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# The Role of Health Equipment Directorate Supervision and Household Health Supplies Over Legal Importing Protection

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Fulfilling the need for medical devices in Indonesia does not come from domestic production. However, this device has purchased to another country (imports). The new era of globalization and free trade at ASEAN Economic Community has increased during the opportunity. Here, the development country needs to help for purchasing purpose of medical device products with the resulting of increasing number and types of imported medical devices circulating in Indonesia. Currently, the number of imported medical devices reaches 92% and the remaining 8% is domestic products (data from the health ministry's medical device info website). The importation of medical devices can only be carried out by business actors who already have a medical device distribution certificate / medical device distribution permit (permit to distribute medical devices) and medical device distribution permit (permit to distribute medical device products) issued by the Indonesian Ministry of Health. Thus, in this study aimed to analyse the process of importing medical devices if the business actor had exclusive rights of the product that has been registered with the Indonesian Ministry of Health or in this case, the owner of the distribution permit. The problem that often occurs is when the distribution permit owner is disadvantaged over the circulation of medical device products that should only be imported by the distribution permit owner, however in reality, the medical device products can be circulated by companies that are not exclusive rights holders. This research examines the legal protection carried out by the directorate of medical device supervision and medical supplies to the owner of a medical device distribution permit in dealing with imported medical devices not by the distribution permit owner.

**Keywords:** Medical Devices, Household Health Supplies Supervision, Legal Protection, Medical Device Distribution Permit.

## 1. INTRODUCTION

Health is a basic human need which is one factor of human right. Indonesia has acknowledged this as stated in Law Number 36 of 2009 concerning Health which states that everyone has the right to have access to health services. [1, 2]. Health services are very broad in scope and require a variety of resources for their administration. Starting from human resources to equipment, instruments, aids, and materials for health services. A goods for health services can be obtained from within the country or from abroad by means of imports. In Indonesia, the proportion of imported medical devices is more than those of domestic products, 92% of imported medical device products and 8% of domestic medical device products [3]. This is shows how Indonesia is still very dependent on -

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imported medical device products. Each type of imported medical device with 1 (one) trade name / brand originating from the Manufacturer or Principal can only be represented by 1 (one) distribution facility for medical devices and imports of medical devices can only be carried out by a company that has a medical device distribution certificate and license with distribution of imported medical devices [4, 5]. In brief, the things mentioned above explain that a brand of medical devices from abroad can only be imported by one medical device distribution facility as a owner of the product distribution permit. The problem occurs when a company that is not the owner of a distribution permit imports the medical device product which in fact is not the owner of the distribution permit. This is as experienced by medical equipment distribution facilities, namely PT. Indomedik

Niaga Perkasa, PT. Medtronic Indonesia and several other companies (will be shown in the data table), as the owner of the medical device distribution permit, but these companies are disadvantaged by other companies that import without their authority [6, 7]. Companies have reported the incident to the Ministry of Health which has an echelon II level work unit, namely the Directorate of Medical Devices and Household Health Supplies Supervision which has the task of carrying out the task of implementing the formulation and implementation of policies, formulating norms, standards, procedures, and criteria. providing technical guidance and supervision, evaluation, and reporting in the field of supervision of medical devices and household health supplies. However, the problem occurs when there are still no concrete rules regarding the actions that can be imposed on importers who violate the exclusive rights of the importer who has the right to import a medical device (the owner of a distribution permit). In addition, there are still many medical device products that can leave the customs area, of course, it is also necessary to strengthen coordination and cooperation between ministries and institutions [8, 9]. Here, we note that the current issue to put forward such as: The legal protection that the Directorate of Medical Devices and Household Health Supplies Supervision can apply to the owner of a medical device distribution permit for the importation of medical devices that is not carried out by the owner of the distribution permit. Here, Follow-up procedure to taken by the Directorate of Medical Devices and Household Health Supplies Supervision of business actors who import medical devices not as the owner of a distribution permit.

## 2. METHODOLOGY

In this study we conducted through an empirical-perspective approach. This legal research is a legal research regarding the enforcement of normative legal provisions (laws) in every event that occurs in a society, by examining directly into the field to see the law in a real sense and see firsthand. application of applicable legislation and conducting interviews with related institutions deemed able to provide information.

### A. Conceptual framework

In order to obtain the result, the implementation of this research, it is necessary to have a theoretical concept to simplify views and explanations so that there is no confusion and confusion in understanding so that it becomes clearer and more focused. Thus, it can be facilitating the delivery of information from the author as a whole as follows [10]:

a. Circulation Permit is a permit for Medical Devices, In Vitro Diagnostic Medical Devices and PKRT produced by Manufacturers, and / or imported by Medical Device Distributors or importers to be circulated in the territory of the Republic of Indonesia, based on an assessment of safety, quality and benefits.

