# ANALYSIS OF PREPAREDNESS FOR THE IMPLEMENTATION OF SIMPLIFIED SYSTEM AND PERMISSION PROCESS IN THE DEVELOPMENT OF MEDICAL DEVICES

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## ABSTRACT

**Background:** In the health national insurance (JKN) era, the need for medical devices was fulfilled by more than 90% of imported products. Therefore, the government issued the Minister of Health Regulation No. 17 of 2017 concerning the action plan for the development of the pharmaceutical industry and medical devices. This study aimed to determine the preparedness for the implementation of simplified system and permission process in the development of medical devices.
**Subjects and Method:** This was a qualitative study conducted in July 2019. The key informants were officials from the ministry of health directorate of medical devices and household health supplies evaluation and supervision. The informants were also people from the Indonesian Association of Medical Device Manufacturers. The study theme was preparedness for the implementation of simplified system and permission process in the development of medical devices. The study variables included the size and objective of the policy, resource, characteristics of the implementing agency, communication between organization, disposition of implementer, as well as the social, economic, and political environment. The data were collected through in-depth interview and observation and analyzed descriptively.
**Results:** Preparedness for the implementation of simplified system and permission process in the development of medical devices based on Minister of Health Regulation No. 17 of 2017 was quite good. The size and objectives of the implementation policy were clear enough. The available resources were sufficient and qualified. Standard operational procedure (SOP) had been prepared and applied to the system. Policy communication had gone well. Implementer disposition in addressing policies was optimal. The economic, social and political environment had a significant influence on policy implementation.
**Conclusion:** Preparedness for the implementation of simplified system and permission process in the development of medical devices has been running well in terms of variable size and policy objective, resource, implementing agency characteristic, communication between organization, implementing disposition, and the social, economic, and political environment.

**Keywords:** medical device, licensing, implementation, policy, domestic

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## BACKGROUND

Medical devices are an important component in health services besides drugs. Medical devices are urgently needed in the efforts to achieve Sustainable Development Goals (SDGs), where the role of medical devices is to support the achievement of specifically the third goal, which is to guarantee a healthy life and encourage welfare for all people at all ages (Ministry of Health, 2017).

The increasing need for medical devices has not been accompanied by an increase in domestic medical devices. Based on data from the Indonesian Medical Devices Employers Association (ASPAKI), the market value of medical devices in Indonesia was Rp


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13.5 trillion in 2018. From this market value, the domestic product market was only 8% (BeritaSatu, 2018). Indonesia is a large market for marketing medical devices with a market value of around 800 million USD in 2015 and estimated to reach 1.2 billion USD in 2019. Unfortunately, the needs of medical devices are still being fulfilled by more than 90% of imported medical devices.

Investment is one of the important elements in economic growth. Based on BKPM data in 2017 regarding investment, it is known that the biggest obstacle to investment in Indonesia is caused by licensing (32.6%), then followed by regulations and policies (17.3%) and land acquisition (15.2%). Based on these data, reforms in the licensing sector need to be carried out to encourage investment growth in Indonesia.

In order to realize the development of the domestic medical device industry so as to produce medical devices that fulfill the aspects of safety, quality, and benefits, and have competitiveness. The government established several regulations and policies, including Government Regulation No. 14 of 2015 concerning the National Industrial Development Master Plan of 2015-2035 and the Ministry of Health's Strategic Plan for 2015 - 2019, and the Economic Policy Package XI which focuses on the development of the pharmaceutical and medical devices industry. In addition, Presidential Instruction Number 6 of 2016 concerning the Acceleration of Development of the Pharmaceutical and Medical Devices Industry and Regulation of the Minister of Health Number 17 of 2017 concerning the Action Plan for the Development of the Pharmaceutical and Medical Devices Industry.

Ministry of Health regulation Number 17 of 2017 is set as a follow-up containing strategies to carry out the mandate of Presidential Instruction Number 6 of 2016. This Ministry of Health regulation is expected to be a guide in increasing the growth of the domestic medical device industry, encouraging the medical device industry to contribute to improving the national economy, namely increasing Domestic Income Gross (GDP), saving and increasing foreign exchange (import substitution), as well as national employment. This action plan is also expected to encourage the transfer and mastery of the latest medical device technology by the Indonesian medical device industry to actualize the independence of medical devices. One of the performance targets is the licensing service for all categories of domestic production of medical devices faster with a maximum target of 30 days. The expected goal of the target is to increase investment in the medical equipment sector.

Based on the descriptions above, the authors analyzed the readiness of implementing the simplification of systems and licensing processes in the development of medical devices based on those listed in Ministry of Health regulation Number 17 of 2017 concerning the Action Plan for the Development of the Pharmaceutical Industry and Medical Devices in terms of the theory of Van Meter policy analysis and Van Horn, namely the size and objectives of the policy, resources, characteristics of implementing agencies, communication between organizations, disposition of implementers, and the social, economic, political environment.

