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The Perspective of Business Law And Criminal Law In The Production And Distribution Of Medical Devices For Consumer Rights Protection

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Abstract

The availability of medical devices is a crucial thing for society, considering that health is a basic human need. The society's demand requires an adequate supply of the product. This encourages some businessmen with no good faith to produce and distribute medical devices without fulfilling the standard as determined by the statutory rules. Deviation from the standard is related to the safety standard of the product use, as well as due to the fact that the requirements related to licensing are not met. This will potentially harm society's rights as consumers. This research will analyze the legitimacy of the sales and purchase contract of the medical devices between the producers and distributors when the marketing authorization has not been fulfilled, and the producers' and distributors' accountability seen from criminal law and consumer protection law.

The research is done by using the normative juridical research method, in which it refers to the prevailing laws and regulations. The research uses the statute approach and conceptual approach. The legal materials used are the primary legal material in the form of laws and regulations and the secondary legal material in the form of legal literature. The data collection technique used is library research. The data is analyzed by applying the deductive way of thinking.

Based on the research done, it is found out that the marketing authorization of medical devices is a condition that must be fulfilled by a producer before distributing the product to the consumers. The sale and purchase agreement between the producer and Distributor before the marketing authorization shows that the object in the agreement does not have a lawful cause (containing elements of lawlessness); hence, the agreement is unlawful. Businessmen who violate the rule related to the condition of the marketing authorization of the medical devices will be asked accountable by paying some compensation for the loss suffered by the consumer, and criminal sanctions can be applied to the producer and Distributor, both to individuals and corporations.

Keywords: medical devices, consumer protection, business law, criminal law.

I. INTRODUCTION

Health is a basic need for human beings. They will try as hard as they can to maintain health in various ways. In order to fulfill this need, in certain conditions, assistance or support of useful medical devices is needed to help prevent, diagnosis, treatment, and also healing. Currently, the medical devices available in Indonesia are still dominated by imported products. The need for the availability of medical devices is high so that at present domestic producers already start producing them.

The production process, which will then be followed up by the product distribution process, must surely be supported by the availability of sufficient regulations. In this case, it can be seen how important the government's role is in supervising the business process in the form of the production and distribution processes of medical devices so as to avoid the society's loss. Hence, law enforcement of consumers' rights deserves great attention.

Until recently, the regulations related to the production activities of medical devices in Indonesia are as follows:

1. Government Regulation Number 14 of 2015 concerning the National Industrial Development Master Plan of 2015-2035 and Strategic Planning of the Ministry of Health 2015-2019. This regulation contains the government policy direction in the industry field, particularly in the health industry field.
2. Presidential Instruction Number 6 of 2016 concerning the Acceleration of Self-Sufficient Development of the Pharmaceutical Industry and Medical Devices.
3. Health Ministerial Regulation Number 86 of 2013 concerning the Roadmap of

the Industrial Development of National Medical Devices.
4. Health Ministerial Regulation Number 62 of 2017 concerning Marketing Authorization for Medical Devices, In Vitro Diagnostic Medical Devices, and Household Medical Supplies.
5. In the protection of consumers, definitely Act Number 8 of 1999 concerning Consumer Protection must also be paid attention to.

Despite these regulations being into force in Indonesia, there are still many cases of medical device production, which does not meet the security standard and medical device distribution, which does not have any marketing authorization. Authorization is one of the controlling instruments functioned by the government. Through authorization, the government is involved in the citizens' activities. The government controls society's activities by using the authorization instrument. Authorization can be intended to meet a certain purpose. One of the purposes intended through authorization is to prevent the environment from danger. [1]

Some examples of the cases of the medical device distribution in Indonesia are as follows:

1. In October 2018, the Special Criminal Offense Unit – Criminal Detective Unit, District Level Police of Gresik arrested a producer of orthopedic screws which were distributed without authorization. The distribution model was done by marketing sales working at the medical device distributors. [2]
2. In August 2019, the Special Criminal Investigation Directorate of North Sulawesi Regional Police found out some shops selling medical devices that did not have any marketing authorization and whose authorization was already expired. The medical devices were digital tens, medical regulators, and HB-hemoglobin mhd-1.[3]

