



The Practice of Illegal Health Equipment Distribution in Indonesia Reviewed from Business Ethics

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ABSTRACT

The emergence of illegally distributed medical devices is certainly not without reason. The expansion of access to health insurance has pushed the need for health services for the people in Indonesia. The high demand for health services will be directly proportional to the need for medical devices that are distributed safely and evenly. Geographical conditions and characteristics and demographic conditions in Indonesia are a real challenge for the distribution of medical devices evenly and according to procedures. The responsibility for distributing medical devices is one form of applying business ethics through applicable policies or regulations.

This study examines the practice of distributing medical devices illegally in Indonesia in terms of business ethics using descriptive analysis methods. With limited research time, the study of illegally distributing medical devices does not reflect healthy and ethical activities when viewed from business ethics outside of relaxation of existing regulations.

Keywords: *Business Ethics, Medical Devices, Authorization*

INTRODUCTION

The Food and Drug Supervisory Agency (BPOM), through Operation Pangea VIII, succeeded in destroying the illegal drugs and food found. BPOM's arrests in these operations were drugs and food. They included fake medical devices or those that had not been officially registered so that they were called illegally distributed medical devices (Ministry of Health, 2015). The capture of medical devices circulating illegally is, of course, a particular concern because the illegal distribution of medical devices has the potential to have a severe impact or threat to public health. Through medical devices that are distributed legally is one indicator that public safety is the main thing. The hope from Operation Pangea VIII is that the public can be better protected from medical devices whose safety is not guaranteed.

The emergence of illegally distributed medical devices is certainly not without reason. The expansion of access to health insurance has encouraged the need for health services for the community in Indonesia (Daya Makara UI, 2018).

With the increasing demand for health services, it is directly proportional to the need for medical devices. As a form of efforts to fulfill medical devices, the import of medical devices is carried out in the hope of meeting the needs of qualified medical devices for the people of Indonesia. If the demand for medical devices increases, this condition will affect the supply or distribution of the required medical devices evenly. Geographical conditions and characteristics and demographic conditions in Indonesia are a real challenge for the distribution of medical devices evenly and according to procedures (Daya Makara UI, 2018).

Table 1.1 Historical Data on Exports and Imports of Medical Devices in Indonesia in 2011-2015

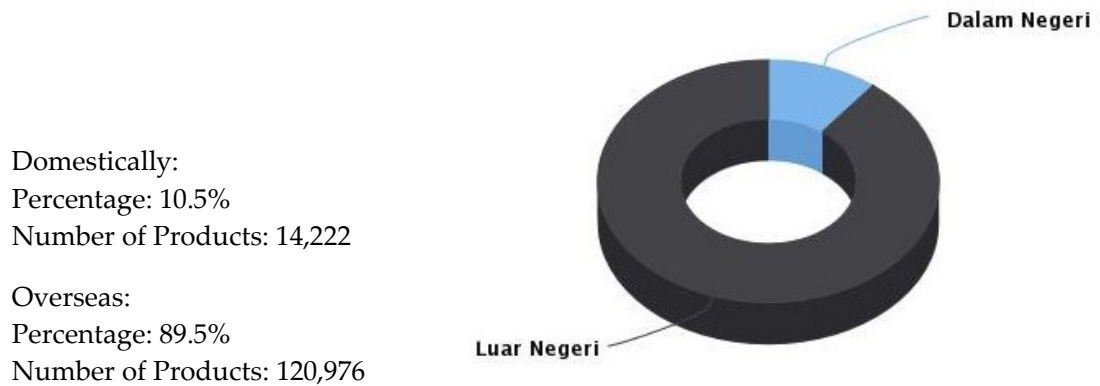
| | Kategori | 2011 | 2012 | 2013 | 2014 | 2015 |
|---------|----------|----------|-----------|-----------|-----------|-----------|
| Exports | Medical | 5,863.37 | 7,263.17 | 8,383.15 | 9,742.39 | 9,061.53 |
| Imports | Devices | 8,288.30 | 12,024.70 | 16,658.31 | 18,255.71 | 17,196.47 |

source: Daya Makara UI (2018)

Table 1.1 describes the increasing need for medical devices as evidenced by the import of medical devices every year in Indonesia from 2011-2015. The average growth in the importance of medical devices during the five years reached 121%, with the highest growth in 2011-2012 at 145%. Based on the data in the table, it can be concluded that Indonesia has a reasonably large niche market for medical devices. With a market niche that can be said to be potential, fraudulent practices can occur. Although ideally in penetrating a possible market niche, it must be accompanied by thinking about the impact and consequences on society (Wahyuni & Turisno, 2019).