## SUBJECTS AND METHOD

### 1. Study Design

The type of this study was qualitative descriptive approach. This study used primary data supported by secondary data. For primary data, there was an in-depth interview with each informant using the tools in the form of interview guides, recording devices and stationery. Informants were determined through purposive sampling. Informants in this study were from the Directorate of Me-


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dical Devices and PKRT Evaluation, the Directorate of Medical Devices and PKRT Supervision and the Association of Indonesian Medical Device Manufacturers (ASPAKI). For secondary data, it was obtained by searching documents to obtain data related to the medical device industry.

This study was conducted in July 2019 within the Ministry of Health related to the implementation of policies for simplifying the system and the process of licensing domestic medical devices and the Association of Indonesian Medical Device Manufacturers (ASPAKI). The informant matrix in this study can be seen in Table 1.

Table 1. The informant's matrix

| Informant | Target Information |
|---|---|
| Director of Medical Devices and PKRT Assessment, Directorate of Medical Devices and PKRT Assessment, Ministry of Health | Policy making and readiness for implementing policies to simplify the system and process for licensing domestic medical device distribution licenses |
| Head of Certification Section, Sub Directorate of Production and Distribution Standardization and Certification, Directorate of Medical Devices and PKRT Supervision, Ministry of Health | Policy making and readiness for implementing policies to simplify the system and process for licensing domestic medical device production facilities |
| Secretariat and Treasurer, Association of Indonesian Medical Device Manufacturers (ASPAKI) | Readiness to implement a simplified system of licensing systems and processes in the development of medical devices in terms of the association of domestic medical device manufacturers |

## RESULTS

### 1. Informant's Characteristcs

Table 1.1 Characteristics of Informants. Source: Processed Primary Data

| Informant | Education | Age (years old) | Gender | Length of Work (years) | Position |
|---|---|---|---|---|---|
| Inf A | S3 Economics | 44 | Male | 16 | Director of Medical Devices and PKRT Assessment |
| Inf B | S2 Public Health | 42 | Female | 13 | Head of Certification Section |
| Inf C | S3 Biochemistry | 39 | Female | 5 | ASPAKI Secretariat and Treasurer |

### 2. Factor of Study Results

#### a. Policy Size and Objectives

The first aspect seen in this study was the size and objectives of the policy. According to Van Meter and Van Horn (Winarno, 2013), implementation would be effective if the size and objectives are understood by the individuals responsible for policy performance. The informants knew the purpose of implementing this policy was to make licensing better so as to provide ease of doing business so that it would encourage the development of the domestic medical device industry.

Whereas regarding policy measures, informants of policy makers stated that the measure of success of this policy was the achievement of licensing service performance


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in accordance with the promise of licensing services after being simplified.

**b. Resources**

**1) Fund**

Funds are an important element in implementing a policy in order to support policy objectives. In this study, the intended financial resources were financial support given in the context of supporting policies. Based on the information obtained, funds were available to support the simplification of the system and process of licensing medical devices in the country, including making digital signature applications, developing IT licensing systems and increasing human resource capacity.

**a) Human Resources**

Human resources are one of the factors needed in the implementation of this policy, not only in terms of numbers but also skills (Situmorang, 2016). Based on interviews, several informants explained about the human resources they have in implementing the policy simplification of the system and the process of medical devices licensing.

**b) Facility**

Physical facilities are essential for successful policy implementation to expedite the policy implementation process. The Ministry of Health has funded to support the implementation of policies to simplify the system and process for medical devices licensing, including computers and internet networks. But because the licensing process runs 24 hours and 7 days a week, it is necessary to procure mobility equipment.

**A. Characteristics of the Implementing Agency**

**1. Relationships Between Organizations**

The aspect of inter-organizational relations in this study explained the collaboration between policy actors or stakeholders in implementing policies. Coordination between institutions or other relevant parties involved in this policy was considered by the informants to be going well enough. This worked well at the level of policy implementers and policy makers.

**2. Organizational Structure**

The organizational structure aspect explained the organization and division of responsibilities among policy implementers. Based on the results of interviews with informants from the Ministry of Health, it was known that there was no overlapping of work related to the application of this policy.

The application of the licensing policy for the production of domestic medical devices was located at the Directorate of Medical Devices and PKRT Supervision, namely the Sub Directorate for Production and Distribution Standardization and Certification. While the application of licensing policy for distribution of medical devices in the country was in the Directorate of Medical Devices and PKRT Evaluation, namely in the Sub Directorate of PKRT Products and Independent Products.

Based on interviews with informants from the association, it was known that ASPAKI has a separate department that encouraged the application of this policy. The task of this department was to disseminate information to members of the association, namely domestic medical device producers, related to the policy of simplifying the system and licensing process of medical devices.

