acts is an act that is against the law committed by a person, which because of his fault has caused harm to others. Which Article 1365 of the Civil Code reads:

"Any unlawful act, which brings harm to others, obliges the person who, for his fault to issue the loss, to indemnify the damages." **Criminal aspects**

According to expert Andi Hamza explained that regarding the type of criminal, there is no fundamental difference between Crime and Offense. Only on Offenses are never threatened criminally. [6]In the context of criminal law, in the opinion of Satochid Kartanegara, "against the law"(Wederrechtelijk) in criminal law is distinguished into: (a) Wederrechtelijk formil, that is, when an act is prohibited and threatened with punishment by law. (b) Wederrechtelijk Materiil, which is an act of "may" wederrechtelijk, although not expressly prohibited and threatened with punishment by law. But also, the general principles found in the field of law (*algemenbeginset*).

2.4. Legal Protection

Legal protection is a relationship given to the subject of law into the form of both preventive and repressive

devices, both oral and written. Legal Protection in general can be referred to as an effort given by the government to protect and protect the community from arbitrary per-artificial by rulers who are not in accordance with the law, as well as to realize order and welfare of the community.

2.5. The theory of Health Law in general

Health According to Law No. 36 of 2009 on Health:

"Health is a healthy health, both physically, mentally, spiritually and socially that allows everyone to live productively socially and economically."

According to health law experts that includes the law "*lex specialis*", which protects specifically the duty of the health profession (*provider*) in the human health care program to the purpose of the declaration of "*health for all*" and protection specifically against patient's "*receivers*" to get health services. Which means that it can be concluded that health law is also a rule that regulates aspects of health for better health efforts in protecting human health.

Health is important for humans, because with health we can do well. The 1948 World Health Organization's healthy understanding was "a physical, mental, and social state of well-being and not just the absence of disease or weakness". To achieve a healthy state, people need to make health efforts.

2.5.1. Scope of Health Law

The scope of the health law depends on how juridical understanding of the word "healthy" means. According to the Health Law that defines the meaning of the word healthy is a prosperous, safe, and peaceful situation for all citizens of the body. The scope consists of several aspects, namely public health, environmental health, occupational health, mental health, medical health, nursing health, and others.

2.5.2. Division in Health Efforts

According to the definition of Law No. 36 of 2009 Health efforts are every activity or series of activities carried out in an integrated, and sustainable manner to maintain and improve the degree of public health in the form of disease prevention, health improvement, disease treatment, and health recovery by the government and /or the community. In the form of these health efforts, the government provides health care facilities to support and improve health in the community. Health efforts are organized in health care facilities with a tool, activity and / or place used to organize health services efforts both promotive, preventive, curative and rehabilitative conducted by the local government, and / or the community. In Article 48 Health Law mentions health efforts implemented through activities: health services, traditional health services, improving health and disease prevention, disease healing and health recovery, reproductive health, family planning, school health, sports health, health services in disasters,

blood services, dental and oral health, tackling vision and hearing loss, health, security and use of pharmaceutical preparations and medical devices, food and beverage security, security of substances addictive and/or surgical corpses.

2.6. Responsibilities

Responsibility is human awareness of intentional or unintentional behavior or actions. Responsibility also means to do as a manifestation of awareness of its obligations. The principle of responsibility is a very important subject in consumer protection law. In case of violation of consumer rights, caution is required in analyzing who should be responsible and how far responsibility can be charged to the relevant parties

In general, the principle of liability in law can be distinguished as Follows: Error, Presumption of always being responsible, Presumption always irresponsible, Absolute liability, Limitation of liability.

2.7. Legal Certainty

According to expert Sudikno Mertokusumo, legal certainty is a guarantee that the law must be carried out in a good way. [7] Legal certainty can be said as a guarantee of the law so that the rules have a juridical aspect that can guarantee a rule that must be obeyed.

Certainty according to Jan Michiel Otto defines as the possibility that in the situation:[8]

- a. There are clear rules available, consistent, and easy to obtain, published by and recognized because of the (power) of the state.
- b. The ruling agencies (government) apply the rule of law consistently and t to obey him.
- c. Citizens principally adjust their behavior to certain rules.
- d. Judges (judiciary) who are independent and do not think apply the rules of law in a consistent manner as they resolve legal disputes.
- e. The judicial review was concretely implemented.