Based on these cases that happened, it is seen that there is a violation of the regulations in business activity, in which businessmen do not prioritize business ethics in doing the transactional activities related to the consumers. A good business is not only about a business that is profitable, but also one that is morally good [4]. A good business also means a business that obeys the law.[5]

The act of a businessman who deviates from the rule can lead to a legal consequence, both privately (civil) and publicly, including the consequence in the criminal law. From the business law perspective, violation of consumer rights is an act that can be held responsible in the civil law, and the contract legitimacy between a producer and Distributor needs to be analyzed further, considering that the object of the transaction is an object that does not meet the condition of the marketing authorization. From the perspective of the criminal law, the criminal responsibility of the businessman or corporations that do the violation needs further analysis.

Thus, in this paper, the legal problems that will be analyzed are:

1. How is the legitimacy of the sales and purchase contract between businessmen (producer and Distributor), when the condition of marketing authorization is not fulfilled yet?
2. How is the responsibility of businessmen (producer and Distributor) of medical devices when there is a consumer's loss due to the distribution of medical devices without marketing authorization in order to protect consumer rights?
3. How is the corporation's criminal responsibility of businessmen (producer and Distributor) of medical devices for the distribution of the medical devices without marketing authorization?

II. METHODS OF RESEARCH

In this research, the normative juridical research method is used; it is research done to find out the positive law of something, an event, or a certain problem.[6] The research type is descriptive analysis, which refers to research that describes the event that is being analyzed based on the facts in the form of secondary data gained from primary, secondary, and tertiary legal materials.[7]

The research uses statutes and conceptual approaches. The data used in the research is secondary data, which is data gained from another party indirectly to support the research, which is the primary law in the form of the laws and regulations in health law and consumer protection law. The secondary legal materials used consist of textbooks written by influential legal experts (*de herseende leer*), legal journals, scholars' opinions, legal cases, jurisprudence, and the latest symposium results related to the research topic. The tertiary legal materials as supporting materials used are dictionaries and encyclopedias. The data collection technique used is library research, and the data are analyzed by applying the deductive way of thinking.

III. DISCUSSION

A medical device is an instrument (a device that fulfills the academic requirement), *apparatus* (equipment), machine, tool, and/or implant, *reagen in*

vitro (laboratory equipment), and calibrator, software, the material of single or combined use, for humans for one or more purposes as follows:

1. Diagnosis, prevention, monitoring, care, or alleviating diseases;
2. Diagnosis, monitoring, care, alleviating, or injury recovery;
3. Examination, replacement, modification, or anatomical support, or physiological process;
4. Supporting or maintaining life;
5. Controlling fertilization;
6. Disinfecting medical devices;
7. Providing information for medical purposes or diagnosis through in vitro testing to human body specimens whose main action in or on the human body does not reach pharmacological process, immunology, and metabolism, but in reaching the function can be assisted by the process. [8]

Medical devices definitely have an important role in recovery, prevention, and diagnosing a disease. Health equipment must have strict performance such as accuracy, sensitivity, reproducibility, and safety aspect so that it will always be ready to use and meet the technical standard of using medical equipment. Equipment with inaccurate output will lead to inaccurate diagnosis and therapy dose. Besides, equipment that has already been used in a certain period of time and which has never had any maintenance will experience less reliability, unguaranteed safety, and uncontrolled condition.

In connection with the global demand of health service quality, ISO (International Standards Organization) 9000 and Act Number 8 of 1999 concerning Consumer Protection, it is necessary to have measurement and calibration of medical devices periodically. Calibration procedure must be done on a scheduled basis with the aim of the user's or operator's and patient's safety as a user.[9]

According to Article 1 Section 1 of the Ministerial Regulation Number 54 of 2015 concerning Testing and Calibration of Medical Devices, calibration testing is defined as the whole action that involves physical examination and measurement to compare devices measured and the standard or to determine the measurement size or measurement error. Furthermore, according to Article 1 Section 2 of the Ministerial Regulation Number 54 of 2015 concerning Testing and Calibration of Medical Devices, calibration is the activity of giving the legal stamp to determine the right value of measuring instrument and/or measuring material.

