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Medical Device Industry Development in Indonesia

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ABSTRACT

Demand for health products in Indonesia is increasing, with an estimated annual growth of 11.9% until 2024. This is driven by population growth and public awareness of the importance of health. Indonesian government believes developing medical devices industry is essential in supporting health resilience in Indonesia. The development and marketing of medical devices does not only focus on the benefits of a product but requires planning and control so that the product can be safe and effective for users, such as by paying attention to quality standardization, patient safety, regulation, and market licensing. This exploratory qualitative research approach yields results in the form of patterns that can increase the availability of safe and quality medical devices, namely 1) research and development of medical devices, 2) regulation of medical devices, 3) assessment of medical devices (health technology evaluation), and 4) management of medical devices (health technology management). The results of this trial will provide valuable information on the process of developing medical device products to choose an approach that suits your needs and conditions.

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1. INTRODUCTION

The world has learned a big lesson from the Covid-19 pandemic, which has impacted all sectors, such as the economy, society, and health [1]. From the health perspective, it is known that there are sections that are directly related to service activities. It is realized that there are at least four essential elements in health services, namely 1) Health personnel, 2) Medical devices, 3) Pharmacy, and 4) Facilities and Infrastructure, which are essential in health service activities.

Medical devices are an important part that is considered capable of playing a significant role in direct health services. [2] explained that medical devices are a part of health services that can be combined with pharmacy. On the other hand, it is known that medical devices are an inseparable part of administering health services today, so it has become something that the state must pay attention to, maintain and develop [3].

Indonesian government realizes that developing medical devices is an important thing to do. Several essential things cause this condition, namely 1) Indonesia has a large population, which impacts the demand for medical devices in the country. 2) Big cities in Indonesia have a hospital system that is well

developed and provides superior health services. 3) Availability of adequate infrastructure and human resources for industrial development. 4) Opening foreign export markets, especially in the Asian, Africa, and Middle East regions. 5) Encouragement for developing medical device standards at the global level, 6) High dependence on imports, and 7) Existence of intergovernmental cooperation in the harmonization framework. Development of the medical device industry is believed to involve many essential factors, and each cannot stand alone and have a measurable measurable measure. This research describes the factors and patterns that are appropriate for the development of medical devices in Indonesia.

2. LITERATURE REVIEW

The development of the medical device industry has been realized to be a big issue in the future; in 1960, China was in the process of developing the industry, which is shown in four stages, which in turn shows that innovation from research & development, stakeholder equality, and appropriate policies greatly influence the success of the industrial development process medical devices in China [4]. [5] provides information related to stakeholder awareness to adjust medical device policies in order to adapt to global challenges, which are related to 1) the latest regulatory scope for medical devices, 2) harmonization of regulations, 3) Clinical investigation requirements, 4) In-House manufacturing of medical devices, 5) In-House Manufacturing of Medical Devices, 6) Rules Regarding Custom-Made Medical Devices, 7) Re-Use of Single Use Devices, 8) Device Traceability and The Eudamed Database, 9) Available Guidance for The New Regulation and 10) Current Challenges with Implementation.

[6] explained that in the case of medical devices, the development process needs to consider the broad regulatory framework, the interests of many organizations, evaluation of the safety and effectiveness of the device before entering the market. [7] explained that there were two phases of the development of the medical device industry. The first phase is related to gathering information about the product and medical device development methodologies and processes implemented with business process models and notations, and the second phase graphically describes the activities of the information collected from various parties.

It is realized that the development of medical devices is increasingly important to support health activities; from this, it faces service challenges related to using "user risk" as the basis for standardizing quality, patient safety, regulations, and market licensing. [8] explain that the health and medical device industry is unique, so it requires clear classification, rules, and strict specifications to carry out development and marketing. From this, it provides an impetus to formulate design, development, and market planning regulations. [9] explained that the use of medical devices is related to the use of medical devices to consider product status, resulting in equipment being unable to be used. The activity is aware of a discrepancy between user features, product appearance, usage functions, and operating errors that create a risk of injury.

