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Effectiveness of the ministry of health of Republic Indonesia's supervision of medical devices distributors

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***Abstract*---**Medical devices are a critical component of the health sector, and their users need to be accompanied by assurances of safety, quality, and benefit. The Indonesian Ministry of Health provided this guarantee by supervising distributors of medical devices. Therefore, this study aims to examine the effectiveness of the Indonesian Ministry of Health's supervision of medical devices distributors in terms of human resources, equipment, and guidelines. The method used was descriptive qualitative research with a case study approach at the Ministry of Health. Data were collected from three informants using in-depth interviews, observation, and documentation techniques. The results showed effectiveness in the supervision since the equipment facilitates work and the guidelines have become a reference for officers in performing their duties, even when the number of human resources is insufficient. However, additional officers are needed to make supervision more effective.

***Keywords*---**effectiveness, supervision, distributor, medical devices.

Introduction

Medical devices are critical components in the health sector, and their optimal use improves community health services(Roza, 2016). For example, hospital beds enhance patients' comfort, an essential aspect of health services(Drayi, 2019). The

government exercises control and supervision over medical devices. Furthermore, the command starts from the pre-market stage by assessing manufacturers and distributors of medical devices and products. Government supervision starts from the production process, distribution, use to destruction as mandated by Law No. 36 of 2009 article 98 paragraph 1, which states that pharmaceutical preparations and medical devices must be safe, efficacious/beneficial, quality, and affordable. Additionally, supervision is part of the production to distribution process that needs to be conducted to improve product safety assurance, prevent the number of damaged products, and prevent wasted costs due to losses incurred(Junais et al., 2018). Therefore, the government is obliged to supervise distributors of medical devices.

Each medical device has benefits and risks contained in the machine. Therefore, the quality produced must be by the standards (Jain et al., 2014). Several measures have been adjusted globally and in each specific country to ensure the quality of medical devices. Good quality is produced from a good process and meets predetermined standards based on market needs (Faizuddin et al., 2016; Kireev et al., 2016). Product quality is the company's focus and is an important policy to increase competitiveness. The optimal use of medical devices can improve health services for the community.

According to research by WHO in 2017, it is estimated that 1 out of 10 health products in developing countries has substandard or counterfeit quality. The sampling results conducted by the Ministry of Health show that the number of non-compliant medical devices has increased from 4 provinces in 2018 to 7 in 2019. This indicates that the quality of these devices used in Indonesia is low. In addition, the results of the 2019 Ministry of Health examination stated that only 6.68% of 404 distributors checked the recommendation for Medical Devices' Good Distribution Practices (MDGDP), which is a guideline that needs to be met to guarantee safe, quality, and valuable devices. The low MDGDP recommendation shows that distributors are not paying attention to the quality of the medical devices, causing harm to the user community. This raises many questions regarding the effectiveness of the monitoring of medical devices.

Previous research on the effectiveness of supervision was more on the management of the quality of work of personnel and less related to the field of administration and health policy(Hannang et al., 2020; Lee & Kusumah, 2020; Nasution, 2017). Therefore, this research is fundamental because medical devices are one of the supportive health services. Medical devices play a role in prevention, therapy, and patient healing. To maintain this function, the quality of medical devices must be guaranteed and supervised and add to the treasures of administrative science and health policy.

Effectiveness is the relationship between output and goals because the more significant the production contribution to the goals achieved, the more meaningful the activity(Buschor, 2013; Van Dooren et al., 2010). Efficacy measurements were performed through an approach that views a system in an organization as having three interrelated essential elements: input, process, and output(Bausewein & Higginson, 2004; Mohajan, 2017). In this study, the examined element was only from the input aspect. Inputs for supervision include

human resources, an inspection of equipment, and supervision guidelines. Given the standard recommendation of the MDGDP, it is necessary to question the effectiveness of the supervision of related parties to create negative perceptions from the community when not handled immediately. The effectiveness of monitoring medical devices is essential to ensure safety, quality, and benefits. Therefore, this study aims to examine the effectiveness of the Ministry of Health's supervision of medical devices from the input aspect.