One form of distributing medical devices illegally is by buying and selling *online* on the internet without a distribution permit. The public will be attracted by the emergence of medical device advertisements on social media with low prices and easy purchasing procedures. In the practice of illegally distributing medical devices, individuals create advertisements posted on social media and violate consumer rights (Nur Zuhaid, Turisno, & Suharto, 2016). Without a distribution permit for medical devices, there will undoubtedly be no feasibility test. The absence of due diligence can pose risks to consumers when using these medical devices. In addition to the Pangea Operation carried out, the Indonesian Ministry of Health also urges the public to buy medical devices. The Indonesian Ministry of Health is intensively conducting socialization so that people are not tempted to purchase medical devices without a distribution permit at low prices. With socialization, the public can also easily see any medical device products that already have a distribution permit through specific web portals (Ministry of Health RI, 2015).

Figure 1.1 Percentage and Number of Medical Device Products that Have Domestic and Foreign Marketing Permits for the Period March 2020 – February 2021



source: Ministry of Health of the Republic of Indonesia (2021)

To tighten the illegal distribution of medical devices, procedures are needed to minimize the distribution of illicit medical devices. By looking at the data from March 2020 - February 2021, it can be seen that the Ministry of Health has issued a distribution permit with a fluctuating amount. However, it can be concluded that the issuance of distribution permits for medical devices reached 85.2%, considering the increasing need for medical devices during the Covid-19 pandemic (Ministry of Health of the Republic of Indonesia, 2021). Referring to Figure 1.1, this condition illustrates that as many as 120,976 foreign medical devices and 14,222 domestic medical devices have obtained valid marketing permits.

The practice of distributing medical devices illegally raises a concern when viewed from business ethics. There is an important theory in business ethics in which there is a theory of honesty which is the main attitude in carrying out a business activity (Turisno, 2011). Not limited to the medical device activity business, every business activity should be carried out by maintaining mutual trust, which significantly influences the community (Wahyuni & Turisno, 2019). Ethics is related to the values that are used as examples. In the context of business activities, it is how the business behaves well and prioritizes morals. Ethics for doing business is good or fair if it has consistently enforced law and justice (Rahayu, 2020). In addition, business ethics have been carried out to the maximum if the company or business actor is consistently loyal to the principles, etiquette, and norms that apply in society.

Based on the explanations and circumstances above, the authors are interested in conducting a study of the practice of illegally distributing medical devices from the perspective of business ethics. The study starts from problems related to business ethics that must be maintained in the practice of distributing medical devices, then why the practice of distributing medical devices illegally needs to be minimized, discussing the practice of distributing medical devices illegally in terms of business ethics, as well as conclusions and suggestions. Due to time constraints, this research uses the descriptive analysis method in its presentation. It is hoped that despite these limitations, this research will still provide added value for academics and can be developed more broadly.

LITERATURE REVIEW

Business ethics can be defined as general ethical principles in human behavior, specifically in economic and business activities (Wahyuni & Turisno, 2019). In the company's business ethics guidelines, companies must recognize interested parties in their business continuity. Companies must establish healthy and ethical relationships with all stakeholders and the environment in which they operate (Mariska, Abdullah, & Syarif, 2017). In addition to the definition of business ethics, it is essential to define what is meant by medical devices. According to Permenkes Number 62 of 2017, medical devices are instruments, apparatus, machines, and/or implants that do not contain drugs that are used to prevent, diagnose, cure and relieve disease, treat sick people, restore health to humans, and/or form structures and improve body function.