**3. SOP**

One of the most basic structural aspects of an organization is its basic standard operating procedures (SOP). By using SOPs, implementers can use the available time, and can equalize actions within the organization and broadly (Situmorang, 2016).

In this study, all informants already have SOPs and have been applied to the online system tailored to the promise of new licensing services.


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**B. Inter-organizational Communication**

The next aspect seen in this study was the communication aspect. Communication related to how the policy is communicated to the organization (Ayuningtyas, 2018). Communication also depends on how the policy is in the process of transmission, clarity, and consistency (Anggara, 2014).

**1. Transmission**

A good transmission process in a policy will have an impact on the policy implemented properly. An informant from the Ministry of Health stated that socialization had been carried out to domestic medical device entrepreneurs related to changes in domestic medical device licensing service promises. The informant from ASPAKI also helped to provide information about this policy to its members in the form of seminars and workshops.

**2. Clarity**

This study showed that the domestic medical device business actors have an understanding of the promise of new medical device licensing services.

**3. Consistency of Information**

The consistency of the information conveyed would lead to well-implemented policy. The policy implementers would be more easily understand the purpose of implementing the policy itself. An informant from the Ministry of Health stated that the socialization of this policy always uses the same presentation source to maintain information consistency.

**C. Disposition Executive**

Disposition is the attitude and commitment of the executor towards the policy in order to achieve the expected policy results (Anggara, 2014). Based on the results of interviews with informants, it showed that the parties concerned in implementing this policy have committed quite well.

**D. Economic, Social and Political Environment**

According to informants, the policy simplification of the process and licensing system for medical devices in the country has influenced the national economic condition and brought social impacts to the community. The implementation of this policy also received support from the government and other ministries and institutions outside the Ministry of Health.

## DISCUSSIONS

Based on the results of the collection and processing of data, the preparation of policy implementation simplification of licensing processes and systems in the development of domestic medical devices was quite good in terms of variable size and policy objectives, resources, characteristics of implementing agencies, communication between organizations, implementing dispositions, and social environment, economics, politics.

The size and objectives of the policy in this study were to explain the size and objectives contained in the Regulation of the Minister of Health No. 17 of 2017 concerning the Action Plan for the Development of the Pharmaceutical Industry and Medical Devices. The general objective of this policy was to realize the independence of domestic medical devices through increasing the growth of the domestic medical device industry in order to be able to produce medical devices that meet the requirements of safety, quality and benefits, were competitive and affordable by the community.

According to Van Meter and Van Horn (in Winarno, 2013), the implementation would be effective if the size and objectives were understood by the individuals who are responsible for policy performance. Based on the results of this study, the Ministry of Health measured the success of this policy which was the achievement of licensing ser-


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vice performance in accordance with the promise of licensing services after simplification.

In terms of resources related to sources of funds, staff and facilities in general have been well fulfilled. Funding support was available in the form of budgets for server procurement, system development and maintenance, and training to improve staff capabilities. Human resources can be seen from the number and competence which in general are pharmacists and pharmacy graduates are considered to be sufficiently capable to support the application of this policy.

Regarding resources and facilities, the Ministry of Health has funded to support the implementation of policies for simplifying the system and the process of licensing medical devices, including computers and internet networks. However, because the licensing process runs 24 hours and 7 days a week, it was necessary to procure mobility equipment to support work outside of hours and workdays.

The relationship between the policy implementing organizations in this study was the Ministry of Health and domestic medical device business operators. The aspect of inter-organizational relations in this study explained the collaboration between stakeholders in implementing policies. Coordination between institutions or other relevant parties involved in this policy was considered by the informants to be going well enough. The existence and clarity of the organizational structure was clearly listed so that it has a clear enough division of tasks to implement the policy. Standard operational procedure (SOP) is the development of internal demands on the certainty of time, resources and uniformity needs in complex and broad work organizations (Winarno, 2005). In this study, the Ministry of Health has made SOPs that were suitable to new policies and have been running quite well.

Successful policy implementation was influenced by policy communication because unclear policy information caused policy implementers to not comply with policies (Weaver, 2009). Based on the results of the study, the communication policy simplification of the system and the process of licensing domestic medical devices has been perceived accordingly. The Ministry of Health has carried out this policy socialization to domestic medical device business practitioners. This concerned the process of delivering or transmitting, the clarity and consistency of the policy information delivered (Akib, 2010).

Disposition is the attitude of the executor or executor's commitment to policy. Commitment or attitude of implementing policies that have a strong desire and high commitment to be able to achieve the expected policy goals (Anggara, 2014). The attitude of the Ministry of Health as the policy maker and implementer has shown a high commitment in implementing the policy. This was indicated by the provision of training to improve the ability of licensing officers or evaluators as well as providing facilities and facilities to support work related to policy implementation.