Supervision of medical devices to ascertain whether the operation of medical devices in the field is by the permits granted and to find deviations in the form of violations of unlicensed medical devices, management, and location of the company not by the approved certificate, to take corrective action in the form of action. Adequate supervision will ensure the quality of services provided to the community so that the violations mentioned above can be reduced or prevented(Evans et al., 2014). Two supervisory orientations are needed to achieve the objectives set out in policy supervision, namely efficiency and effectiveness. Efficiency is the minimal use of existing resources to produce something that has been determined according to plan. Effectiveness is the achievement of predetermined targets on time using existing and allocated resources (Korhonen & Syrjänen, 2004; Ugoani, 2019). Effective oversight doesn't just publish information as a basis for action; but also collects data for feedback, which is critical in measuring achievement, updating plans, and initiating corrective action (O'Hare & McGuinness, 2009; Obaob et al., 2014). The effectiveness of supervision is measured through a systems approach which consists of three interrelated essential elements(Arnold & Wade, 2015). These elements are inputs, processes, and outputs that function as performance.

Materials and Methods

Sampling technique

The method used was qualitative research with a case study approach. This research was conducted in 2020 at the Ministry of Health and medical device distributors' organization. The sampling technique used was purposive, namely the direct sample selection technique. Researchers choose samples who have experience or knowledge of the information needed for research (Tongco, 2006). The sample criteria can be seen in table 1.

Table 1
Sample criteria and information

Sample	Inclusion Criteria	Information you want to know
Head of Distribution	Understand the medical device distributor registration procedure	a. Monitoring input b. Supervision process c. Monitoring output
Facilities Supervision Section	Understand the inspection procedures for medical device distributors	a. Monitoring input b. Supervision process c. Monitoring output

Head of the laboratory	Representing distributors of medical devices that the government supervises	a. Distributor registration response b. Distributor inspection response c. Efforts to apply standardization

Research design

This study went through several stages to get valid data. The results could be used as material for a survey of the effectiveness of the Ministry of Health's supervision of distributors of medical devices. The stages of research activities can be seen in table 2.

Table 2
Research Design

Descriptions	Collecting Data Techniques	Analysis Techniques	Information's	Output
Analysis of distribution certificate licensing data and inspection result data	Interview and document observation	In-depth interviews, distribution certificate licensing data and inspection results data	Head of Sub-Directorate for Standardization and Certification, Head of Distribution Facilities Supervision.	Interpretation of distribution certificate licensing data and inspection result data
Interviews with other stakeholders.	Deep interview	In-depth interview and observation	Head of the laboratory	Analysis of the participation of other stakeholders to improve the implementation of standardization

Data Collection Techniques

Data collection techniques through observation and interviews. Observation is a qualitative research method used in case studies where observational data can serve as an addition or confirmation(Jamshed, 2014). Researchers conduct observations to present a realistic picture of behavior or events, evaluate certain aspects, and provide feedback on these measurements. Researchers will observe the field and secondary data, namely, licensing data and the results of inspections of distribution facilities and other supporting data.

An interview is a means of proving the information or information obtained previously. The interview technique used in this research is an in-depth interview. An in-depth interview is a method to acquire detailed information from an informant intensively, openly, and discovery-oriented, which aims to explore in-depth the informant's point of view, experiences, feelings, and perspectives (Sakdiah, 2015). Some things that need to be considered in the interview process are voice intonation, speaking speed, sensitivity to questions, eye contact and

non-verbal sensitivity. Researchers will conduct in-depth interviews with three informants using tools in the form of interview guides, recording devices, and writing instruments. The results of these interviews will be used as primary data.

Data analysis technique

Data analysis is a complex process that requires researchers to read, think and reflect a lot because researchers must explore the information conveyed by informants, both express and implied, to avoid premature conclusions and ensure comprehensive findings (Webber-Ritchey et al., 2021). In this study, the researcher will analyze the data in the following steps:

1. Data compilation
   The process of transcribing data from all recorded interviews with informants. All data, including field notes, collected are made with the date, time, identification number or pseudonym for easy compilation. They were given a number or alias to maintain the confidentiality of participants.
2. Reading and reflection
   The data and the informants' perspectives are reflected in an analytical framework to be analyzed.
3. Coding and categorizing
   Retrieval of important information from the transcript and coded according to the category to be obtained.
4. Develop a conceptual theme/model or theory.

Results and Discussions

During the research, the limitation encountered was the difficulty of interviewing informants due to their busy schedules. Furthermore, the informants were three individuals, including two from the Ministry of Health and one from the laboratory.

Human Resources

There are a total of 18 officers in the Ministry of Health that are responsible for supervising distributors. The number of officers is divided into two parts: the Sub-Directorate of Standardization and Certification, which is led bone Head of the Sub-Directorate, and the Section for Supervision of Distribution Facilities. Furthermore, the Standardization and Certification Sub-Directorate is divided into two sections, namely the Standardization and the Certification Section, where each unit consists of five staff and one section Head. Meanwhile, the Distribution Facilities Supervision Section consists of four teams and one section Head. The education level of the officers consists of one person having a Diploma education, six people having a Bachelor's degree, Eight people having a Professional degree in Pharmacist, and three peoples having a Master's education. Based on the level of education possessed by the officers, the quality of the officers is adequate and sound since they are well educated.