[10] provide the view that problems in medical device development should focus on something other than the benefits of the product being developed. In this case, it provides an impetus that appropriate education is needed in order to improve skills in designing good medical device products. [11] provide a report discussing the challenges of developing the medical device industry in the future, namely: 1) insufficient funding, 2) incomplete understanding of the medical device industry, 3) understanding regarding regulations related to the science of developing new devices, standards, and approaches, 4) lack of collaboration, 5) inadequate understanding of project management, 6) communication that is not built, 7) Companies and medical device markets that are still fragmented.

[12], in research related to the development of medical device technology faced with regulations, this condition provides a view of new technology in medical devices that are believed to be able to provide benefits to patients. However, the time for these products to be marketed requires a long time. In this case, an adjustment related to providing convenience in the process of requirements and other administration is needed. [13] explain that regulations for the development of medical devices are faced with several things, namely: 1) National legal basis, 2) Higher classification, 3) Product certification, 4) Capacity of those who manage and the number of experts who are still lacking, 5) Product supervision on the market.

3. METHODS

Research related to medical devices is a unique industry in terms of content and context. [14] explain that a study will have an advantage if the object is specific to its context. This is the basis for conducting studies with a qualitative exploratory approach. The basis for this approach is creating theoretical constructs or propositions from empirical evidence in the cases studied [15], [16].

The research is a form of case study, which has the advantage of needing substantial, complete, in-depth, and detailed information related to the case. In essence, a case discussed and supported empirically can significantly deepen its understanding and clarification [17]–[19].

Data and information in this study were obtained from various sources, namely journals, and reports related to domestic and foreign medical devices. This becomes the basis for providing an initial view and learning in the case development process studied. Critical data were obtained from focus group discussion activities in various meetings involving various essential stakeholders in the medical device industry. Questions built-in research center on what, why, and how. These questions are carried out to answer critical conditions and activities that have been carried out from time to time [20].

Data processing underwent descriptive analysis and graphical analysis, which help provide a scientific explanation of the findings obtained. The information obtained is mapped to get an integrated pattern to provide views for stakeholders regarding steps that need to be considered in the future. [21] explain that a description of the findings needs to be done to get the best pattern and provide recommendations for the development of a case.

4. RESULTS AND DISCUSSION

Medical device industry in Indonesia has proliferated from time to time, which can be described from upstream to downstream. By 2022, the market value of medical devices in Indonesia will reach around USD 3.6 billion, with an estimated annual growth of around 11.9% until 2024. This is supported by the increasing demand for health products in Indonesia, which is driven by a growing population and public awareness of the importance of health. It is known that before 2022 the dependence on medical devices from abroad for Indonesia was very high; it was recorded that before 2022 it reached 88% and then decreased to 70% (Ministry of Health 2022). This indicates a strengthening of the domestic industry, as evidenced by the increased absorption of domestic medical device products.

Indonesian government believes that developing medical devices is essential to support health resilience in Indonesia. Its implementation focuses on developing medical device research, manufacturing, and markets, which are fully supported by regulations. Implementation in encouraging research is carried out by 1) reverse engineering, 2) joint ventures, and pioneering research. Manufacturing is supported by business facilities, tax holidays, tax allowances, and tax deductions, the impact of which has been an increase in domestic medical device distribution permits and types of domestic medical devices. Market

strengthening activities are supported by the application of the Domestic Component Level, which significantly impacts sales in 2022, which has increased 5 times from the previous year. Apart from that, several things were carried out to support the increase in the use of domestic medical devices, such as support for imported product substitution "If domestic products meet national needs, then imported products will be frozen." Implementing Domestic Products (PDN) with distribution licenses for Domestic Alkes (AKD) and TKDN certificates is the leading solution in procuring goods and services. One-on-one business matching between users (Hospitals and Health Services) and the domestic medical device industry and affirmative action exhibitions to increase the use of domestic medical device products. The medical device development process requires special stages which require planning and control so that the product results can be effective and safe for users.

[22] provides a view that medical device development starts with medical device design, clinical trials, risk management, and manufacturing management. [23] issued regulations for the development of medical devices in 5 stages, namely i) Initiation "opportunity and risk analysis," ii) Formulation "concept and feasibility analysis," iii) Design and development "including verification and validation to ensure the design output matches the specified design input," iv) Final validation and product launch preparation and v) Product launch and postlaunch assessment. The process of developing medical devices in the early stages is constantly faced with a framework for developing technology, economics, and usage. From this, various new challenges emerge that can be related to the performance of medical devices, the cost of medical devices, the competitiveness of medical devices, and the efficiency of medical devices [24].