Policy simplification of systems and processes for licensing domestic medical devices, according to interviews with several informants, greatly influenced the country's economic condition. With the implementtation of this policy, the revenues have increased through PNBP.

In addition, if this policy reaches its goal, it can increase investment figures. Macroeconomic growth would also move to a positive trend. The policy of simplifying the system and process of licensing domestic medical devices also affected socially, given the existence of a health insurance system by the government, namely the National Health Insurance.


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This policy also contributed to the increased supply of medical equipment for domestic production in hospitals and public health center. From the political environment aspect, the implementation of the simplified policy process and licensing system for medical devices in the country received support from the government and other ministries and institutions outside the Ministry of Health.

The limitation in this study was that it did not involve domestic medical device business actors as informants because of the limited time of the study. The policy simplification of the system and process for licensing domestic medical devices is expected to increase the growth of the domestic medical device industry so as to reduce the percentage of imports of medical devices.

The readiness of implementing policies to simplify the system and process of licensing domestic medical devices has been quite good from the aspect of policy size and objectives, resources, characteristics of implementing agencies, communication between organizations, implementing dispositions, and the social, economic and political environment. The Indonesian Medical Devices Manufacturers Association (ASPAKI) has also been prepared with new domestic medical device licensing policy regulations.

## REFERENCES


Akib H (2010). Implementasi Kebijakan: Apa, Mengapa, Dan Bagaimana Haedar Akib (Policy Implementation: What, Why, And How Haedar Akib), 1(1): 1–11.

Anggara S (2014). Kebijakan Publik (Public Policy). Bandung: Pustaka Setia.

Ayuningtyas D (2018). Analisis Kebijakan Kesehatan Prinsip dan Aplikasi (Health Policy Analysis Principles and Applications). 1st edn. Jakarta: PT. Raja Grafindo Persada.

Berita Satu (2018). Pasar Alat Kesehatan di 2018 Diprediksi Capai Rp 13,5 Triliun (The Medical Device Market in 2018 is Predicted to Reach Rp 13.5 Trillion). Jakarta. https://www.beritasatu.com/ekonomi/481898-pasar-alat-kesehatan-di-2018-diprediksi-capai-rp-135-triliun.html accessed in July 28th, 2019

BPJS Kesehatan (2017). Sebuah Catatan 72 Tahun Kemerdekaan Indonesia: Kontribusi JKN-KIS Bagi Pertumbuhan Ekonomi Indonesia (A Note of 72 Years of Indonesian Independence: JKN-KIS Contribution to Indonesia's Economic Growth). https://www.bpjs-kesehatan-.go.id/bpjs/index.php/post/read/2017/501/Sebuah-%20Catatan-72-Tahun-Kemerdekaan-Indonesia-Kontribusi-JKN-KIS-Bagi-%20Pertumbuhan-Ekonomi-Indonesia accessed in July 27th, 2019

Kemenkes (2017). Peraturan Menteri Kesehatan Republik Indonesia Nomor 17 Tahun 2107 Tentang Reancana Aksi Pengembangan Industri Farmasi Dan Alat Kesehatan (Regulation of the Minister of Health of the Republic of Indonesia Number 17 Year 2107 Concerning Reancana Action for the Development of the Pharmaceutical and Medical Devices Industry). Jakarta.

Kemenkes (2017). Peraturan Menteri Kesehatan Republik Indonesia Nomor 62 Tahun 2107 Tentang Izin Edar Alat Kesehatan, Alat Kesehatan Diagnostik In Vitro Dan Perbekalan Kesehatan Rumah Tangga (Regulation of the Minister of Health of the Republic of Indonesia Number 62 Year 2107 Concerning Circulation of Medical Devices, In Vitro Diagnostic Medical Devices and Household Health Supplies). Jakarta.




https://doi.org/10.26911/the6thicph-FP.04.31

Roziqin M, Muchlas (2018). Faktor Penghambat Investasi 32,6% Karena Perizinan (Investment inhibiting factor 32.6% due to licensing). https://www.borneonews.co.id/berita/102650-faktor-penghambat-investasi-32-6-persen-karena-perizinan accessed in July 28th, 2019.

Situmorang CH (2016). Kebijakan Publik (Teori Analisis, Implementasi dan Evaluasi Kebijakan) (Public Policy (Theory Analysis, Implementation and Evaluation of Policies)). Depok: Social Security Development Institute (SDDI).

Weaver RK (2009). Target Compliance: The Final Frontier of Policy Implementation Governance Studies.

Winarno B (2013). Kebijakan Publik Teori, Proses, dan Studi Kasus (Public Policy Theories, Processes, and Case Studies), Center of Academic Publishing Service, Jakarta.


https://doi.org/10.26911/the6thicph-FP.04.31