When performing supervision, the officers need to know and master the administrative and technical supervision process to prevent the emergence of

obstacles in the implementation. Furthermore, officers with higher education will have a much better mindset and analytical power and more innovative thinking skills in overcoming problems related to the supervision of medical device distributors than people with low education(Glerum et al., 2020; Yeager et al., 2019).

The pre-market supervision is only performed by five staff from the Certification Section and two officials, namely the Head of the Certification Section and Standardization and Certification Sub-Directorate. In addition to supervising pre-marketing, they also served as post-market supervisors, especially in MDGDP audit activities. While the remaining 13 people oversaw post-market supervision, six persons from the Standardization Section (5 staff and 1 Section Head) served as MDGDP audit officers. The inspection activities are conducted by five people (4 staff and 1 Section Head) from the Supervision Section of Distribution and Export-Import Facilities.

With a limited number of officers, the Ministry of Health is obliged to supervise distributors throughout Indonesia. Of course, this isn't easy to perform. Moreover, this difficulty increases with the annual increase in registered medical device distributors. Therefore, it is necessary to have additional officers in performing the supervision. The Ministry of Health included regional officers (Provincial and District/City Health Offices) as assistant officers in post-sale supervision to overcome this problem. In MDGDP audit activities, Ministry of Health officials is accompanied by one officer from the Provincial Health Office. In contrast, Ministry of Health officials attended one officer from the Provincial Health Office and one from the District/City Health Office during inspection activities.

The assistance from these regions serves as a training facility for regional agents that have not received training from the Ministry of Health to supervise distributors in their area. It also helps to apply the training results to officers trained by the Ministry of Health. In addition, the Provincial Health Office also plays a role in monitoring the effects of post-market activities provided by the distributors, where the part of the Provincial Health Office is to provide recommendations for the revocation of distributor certificates.

The Health Office's cooperation is expected to increase the number of distributors inspected. It is, however, insignificant in comparison to the 4,806 that will be overseen in Indonesia. According to the Ministry of Health, just 204 distributor certifications were inspected in 2020. Thus, from 2016 to 2020, the Ministry of Health investigated and certified 26 per cent of distributors in Indonesia, while 3 per cent acquired an MDGDP certificate. Meanwhile, 71% of them lack an MDGDP certificate and have never been subjected to inspections with varying conditions based on their function, company scope, and organization can see in Figure 1.

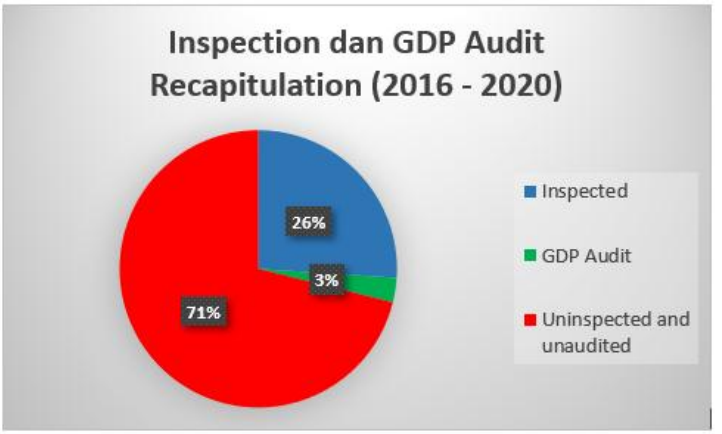

Figure 1 Inspection and GDP Audit Recapitulation (2016 – 2020)

This shows that the existing resources are insufficient compared to the number of distributors in Indonesia. The limited number of officers renders distributor supervision ineffective because the resulting performance is not proportional to the number of existing distributors. Furthermore, it is the responsibility of the Ministry of Health to supervise distributors, medical device manufacturers, and PKRT producers, as well as make norms, standards, regulations, and policies. Supervision is adequate when the number of officers is sufficient and by their respective duties and functions to detect the violations. The needs of civil servants in government agencies can be met by planning through the calculation of job and workload analysis(Amrizal, 2017). According to the estimate of job and workload analysis conducted by the Ministry of Health, an additional 41 officers are required to serve as supervisory officers. Furthermore, it is expected that the supervision will be effective with this addition.