According to Article 2 of the Ministerial Regulation Number 54 of 2015 concerning Testing and Calibration of Medical Devices, the aim of calibration examination is:

a. Giving some reference to the government, local government, and the society in doing Testing and/or Medical Device Calibration;
b. Guaranteeing the availability of medical devices that fit the service standard, quality requirements, security, benefit, safety, and feasibility in Health Care Facilities and other Health Facilities;
c. Increasing accountability and service quality of Health Facility Testing Center and Health Facility Testing Institution in Testing and/or Calibration of Medical Devices.

In relation to the marketing authorization, a medical device must meet some criteria as arranged in Article 6 of the Ministerial Regulation Number 62 of 2017 concerning Marketing Authorization for Medical Devices, In Vitro Diagnostic Medical Devices and Household Medical Supplies, which are the criteria of quality, safety and benefit, measure, and the fact that the medical device does not use any prohibited substances. When all the criteria are already met, based on Article 4 of the Ministerial Regulation 62 of 2017, the marketing authorization can be issued by the Minister.

The government sets the regulations related to the medical device marketing authorization to protect the consumer rights as arranged in Article 4 number 1 Act Number 8 of 1999 concerning Consumer Protection, namely the rights of comfort, security, and safety in consuming products and services. In Article 7 item d Act Number 8 of 1999 concerning Consumer Protection, it is stated that businessmen are obliged to guarantee the quality of the products and/or services that are produced and/or traded in accordance with the quality standard provisions of the products that are applied.

The analysis related to the legal problems identified in this paper is elaborated as follows:

A. Analysis of the validity of the sales and purchase contract of medical devices between businessmen (producer and Distributor), in the case of the condition of the marketing authorization, has not been met yet.

The production and distribution processes are common processes in economic activities. A product is produced by a producer, and it gets to the consumer through the distribution process. In this part, the legal relationship between a producer and Distributor will be elaborated, in which the two sides have the position as businessmen. Besides, several legal consequences arising from the legal relationship will

also be described. There is a civil law relationship between a producer and Distributor, which is based on the trade agreement. Trade agreements are arranged in Article 1457 Civil Code, which stipulates that trade is an agreement or approval in which one party is bound to submit a thing, and the other party is bound to pay the price being agreed on.

The Distributor is defined as follows:

> "Distributor is any individual, partnership, corporation, association, or other legal relationship which stands between the manufacturer and retail seller in purchases, consignments, or contract for sale of consumer's goods. A wholesaler jobber or other merchant middlemen authorized by a manufacturer or supplier to sell chiefly to retailers and commercial users"[10]

In the relationship between a distributor and principal in marketing and selling the principal's products in a certain area and period based on their agreement, a distributor is appointed by a principal. In this case, a distributor is not authorized by his principal, but he acts for and on behalf of himself (independent trader). A distributor buys the things from a principal to be sold later.[11] The agreement taking place between a producer and Distributor can be categorized as a commercial contract. According to Karla C. Shippey, a commercial contract can be simply defined as an agreement made by two or more parties to make a transaction. [12] Every agreement can be claimed to be legitimate if they satisfy the conditions stated in Article 1320 Civil Code, namely consent of the parties to be bound, legal capacity to enter into an obligation, specific subject matter, and permitted cause.

In the case of a sale and purchase transaction of a medical device between a producer and Distributor and the device does not have marketing authorization yet, this will then be connected with Article 1320 Civil Code, as follows:

a. The consent of the parties to be bound has been met. The parties, in this case, the producer and Distributor, have met the wills, in which the producer acts as the seller, and the Distributor acts as the buyer. The parties have agreed on the essential part of the agreement, such as the goods and prices, as well as on the goods delivery, the mechanism of the goods delivery, and other things stated in the distributorship agreement.
b. The legal capacity to enter into an obligation has been met. The parties, whether on their own behalf or in the capacity of representing the company, have met the legal capacity, in which they have met the conditions of the maturity age, the ability to act on the common sense (no psychiatric disorders), and in the case of the parties representing the companies, they have lawful authority, in accordance with their positions.
c. Specific subject matter; as arranged in the Civil Code, an agreement is legitimate if it has a certain object, whether it already exists or it will exist in the future. In this case, the object of the agreement is a medical device.
d. Permitted causes, in this case, are not met, considering that the permitted causes will be met if the contents of the agreement are not contrary to law, decency, propriety, and public order. When the object being traded is a medical device with no marketing authorization, this is something against the law, namely a violation of Article 9 of the Health Ministerial Regulation 62/2017. In this article, it is firmly stated that a producer is obliged to apply for the authorization. Since this obligation is the producer's obligation, when a distributorship agreement is signed, and the marketing authorization is not met yet, there is a law violation that violates the permitted cause. Hence, the agreement is not legitimate, and it is null and void.