2.7.1. Legal Protection for Consumers according to Consumer Protection Laws

Legal protection is a relationship given to the subject of law into the form of devices both preventive and repressive, both oral and written. The principle of legal certainty is intended so that both businesses and consumers obey the law and obtain justice in the organizers of consumer protection, as well as the state guarantees legal certainty.

Consumer protection efforts in the misuse of medical devices rapid test is very important for consumers. Consumer protection efforts to ensure legal certainty to consumers. In article 4 of the CONSUMER PROTECTION LAW on consumer rights explains that; the right to comfort, security, and safety in consuming

goods and/or services; the right to choose goods and/or services and obtain such goods and/or services in accordance with the exchange rate and conditions and guarantees promised; the right to true, clear, and honest information regarding the conditions and warranties of goods and/or services; the right to be heard his opinions and complaints over the goods and/or services used; the right to appropriate advocacy, protection, and efforts to resolve consumer protection disputes; the right to coaching and consumer education; the right of to be treated or served properly and honestly and non-discriminatory; the right to compensation, indemnification and/or reimbursement, if the goods and/or services received are not in accordance with the agreement or not as appropriate.

Based on the results of the study authors, in this case consumer protection against victims of misuse of medical devices, is still not in accordance with the legal procedures applicable to the CONSUMER PROTECTION ACT. Because so far, no consumer has filed a complaint to Consumer Dispute Resolution Agency or Indonesian Consumer Institute Foundation related to the losses felt by consumers. According to the agency, they can only move if there are complaints submitted by victims, if there are no complaints or reporting then they cannot help and move to do consumer protection. In this case the Institution can only provide advice and advice to consumers for the future.

Referring to the legal protection of Consumer Protection Act Article 4 in the context of the right to comfort, safety, and safety of consumers with the relationship of cases of abuse of medical devices antigen rapid test used there is no legal certainty. Because the government does not conduct strict supervision and does not facilitate legal certainty, so consumer rights are not fulfilled. From the data obtained from the results of the study, about 37,500 victims did not get the right of compensation that they should get as written in Article 4 of the Consumer Protection Act. In fact, the Consumer Protection Act is intended to avoid unpleasant actions taken by businesses to consumers. In Article 8 letter (b), (d), and (e) the CONSUMER PROTECTION ACT it is explained that there is a prohibited act for businesses not to produce and/or trade the preparation of damaged, defective, or used and contaminated goods and food, with or without providing complete and correct information. In addition, there are some prohibited actions, among others; does not comply with any net load, clean or clean content, and is not in accordance with certain conditions, warranties, privileges or efficacy, and does not conform to the quality, level, composition, processing process, style, mode or use of a particular as owed in the label or description of the goods or services.

2.7.2. Legal Protection according to HEALTH LAW

Based on the results of the study appointed by the authors, in this case there is a correlation between the Consumer Protection Act and the Health Law, against the misuse of medical devices rapid test antigens stipulated in the Health Law.

In the Health Law, efforts provided by the government include health efforts in security and pharmaceuticals and medical devices. The health efforts to realize the degree of health for the community contained in the provisions of article 48 of the Health Law.

Referring to the results of the author's interview with the Ministry of Health, especially the Farmalkes sector, health efforts conducted by the government in the form of health today, one of which is KIE or called communication, information, and education to the public through the web and other social media. In addition to the form of KIE, the latest efforts made to prevent the misuse of medical devices is to build synergy with the Ministry of Communication and Information. The form of cooperation is done by sending SMS to the public, about the importance of how to use rapid tests that are correct and clear. Also enhance and develop cooperation between governments and cross-sectors.

Based on Health Law, the Ministry of Health through the local government encourages for strict supervision from the Local Government to the community and businesses to be more careful in consuming antigen rapid test tools. The Ministry of Health urges businesses to pay more attention to the Standard Operation Procedure (SOP) and pay attention if there are people who commit serious violations. The Ministry of Health also urges that if found guilty, the person must be strictly acted upon and given severe sanctions in accordance with applicable law. The Ministry of Health encourages businesses to conduct extra monitoring and laboratory examinations to control the authenticity and quality of the rapid test equipment.