Some researchers are interested in researching the principles of business ethics, but not many have linked business ethics with the practice of illegally distributing medical devices. Another research related to business ethics was carried out by Wahyuni & Turisno (2019). Not on the theme of health, research on the application of business ethics is carried out by taking illegal financial technology practices in the form of loans *online*. When viewed from business ethics, loan activities *online* can be carried out by maintaining mutual trust. However, suppose there is an act of fraud. In that case, this condition indicates the absence of the principle of honesty and the focus of business ethics, which is a fundamental guarantee for the continuity of business activities.

On the other hand, Rahayu (2020) researched the application of Islamic business ethics in hoarding masks during the Covid-19 outbreak. In his research study, Rahayu (2020) wrote that after all companies have specific policies, Islamic business ethics is essential for making decisions. Then as a research suggestion, Rahayu (2020) argues that the authorities should immediately act for the perpetrators of hoarding masks because they are not in line with the rules of business ethics.

In addition, Nugroho (2009) tries to write down the relevance of business ethics in the health service industry by taking the example of a hospital. In his

research, Nugroho (2009) explained that in the beginning, health services were a practice of solidarity from the past. However, the practice of solidarity has turned into a commodity that has a price and is determined by the market. In his conclusion, Nugroho (2009) argues that to restore health services as part of solidarity action in accordance with the rules of business ethics, the role of state administration is needed, so that market mechanisms do not fully control the health service industry.

RESEARCH METHOD

The research method used is descriptive analysis, a research method that aims to summarize, describe, and analyze an object and then describe it in an analytical narrative to get conclusions about the object under study (Sugiono, 2009). This research method was chosen because in addition to the limited time of the study, this method is considered the most appropriate for analyzing cases of illegal distribution of medical devices from the point of view of business ethics.

RESULT AND DISCUSSION

Circulation permit is one of the preventive measures from the emergence of doubtful medical devices and may pose risks. This means that every medical device circulating in the community must have a distribution permit as an identifier that the product is safe to use in large quantities. The distribution permit will be granted after going through an evaluation process and declared to meet specific standards consisting of safety, quality, and benefits.

By the Regulation of the Minister of Health Number 1190/Menkes/Per/VIII/2010 concerning Circulation Permit of Medical Devices and PKRT, for medical device products that have obtained distribution permit approval, the distribution permit number must be stated on the packaging/container/wrapping, label, product, brochure / medical device leaflet. Writing the correct distribution permit for medical devices can be exemplified by dividing medical devices into two categories: 1) Distribution permit for imported medical devices with an example of circulation permit number of the Ministry of Health of the Republic of Indonesia AKL XXXXXXXXXXXX, and 2) Marketing permit for domestic medical devices with an example of distribution permit number of the Ministry of Health of the Republic of Indonesia AKL XXXXXXXXXXXX (Ministry of Health RI, 2014).

Some individuals who find it challenging to obtain a distribution permit have chosen a shortcut by illegally distributing medical devices without a distribution permit. These conditions can be dangerous for society and violate business ethics, so they need to be minimized. The factors that are predicted to be the cause of the illegal circulation of medical devices are as follows (Nur Zuhaid, Turisno, & Suharto, 2016):

1. Profits

2. Import taxes or administrative costs
3. Politics
4. Avoiding procedures

The Three factors above are carried out by business actors and perpetrators of illegal distribution of medical devices without regard to the impact that may be caused to the community. If the medical device does not have a distribution permit, the community will be the most disadvantaged. The public will find it challenging to claim responsibility if side effects arise from the use of medical devices without marketing authorization.

Every business actor in the distribution of medical devices has been facilitated through a socialization program to distribute medical devices properly. By the Regulation of the Minister of Health of the Republic of Indonesia Number 4 of 2014, every distributor of medical devices and branches of distribution of medical devices is obliged to carry out CDAKB or what can be called the Good Distribution Method of Medical Devices. CDAKB, according to Permenkes RI No. 4 of 2014, includes the following aspects: 1) Quality management system, 2) Resource management, 3) Buildings and facilities, 4) Storage and inventory handling, 5) Product traceability, 6) Handling complaints, 7) Corrective actions on security in the field, 8) Return/return of medical devices, 9) Destruction of medical devices, 10) Illegal and unqualified medical devices, 11) Internal audits, 12) Management studies, 13) Third-party activities.