If the product is an imported product, according to Article 10 of the Health Ministerial Regulation 62/2017, the obligation to apply for authorization is the importer's and/or Distributor's obligation. In this case, the producer's action of selling an imported medical device with no marketing authorization is not an action that is against the law, so that the agreement is still considered legitimate. The application for the authorization must be followed up by the importer and/or Distributor before the product is distributed to the society.

B. Analysis of the responsibility of businessmen (producer and Distributor) of medical devices for the consumers' loss caused by the distribution of medical devices with no marketing authorization in connection with consumer's rights protection.

Legal protection is all efforts to fulfill the rights and give assistance to provide a sense of security to witnesses and/or victims; legal protection of victims of a crime as part of a community's protection can be realized in various forms, such as giving restitution,

compensation, medical service, and legal aid.[13] Satjipto Raharjo defines legal protection as giving protection to human rights that are harmed by others, and the protection is given to the society so that they will enjoy all their rights given by the law.[14]

Consumer protection law is all the principles and rules which set and protect consumers (related to the product provision and consumers' use of the product); the laws that set the relationship between the product provider and product user in the society. [15] (paraphrased by the researcher). Consumer protection law can be related to civil law in the case of consumer dissatisfaction with a product which has been used; however, despite the close relationship to civil law, it does not mean that consumer protection law is in the area of civil law because there are also some aspects of consumer protection law which are in the area of public law, especially criminal law and state administrative law.

The meaning of *consumer* (American English), or *consument/konsument* (Dutch) is based on its position. The literal meaning of *consumer* (the opposite of *producer*) is every person who uses goods. The aim of using a product or service will determine which category the consumer belongs to.[16] The term *consumer*, according to Act Number 8 of 1999 concerning Consumer Protection Law Article 1 number 2, is defined as follows "A consumer shall be anybody using goods and/or services which are available in the community, both for his own purpose, for the purpose of his family and other people as well as other living creatures and which are not to be traded."

In order to find out the legal responsibility of the producer and Distributor, it is necessary to analyze first the legal relationship between a producer and a consumer, as well as the legal relationship between a distributor and a consumer.

The legal relationship between a producer and a consumer is an alliance that takes place because of the law. In this case, between the parties, there is no agreement. A producer is a businessman, as defined in Article 1 number 3 of Consumer Protection Law, and a consumer is an ultimate user, as defined in Article 1 number 2 of Consumer Protection Law. Thus, the parties' rights and responsibilities are subject to the conditions in the Consumer Protection Law.

When a consumer experiences losses due to the use of the medical device produced by a producer, the problem is in the product quality whose safety is not guaranteed. Product defects are a producer's responsibility, regardless of whether it has a marketing authorization or not. The fulfillment of the requirement of marketing authorization is a fulfillment of the administrative requirement, whereas the fulfillment of the requirement of producing goods and/or services according to the applicable quality standard is a substantial obligation as arranged in Article 7 item d of Consumer Protection Law, and Article 8 section (1) item a. Violation to the obligation of fulfilling the requirements will result in legal consequences, such as civil liability, namely providing compensation as arranged in Article 19 section (1) of Consumer Protection Law.

In the consumer protection regime, there is the term *product liability*, which is a legal responsibility of a person or institution producing a product (producer/manufacture), or of a person or institution doing a process to produce a product (processor, assembler), or of a person or institution selling or distributing a product (seller, Distributor).

In the researchers' opinion, despite the above statement, a distributor is also a party subject to product liability, but the liability needs to be analyzed based on cases, especially in the case of the distribution of medical devices with no marketing authorization. A distributor is a party that distributes a product to a reseller, and then the product arrives at the consumer. In trade activities, usually, a product is not directly sold by a distributor to a consumer. The product is usually sold by a reseller. Yet, it is not impossible that a consumer gets the product from a distributor. When a consumer is not directly related to a distributor, the legal relationship taking place is based on the law. If a distributor is directly related to a consumer, the legal relationship between a distributor and a consumer is based on the sales and purchase agreement.