2.8. Responsibility of Businesses and Governments

In general, the principle of responsibility in consumer protection is very important. The principle of absolute responsibility can protect consumers who are harmed by businesses, which businesses violate a guarantee whose efficacy arises not in accordance with what should be promised in a goods / services.

The officer of the misuse of medical devices in this case, can be said to be a businessman who is responsible for the actions committed. Forms of liability of business actors that are not in accordance with the regulations in producing and/or trading goods and/or services may be penalized i.e., Article 8 letter (b), (d) and (e) Jo article 62 paragraph (1) of Law Number 8 of 1999.

In addition to the form of liability imposed by the CONSUMER PROTECTION LAW sanctions, the officer

may be penalized from the provisions of Article 98 paragraph (3) Jo Article 196 of Law Number 36 of 2014 concerning procurement, storage, processing, promotion, distribution of pharmaceutical preparations and medical devices that must meet the quality standards of pharmaceutical services set by the government.

2.8.1. Government Responsibility to Businesses That Abuse Medical Devices Rapid Test

The responsibility of the government is to supervise both pre and post market. In this case the guarantee of delivery of the use of medical devices to the public that turned out to be misused by washing and using them again. Some experts state that these events and actions are the first in the world, so law enforcement should give the highest possible punishment to bring deterrent effect for all parties. Government responsibility is a supervision and guidance on the implementation of consumer protection that ensures that consumers and businesses get their rights and obligations fairly.

Based on the results of interviews with the Ministry of Health of the Republic of Indonesia farm sector medical stuff, the author concluded the answers from both sources, related to the responsibility of the government to businesses misuse of medical devices rapid test antigen used by sanctioning the dismissal of directors of PT. Chemical Farma Diagnostika. According to the Ministry of Health if there is an indication of losses due to the use of medical devices, the Ministry of Health will conduct a search to immediately take further actions such as sanctions, namely oral warning, written, or revocation of circulation permits.

The government's responsibility to businesses, based on the results of the author's research through interview sessions with the Ministry of Health, namely in terms of coaching and supervision, which aims to make businesses service health facilities in the use of medical devices rapid test antigens still follow and comply with applicable regulations in accordance with the HEALTH LAW and CONSUMER PROTECTION LAW.

2.8.2. Government Responsibility to Consumers

2.8.2.1. Government Development

Coaching in terms of health aims to conduct coaching on consumers related to the field of health and health efforts. This coaching effort in order to meet the needs of every person or consumer to be smarter in choosing, using, and knowing more about medical devices rapid test antigens in accordance with applicable regulations.

2.8.2.2. Government Supervision

Supervision in consumer protection against misuse of medical devices is aimed at businesses to carry out their responsibilities properly and compensate for losses

suffered by consumers. The form of supervision in consumer protection is to follow up if there are complaints about unlawful acts that occur between businesses and consumers. If there is a complaint to the government about an act against the law, the government will follow up the process through an investigation in accordance with article 59 paragraph (2) of the CONSUMER PROTECTION LAW. The supervision of consumer protection of officers who have abused medical devices is given action in the form of sanctions. There are sanctions in consumer protection, namely, administrative sanctions and criminal sanctions.

Based on the results of interviews with the Consumer Protection Agency Foundation or YLKI, there are many cases in violations of consumer rights. As is the case raised in this thesis. As a result of the law of violations committed by businesses on consumers, there are 2 (two), administrative sanctions, and criminal sanctions and fines. But for now, the government is more applying criminal sanctions and fines.

First, this administrative sanction is a sanction in which the settlement of disputes can be done through BPSK, so that BPSK will be authorized to impose administrative sanctions against businesses that violate in accordance with the determination of applicable regulations at most Rp. 200,000,000.00. Second, further criminal sanctions and fines, criminal sanctions are carried out against the prosecution of business actors and / or their administrators. In criminal sanctions according to article 63 of the CONSUMER PROTECTION LAW there are additional penalties, namely the seizure of certain goods, the announcement of the judge's decision, payment of compensation, orders for termination of certain activities that cause consumer losses, the obligation to withdraw goods from circulation, and revocation of permits. Business actors and / or managers if they commit violations that result in injury, serious illness, disability, or death to consumers are immediately penalized for at least 2 years and a maximum of 5 years. as the result of the author's interview with YLKI, the usual sanctions are fines by paying a minimum of Rp.500.000.000,00 and a maximum of Rp.2.000.000.000,00.