- b. Principals are Manufacturers or overseas representatives appointed and authorized by the Manufacturer or Product Owner to appoint PAK or PKRT Importers in Indonesia.
- c. Medical Device Distributor, hereinafter abbreviated as PAK, is a company in the form of a legal entity in the form of a Limited Liability Company or Cooperative that has a license for the procurement, storage and distribution of Medical Devices and In Vitro Diagnostic Medical Devices.
- d. Sole Agent / Sole Distributor / Exclusive Distributor is PAK or PKRT Importer appointed by the Producer or Manufacturer or Principal as its representative to register and distribute Medical Devices, In Vitro Diagnostic Medical Devices and PKRT within the territory of the Republic of Indonesia and carry out after-service services. sale of Medical Devices, In Vitro Diagnostic Medical Devices and PKRT where the appointment is made based on an order / authorization by giving certain limits of authority to act for and on behalf of the Producer or Manufacturer or Principal.
- e. Import is the activity of entering Medical Devices, In Vitro Diagnostic Medical Devices and PKRT into the customs area
- f. Business actor is any individual or business entity, whether in the form of a legal entity or non-legal entity established and domiciled or carrying out activities within the jurisdiction of the Republic of Indonesia, either individually or collectively through an agreement to carry out business activities in various economic fields.
- g. The Directorate of Medical Devices and Household Health Supplies Supervision is an institution under the Indonesian Ministry of Health in Indonesia which is tasked with overseeing the circulation of medical devices in Indonesia. Thus, the roles in medical device regulation as follows:
  - i. Role is the player who is assumed in the play, so he is the play or the main player.
  - ii. Role is the part that a player plays in a play, he tries to play well in all given roles.
  - iii. The role is part of the main task that must be carried out.

### B. Legal Protection Theory

Legal protection in English is known as "protection of the law". The definition of legal protection is all the efforts made consciously by every person or government institution, and the private sector which aims to safeguard, control and fulfill the welfare of life in accordance with existing human rights. In principle, the legal protection does not differentiate between men and women, the state government system as stated in the explanation of the 1945 Constitution, among others states the principle,

"Indonesia is a country based on law (rechtsstaat) and a government based on a constitutional system (basic law)". The main element of a rule of law is the recognition and protection of human rights. Thus, the purpose of legal protection is to provide protection for human rights that are harmed by others and this protection is given to the community in order to enjoy all the rights provided by law [11, 12]. Here, a legal protection is related to the state's action to do something by exclusively enforcing state law with the aim of guaranteeing the certainty of the rights of a person or group of other people [13].

### C. Definition of Health Law

The health law, including the law "lex specialist", specifically protects the duties of the health professional (provider) in the human health care program towards the goal of the declaration of "health for all" and the special protection of "receiver" patients to get health services. By itself, this health law regulates the rights and obligations of each service provider and service recipient either as an individual (patient) or a community group [14]. Here, the Indonesian Health Law Association in its articles of association states "Health law is all legal provisions that are directly related to health care or service and its application as well as the rights and obligations of both individuals and all levels of society as recipients of health services and from health service providers in all aspects of the organization; means of national or international medical guidelines, medical law, jurisprudence and medical and medical science [15].

### D. Medical Device Product License

Definition of Medical Device Distribution Permit is circular Permit is a permit for Medical Devices, In Vitro Diagnostic Medical Devices and PKRT produced by producers, and / or imported by PAKs or importers to be circulated in the territory of the Republic of Indonesia, based on an assessment of safety, quality and benefits. This is in accordance with the regulation of the minister of health number 62 of 2017. Thus, the process of obtaining a distribution permit for medical devices. Here, in Vitro Diagnostic Medical Devices and PKRT which are produced, imported, assembled and / or repackaged, which will be circulated in the territory of the Republic of Indonesia must have a distribution permit. The distribution permit is issued by the Director General of Medical Devices and Pharmaceuticals and Medical Devices and delegated to the Director of Assessment of Medical Devices and Household Health Supplies [16].

### E. Organization structure

The organizational structure of the Directorate for Supervision of Medical Devices and Household Health Supplies (PKRT) consists of:

- Sub directorate of Standardization and Certification of Production and Distribution.
- Sub-directorate of Production and Distribution Facilities Supervision.
- Sub-directorate of Product Control.

The structure of the organizational structure of the directorate for supervision of medical devices and household health supplies (see Figure 1).