The consequences occurring related to legal responsibility are: A distributor is a businessman, but a distributor cannot be held responsible for the product quality as it is a producer's responsibility. A distributor is bound to the obligation as a businessman asset in Consumer Protection Law as follows:

a. Based on Article 7 item b, a businessman must provide correct, clear, and honest information about the condition of goods.
b. Based on Article 8, section (1) item a, a businessman is prohibited from trading goods that do not conform to the standard required by the laws and regulations.

Violation of these articles will result in a distributor getting civil liability, namely the compensation set in Article 19 of Consumer Protection Laws. On the other hand, Consumer Protection Law can be specifically reviewed based on Health Ministerial Regulation Number 62 of 2017 concerning Marketing Authorization for Medical Devices, In Vitro Diagnostic Medical Devices and Household Medical Supplies in a number of ways, such as:

a. Withdrawal based on Article 58 of Health Ministerial Regulation Number 62 of 2017. Medical Devices, In Vitro Diagnostic Medical Devices and Household Medical Supplies that do not fulfill the requirements and/or whose marketing authorization, is revoked will be withdrawn from circulation; this will be done by and become the responsibility of the company producing and/or distributing medical devices, in vitro diagnostic medical devices and household medical supplies.
b. Destruction based on Article 59 of Health Ministerial Regulation Number 62 of 2017. Destruction of Medical Devices, In Vitro Diagnostic Medical Devices and Household Medical Supplies, is done to Medical Device, In Vitro Diagnostic Medical Devices and Household Medical Supplies: a. which do not fulfill the requirement for safety, quality and usefulness; b. which have expired; c. the marketing authorization of which has been revoked; d. which are not manufactured and/or imported in compliance with the prevailing laws and regulations; dan e. are connected with a criminal offense, done by a producer, Medical Device Distributor, importer of household medical supplies with marketing authorization, health service facility, central government, provincial government, and/or district/city government. If the destruction of Medical Devices, In Vitro Diagnostic Medical Devices, and Household Medical Supplies related to criminal offenses is done by authorized government agencies in accordance with the laws and regulations, the whole destruction must be done by paying attention to the impact on human and environmental health.
    c. The sanctions based on Article 63 (1) can be:
        i. Administrative sanctions, namely: written warning, temporary activity termination, and revocation of Marketing Authorization.
        ii. Revocation of Marketing Authorization, if: Medical Devices, In Vitro Diagnostic Medical Devices and Household Medical Supplies, cause a dangerous impact on health; they do not meet the criteria stated as the data proposed when registering the marketing authorization; the production certificates are revoked; Medical Device Distributor license is revoked, or termination of appointment as Sole Agent/Sole Distributor/Exclusive Distributor and/or authorization.

If the rule in this Ministerial Regulation is violated – fabricating and/or distributing Medical Devices, In Vitro Diagnostic Medical Devices and Household Medical Supplies without marketing authorization – and causes someone to have a serious health problem, disability, or death, a consumer can be protected through the criminal sanction according to the laws and regulations. Thus, the responsibility aspect of the medical device businessmen (producer and Distributor) can be applied based on Consumer Protection Law and Health Ministerial Regulation for causing consumer losses due to the distribution of medical devices without marketing authorization.

C. Analysis of criminal responsibility of medical device corporations (producer and Distributor) for distributing medical devices without marketing authorization

Violation of fulfilling the requirement of the medical device marketing authorization as an administrative rule violation will lead to administrative sanction consequences. On the other hand, the distribution of products without marketing authorization violates the consumer protection law, as arranged in Article 8, section (1) item a Consumer Protection Law, which states that businessmen are prohibited from trading goods which do not meet the standard required by the laws and regulations. The lack of marketing authorization shows that the product has not passed the testing phase of the eligibility standard. If the product being distributed is proved to cause danger, the businessmen can be given the criminal law consequence. This is mentioned in Article 61 of Consumer Protection Law, which states that the criminal prosecution is done to businessmen and/or the management.