Development of domestic medical device industry can encourage and promote economic development. The development of the domestic health industry requires some support from related industries, such as local suppliers, which will have an impact on the absorption of domestic products, an increase in the world of education due to the needs of the domestic industry, and investment sustainability [25]. [26] provides an outlook on developing domestic medical devices in Africa, which can be an example for other countries. The development process is divided into several phases to strengthen the local industry and the support needed for the development process. In this process, on the production side, strengthening is carried out in determining the equipment and producers who will produce, technical specifications, local procurement, absorption, and control procedures.

Discussion

Health systems depend on health technology to achieve desired health outcomes. Designing medical device programs according to policies and protocols that result in equitable access to safe, appropriate, and high-quality medical devices is essential. Medical devices are essential to provide health care and improve population health. From the innovation to the exchange phase, the medical device agenda consists of four essential features: Availability, Accessibility, Suitability, and Affordability.

These four keys help broaden the scope of the medical device agenda to focus not only on “early stage” innovation efforts but also on choosing which medical devices to purchase wisely and appropriately and ensuring that they are used effectively and fairly. Based on research results, four critical medical device life cycle levels can increase the availability of safe and quality medical devices. Integrating and building on these four keys can become the engine needed to achieve sustainable national health goals. In general, these steps are 1. Research and development of medical devices 2. Regulation of medical devices 3. Assessment of medical devices (health technology evaluation) 4. Management of medical devices (health technology management). The pattern

obtained was developed while developing the medical device industry, as shown in Figure 1.

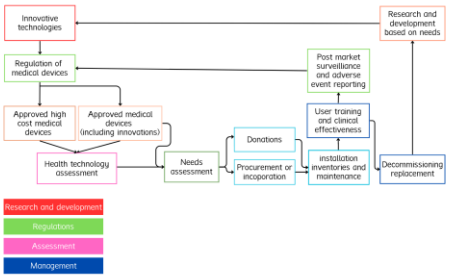

Figure 1. Four Key Linkages and Development Patterns in the Medical Devices Industry

Figure 1 shows that the four keys have been related to the development of medical devices. This condition reinforces that it is impossible if each part is run independently. On the other hand, the implementation process needs to be deepened by taking into account the characteristics of each key for the development of the medical device industry, while the description of characteristics of each key is described as follows:

1. Research & Development
   - Persepective : Innovative products, applications, and tools to support health services
   - Orientation : Health services that are effective, affordable and available
   - Requierment : Improvements and discoveries in medical devices and health services.
   - Method : Innovation and improvement
   - Criteria : Community needs and future forecasting
   - Outcome : Medical device products that can increase the effectiveness, efficiency, and safety of health services
2. Regulation of medical devices
   - Persepective : Ease of doing business for industry, protection, safety and security
   - Orientation : Health services are available, affordable and safety.
   - Requirement : Mandatory compliance
   - Method : Reporting, product testing, product evaluation and market maintenance.
   - Criteria : Minimum criteria, certification and product testing
   - Outcome : Attractive and robust industry, as well as the availability, effectiveness and safety of medical device products for its users.
3. Assessment of medical devices
   - Persepective : Population served
   - Orientation : Population health
   - Requirement : Recommendations on highly complex technologies
   - Method : Systematic analysis, critical review
   - Criteria : Epidemiology data, statistics, analysis of efficacy, effectiveness and appropriateness
   - Outcome : Responsiveness and maximization of clinical outcomes and cost- effectiveness.
4. Management of medical devices
   - Persepective : Health services provider
   - Orientation : Community health services
   - Requirement : Operational rules and guidance for all medical devices
   - Method : Operational management of technology life-cycle
   - Criteria : Needs analysis, specifi cations, reliable device availability for clinical use.

- Outcome : Improved health delivery; sustainable availability of high- quality and safe device.

5. CONCLUSION

The keys to broadening the scope of the medical device agenda stem from innovation through to the exchange phase, namely availability, accessibility, suitability and affordability. The process to achieve national health goals in developing the medical device industry requires patterns, 1) research and development of medical devices, 2) regulation of medical devices, 3) assessment of medical devices (health technology evaluation), and 4) management of medical devices (health technology management), as well as the characteristics needed in their development.

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