In addition to having been facilitated by Permenkes RI No. 4 of 2014, the Ministry of Health of the Republic of Indonesia also provides facilities to distributors of distribution of medical devices regarding procedures for applying for a distribution permit for medical devices. Adhering to the Guidelines for Assessing Medical Devices by Permenkes No. 62 of 2017, the technical procedures for applying for a distribution permit for medical devices are as follows:

1. Application for *ID* and *password*
2. Application for a new distribution permit
3. Application for extension of distribution permit
4. Application for a change in distribution permit
5. Application for attachment with a shift in distribution permit
6. Technical guidance
7. Technical consultation

The existence of such a technical procedure should be able to minimize the difficulty of each distributor registering a distribution permit.

In business, practice often arises *conflicts of interest* between two different parties (Nugroho, 2009). If the case in business ethics is examined and dissected, then the hidden ethical problem that arises is a conflict of interest. Conflicts of interest usually occur between two different parties with their respective motives of interest. The issue of conflict of interest in business activities is a fact that should

be overcome. It should be in the world of health business; every business actor needs to understand ethical signs that can minimize conflicts of interest.

It should be realized that there are two inherent functions for business actors or distributors of medical devices. As a distributor, a business actor can take advantage of his business but still pays attention to consumers' safety, security, and health. A bank business entity can exemplify this condition. As a business entity, banks are allowed to take profits as the basis for operational turnover. However, it must still pay attention to the essential obligations to maintain stability in the value of money, encourage economic activity, and expand employment opportunities (Murwaji, 2016).

Referring to business ethics in running a business, competitive pressure is one of the causes for the emergence of unethical behavior or low business ethics (Nugroho, 2009). Competition in the medical device distribution business risks low ethical performance in the relationship between distributors and consumers. If every medical device distributor has applied excessive business orientation and tips, then honest performance will be fragile if they do not heed the rules of business ethics.

The importance of business ethics in terms of two sides: 1) Social, and 2) Moral. When reviewing business ethics from a social perspective, ethics is made to compete while still complying with applicable regulations. However, the competition must still pay attention to the moral aspect, where the match occurs pretty and positively. Attention to business ethics will be in line with the age of the business and by considering positive or negative benefits (Murwaji, 2016).

With the Regulation of the Minister of Health of the Republic of Indonesia Number 4 of 2014, it is hoped that it will regulate and minimize the risk of the fragility of ethical performance in the practice of distributing medical devices. Minimizing the risk of fragility in the version of business ethics is also expected to uphold the moral and social aspects of business ethics. The distribution permit or business license required to be owned by every business actor in the distribution of medical devices is one of the mandatory procedures according to ethical principles. Suppose the distributor has registered a distribution permit voluntarily. In that case, it can convince the government and the broader community that the business is very concerned about the safety, health, and security of consumers. If you have obtained a business license or distribution permit, then the medical device distributor is well received and considered to pay attention to consumer safety (Prihatminityas, 2017).

However, it should be understood that exceptions may arise regarding the need for distribution permits that do not deviate from the principles of business ethics, one of which is the need for medical devices during the COVID-19 pandemic. By Minister of Health Regulation No. 7 of 2020 and Minister of Finance Decree No. HK. 01.07, which regulates the relaxation of several medical devices to handle the COVID-19 pandemic. With the issuance of these regulations, medical

devices included in *vitro* or tools to examine specimens from inside the human body and household health supplies to cope with COVID-19 are no longer required to have a distribution permit. This means that medical devices that have issued new regulations can circulate by obtaining a permit exemption recommendation from the National Disaster Management Agency (BNPB).

CONCLUSION

It is understood that in conducting business activities, every business actor must pay attention to ethical elements. If business people apply business tips excessively, it can be predicted that fragile honest performance will emerge. In distributing or distributing medical devices, distributors must apply business ethics by implementing the Good Medical Device Distribution Method (CDAKB). On the other hand, the control of CDAKB violations is carried out by conducting Pangea Operations to implement business ethics further. However, one of the standard rules regarding CDAKB is that the distribution permit can be annulled under certain conditions, such as a situation of urgent need through authorized authorization, and remains under supervision. The relaxation of regulations by the approved permission can be said not to violate the principles of business ethics because it considers the urgent needs and safety of consumers or the public.

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