The criminal sanction to the violation of Article 8 section (1) an of Consumer Protection Law is set in Article 62, namely imprisonment of maximum 5 years or being fined for maximum Rp. 2.000.000.000,00 (two billion rupiahs). Hence, based on the legality principle, a businessman whose action meets the elements mentioned in Article 8 section (1) can be given a criminal sanction.

A criminal responsibility can be given to both individual businessmen and corporations. In the case

of the production and distribution of medical devices without marketing authorization, this involves a producer and Distributor. From the perspective of criminal law, the producer's and Distributor's action meets the elements in Article 8 section (1) item a, in which there are the elements of 'producing' and/or 'trading.' The word 'produce' refers to the producer's action, while the word 'trade' refers to the Distributor's action. Consequently, both a producer and a distributor can be given the same criminal sanction, although the two parties are given different administrative sanctions. This is related to the fact that taking care of the marketing authorization of the medical devices produced in Indonesia is a producer's obligation, and for imported products, it becomes an importer or Distributor's responsibility. As a result, the administrative sanction depends on the product status, whether a local or imported product.

The criminal sanctions to producers and distributors do not depend on which party is obliged to take care of the authorization. In this case, when a medical device is found in the market, and it does not have any marketing authorization, the producer and Distributor are threatened with criminal penalties. For example, a distributor who trades a local medical device but with no marketing authorization can still be subjected to criminal penalties, despite the fact that the marketing authorization is the producer's obligation. This is related to the nature of criminal law as public law. In this case, the country gives the sanction due to the losses and/or danger from which the society using the product has suffered or will suffer. The country protects consumer interest. The aim of giving a criminal penalty is not to recover the losses suffered by individuals.

Consumer Protection Law states that criminal prosecution can be done to both the corporation and the administrators. In this case, several theories related to prosecuting a corporation are relevant to apply. The first is the Identification Doctrine, in which a corporation is only responsible for an individual's action who acts on behalf of the corporation, and the individual has a high position or key function in the structure of the corporation's decision making.[17] The prosecution of administrators can be done if the administrator has the position as the directing mind that sets the corporation policy. In the case of the medical device without marketing authorization, the administrator can be sanctioned if proved to be involved in approving the production process and/or distribution of medical devices that do not meet the standardization according to the laws and regulations.

The second theory is Strict Liability Theory. In principle, the concept of strict liability refers to the absolute responsibility without seeing the doer's inner attitude or *mens rea*. This theory is in line with the requirement of product liability in the system of consumer protection law. Natalie O'Connor states: *"*product liability, these were designed to protect the consumer from faulty or defective goods by imposing strict liability upon manufactures.*"*[18]

As a result, businessmen can be subjected to criminal penalties if it proved that the traded products are defective and cause danger to consumers (the wider community). The criminal penalties subjected to corporations definitely need to pay attention to Supreme Court Regulation Number 13 of 2016 concerning Procedure for Handling a Corporate Criminal Act Case.

IV. CONCLUSION AND SUGGESTIONS

Based on the elaboration in the previous parts, there are several concluding points drawn:

1. The lack of marketing authorization of medical device products is a violation of the law, and thus, if the product becomes the object of a transaction between a producer and Distributor, the sales and purchase agreement does not meet the valid cause so that the agreement becomes null and void.
2. The producer's and Distributor's legal responsibility is arranged in Consumer Protection Law and Health Ministerial Regulation. Due to consumer losses, a producer and Distributor can be obliged to pay compensation; a preventive effort if suspected to harm the society can be in the form of withdrawal and destruction; and if a violation of the marketing authorization is proved, a sanction can be given, such as administrative sanction, revocation of marketing authorization; and if there is an indication of causing a serious problem, death, a criminal penalty can be given.
3. The producer's and Distributor's criminal responsibility as a corporation for the production and distribution of medical devices without marketing authorization, based on the product liability requirement and set in Article 8 section (1) a jo. Article 62 Consumer Protection Law, in which the sanctions given can be imprisonment and fine.

The suggestions put forward are as follows:

1. To the government: expected to have stricter supervision of the distribution of medical devices and to take firm action/enforcement action against ineligible businessmen.
2. To businessmen (producer and Distributor): fulfilling the requirement for the marketing

authorization before distributing the product, in accordance with laws and regulations.

3. To consumers: Paying attention to the marketing authorization in the medical device product before deciding to buy and use it.

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