The supervision in the HEALTH LAW also aims to control the health workers, to work in accordance with the standards and quality that has been set by the government and the company. Supervision aims to provide sanctions if health officials violate established procedures.

Based on the results of the author's research, according to the Ministry of Health, the Republic of Indonesia conducts a form of supervision on the practice of misuse of medical devices rapid test antigens. The form of supervision carried out aims to maintain the quality of distribution of medical devices rapid test, quality of laboratory examinations, as well as conduct further monitoring.

The provisions based on Regulation of the Minister of Health Number 62 of 2017, supervision in the form of audit of technical and clinical information, examination of production and distribution facilities, sampling and testing, and supervision of marking and advertising. Misuse of medical devices is an unlawful act in the field of health

and health efforts. This treatment can be subject to criminal sanctions in accordance with the Health Law and administrative sanctions in accordance with Ministry of Health Regulation No. 62 of 2017. In the determination of sanctions that should be given in accordance with Article 196 and 197 HEALTH LAW to officers, namely, criminal sanctions and fines.

Criminal sanctions and minimum fines of Rp1,000,000,000.00 and a maximum of Rp1,500,000,000.00. A minimum penalty of 10 years and a maximum of 15 years in prison. Furthermore, the determination of sanctions in accordance with The Ministry of Health Regulation Number 62 of 2017 is administrative sanctions. The administrative sanctions in question are written warning, suspension of activities, and revocation of circulation permits.

Based on the above statements, there is still a lack of legal protection for consumer rights in the field of health, so that officers or businesses can commit unlawful crimes. Therefore, the government both on the side of consumer protection and in the field of health must be faster response and stricter in the care and coaching of actors, in the use and distribution of medical devices rapid antigen test. So, it does not happen again in the future.

In terms of consumer protection, the government must educate in providing information periodically to consumers, so that consumers can know the importance of consumer protection itself. Then, from the ministry of health should further improve health efforts in the community, by providing information and socialization related to the use of medical devices rapid test antigen. The government is also obliged to provide education, about how important it is to know the difference between used and still gel antigen rapid tests, as well as provide health care facilities that are safe, fair, and free from certain persons / officers who want to commit unlawful acts.

3. CONCLUSION

Based on the description of the discussion that the author described in the previous thesis writing chapters, the author draws conclusions from the issues raised related to consumer rights which are important rights for society. The existence of consumer rights can help and protect the public from irresponsible businesses. Misuse of medical devices rapid test antigen is an unlawful act committed by businesses in one of the airports in Indonesia that has harmed many consumers. This case shows the lack of supervision and guidance from the government towards businesses and consumers. Although there are regulations that govern consumer protection and health efforts, in fact there are still businesses who commit unlawful acts, and even misuse of medical devices rapid test antigens. This is the first crime committed in the world and occurred in Indonesia. The role of government and consumer relations in consumer protection is very important, because the government as a regulator must be

responsible for how an item is distributed in the form of medical devices safe and comfortable for use by consumers.

Similarly, the role of consumers is, consumers must also be smart and smart in choosing, wearing, and using an item and / or service, especially in medical devices rapid test antigen. If the consumer feels harmed by the business, then the consumer can report and file a complaint with the consumer protection agencies namely BPSK and YLKI or the police.

For the Government:

The government is advised to further foster businesses and consumers in the use of medical devices rapid test antigens that are true, clear, and honest. Coaching how to distinguish the correct rapid test. Similarly, in its supervision of businesses, the government must be strictly in following up on unlawful acts correctly, honestly, and transparently.

For The Community:

For the community, the public is expected to be a smart and clear consumer in choosing, wearing, and using a product moreover in the medical device rapid test antigen. People should dare to ask businesses about the products to be used, to avoid unwanted things.

For Businesses:

For businesses, it is expected not to do things that harm consumers in any form, especially in the health of consumers. It is expected that businesses are honest with consumers in providing true and clear information in a product

ACKNOWLEDGMENT

This work is supported by the Indonesian Consumer Institute Foundation, the Ministry of Health, the Ministry of Home Affairs for Consumer Empowerment and Protection, Lecturer of Universitas Tarumanagara

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