Equipment

When performing supervisory duties, it is advantageous to have the appropriate equipment, which is classified into two groups based on the type of supervision. Electronic pre-market surveillance is undertaken at sertifikasialkes.kemkes.go.id. Post-market leadership uses an electronic system called e-inspection and manual equipment such as the document investigation, the document investigation of Security for Facilities/Warehouses, inspection results rejection, thermogenesis to check room temperature, and security equipment such as padlocks, stickers, and security lines.

The officer supervises the pre-market with sertifikasialkes.kemkes.go.id through an internet-connected laptop available on each officer's seat. Furthermore, a smooth and robust internet network makes it easier for officers to check documents submitted by distributors. Electronic systems make work flexible, allowing distributors to send the registration requirements document remotely and no longer need to have face-to-face meetings with registrars, reducing corruption, increasing transparency, and reducing costs(Berg et al., 2018). In post-market supervision, officers are equipped with several types of equipment. At

the same time, inspection forms are performed through an e-inspection system, accessed when officers inspect distributors using a mobile phone or tablet.

Electronic systems play a role in the processing, collecting, compilation, and storing data to produce accurate, quality, timely, and accountable information for the public interest(Erçin et al., 2021; Singh & Burgess, 2006). In government, they are a manifestation of intelligent and digital administration to optimize government services(Qi & Wang, 2021). Furthermore, the utilization of electronic systems improves services. It provides practical solutions (Chen et al., 2021; Hong et al., 2018) to various challenges and problems related to private and government jobs (Ananadharaj & Balaji, 2021; Kumar et al., 2019; Radouan Ait Mouha, 2021), such as distributor inspection, which can be helpful to officers to ensure the effective and efficient running of the supervision.

Guidelines

Since 2014 the Ministry of Health has issued guidelines related to the supervision of distributors. Also, they published a Certification Procedure Guide that officers and distributors used in registering. Furthermore, in 2019 the Ministry of Health issued two technical guidelines: the Technical Guide to Supervision of Non-Electromedical Sterile and In Vitro Diagnostic Medical Devices and Technical Instructions for Supervision of Supervision Medical Device Distribution Facilities. Officers use these two technical guidelines in conducting inspections.

In 2020, the Ministry of Health planned to revise the 2014 guidelines for certification procedures to align with the current supervision process. However, the COVID-19 pandemic stopped changing these guidelines because they are not to the pandemic conditions. Therefore, the Ministry of Health has issued a replacement guideline to adapt to the current pandemic conditions, namely the Public Service Certificate of Production and Distribution of Medical Devices and PKRT Guidelines during the Covid-19 Pandemic Condition, which is used for pre-market supervision. The completion of this replacement guide implies that the officers are responsive and adaptive to changes that occur in the community.

The guidelines issued by the Ministry of Health are prepared from the government's point of view and the distributor as the implementer of a regulation. This was observed from the involvement of Gakeslab as representatives in the preparation of guidelines that provide input and impact analysis on distributors. Organizational involvement in manufacturing guidelines is necessary; hence, the resulting policies are implemented and misused. Also, When the private sector is excluded from developing the rules, a policy's widespread application is unlikely to be accepted(Halwatiah & Susanti, 2017; Ribka & Wijaya, 2013). Several Gakeslab members are companies with Foreign Investment status, providing them with speed to adopt current technological developments(Hamoudi & Aimer, 2017; Mohamed et al., 2021). Finally, the existence of guidelines used by officers as a reference in supervising distributors enhances focus that prevents violation of duties.

Conclusion

The supervision of medical devices distributors by the Ministry of Health of the Republic of Indonesia in terms of the input aspect was effective. This is because the tools used to support the work and the standards used to train officers in human resource control are insufficient. Therefore, additional officers are needed for more effective supervision. There are two factors that cause many distributors to violate standardization compliance. The first is the internal factor of the distributor due to the low compliance commitment of the distributor leadership to standardization. The two external factors that come from outside the distributor, namely the regulations made by the Health Service are very general in nature, causing a diversity of understanding of the rules between the central and local governments which makes it difficult for distributors to understand these regulations.

Limitations Researchers do not participate in all audit and inspection activities carried out by the Ministry of Health due to the wide area of inspection carried out by the Ministry of Health. Researchers only participate in audit and inspection activities in the Greater Jakarta area. This study did not carry out the Focus Group Discussion method due to field conditions during the covid-19 pandemic and it could not also be done online because in the range of May to November 2020 the city of Jakarta was in the red zone where informants did not have an empty schedule at the same time due to focusing more on acceleration of licensing and inspection of distributors of medical devices related to covid-19 that is being carried out so that the results of the research are still less detailed and far from perfect.

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