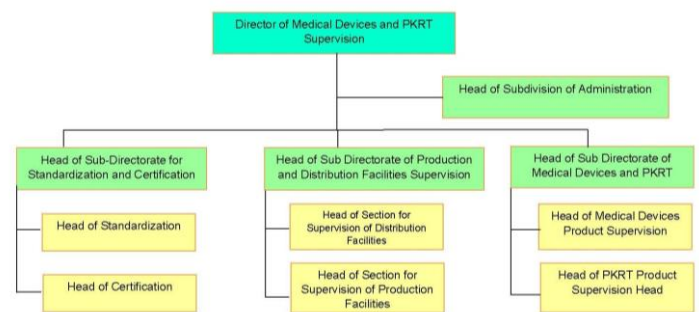


Figure 1. The structure of the organizational

## 3. RESULT AND DISCUSSION

The Directorate of Medical Devices and Household Health Supplies Supervision has the task of carrying out the formulation and implementation of policies, formulating norms, standards, procedures and criteria, providing technical guidance and supervision, evaluation, and reporting in the field of monitoring medical devices and household health supplies. Thus, in carrying out its duties, the Directorate of Medical Devices and Household Health Supplies Supervision carries out the following functions:

- Preparing the formulation of policies in the field of standardization and certification of production and distribution of medical devices and household health supplies, and supervision of production facilities, distribution facilities, export-import, vigilance, products and advertisements for medical devices class A, class B, class C, class D, products in vitro diagnostics, special medical devices and household health supplies;
- Implementation of policies in the field of standardization and certification of production and distribution of medical devices and household health supplies, and supervision of production facilities-

- distribution facilities, export imports, vigilance, products and advertisements of medical devices class A, class B, class C, class D, diagnostic products invitro, special medical devices and household health supplies;
- c) Preparing the preparation of norms, standards, procedures and criteria in the field of standardization and certification of production and distribution of medical devices and household health supplies, and supervision of production facilities, distribution facilities, export-import, vigilance, products and advertisements for medical devices of class A, class B, class C, class D, in vitro diagnostic products, special medical devices and household medical supplies;
- d) Facilitation of management in the field of standardization and certification of production and distribution of medical devices and household health supplies, and supervision of production facilities, distribution facilities, export imports, vigilance, products and advertisements of medical devices class A, class B, class C, class D, diagnostic products invitro, special medical devices and household health supplies;
- e) Implementation of technical activities on a national scale in the field of standardization and certification of production and distribution of medical devices and household health supplies, and supervision of production facilities, distribution facilities, export-import, vigilance, products and advertisements for medical devices class A, class B, class C, class D, In vitro diagnostic products, special medical devices and household health supplies;
- f) Providing technical guidance and supervision in the field of standardization and certification of production and distribution of medical devices and household health supplies, and supervision of production facilities, distribution facilities, export-import, vigilance, products and advertisements for medical devices class A, class B, class C, class D, In vitro diagnostic products, special medical devices and household health supplies;
- g) Monitoring, evaluation, and reporting in the field of standardization and certification of production and distribution of medical devices and household health supplies, and supervision of production facilities, distribution facilities, export-import, vigilance, products and advertisements of medical devices for class A, class B, class C, class D, in vitro diagnostic products, special medical devices and household health supplies; and
- h) The implementation of the administrative affairs of the Directorate.
- In order to maintain the safety requirements related, quality and benefits of medical devices in circulation, the directorate of supervision carries out

comprehensive surveillance activities starting from importation to distribution to distribution. Therefore, this monitoring activity includes monitoring the condition / quality management of distribution facilities / facilities, facilities / facilities where products are circulated, as well as monitoring the consistency of safety standards and the quality of these products in circulation.

Thus, the following are supervisory activities carried out by the directorate for monitoring of medical devices and household health supplies, as follows:

- i. Inspection of the facilities and / or facilities;
- ii. Sampling and testing;
- iii. Supervision of marking and advertisements;
- iv. Vigilance surveillance;
- v. Audits of technical and clinical information; and
- vi. Supervising the import trade system outside the customs area (post border).

#### *A. The Directorate of Medical Devices and Household Health Supplies Supervision*

The Directorate of Medical Devices and Household Health Supplies Supervision has the duty to supervise medical devices circulating in Indonesia, whether they are products made domestically or imported products from abroad. As stated in the introduction, 92% of medical devices circulating in Indonesia are imported products. Here, the strict supervision must be carried out to protect the public from insecure safety, quality and benefits of imported and circulated medical device products. The distribution permit for medical devices is one of the instruments for determining pre-market standards carried out by the government, in this case the directorate of assessment of medical devices and household health supplies (echelon II units of the Indonesian Ministry of Health) to assess whether these medical devices are guaranteed safety, quality and safety. benefits and can be imported and circulated in Indonesia or not. and the directorate for the supervision of medical devices and household health supplies which will later ensure the suitability of the distribution permit for medical devices is still in accordance with or not according to the distribution permit guidelines that have been issued. In Indonesia, the distribution permit for medical devices of each type of imported medical device with 1 (one) trade name / brand originating from the Manufacturer or Principal can only be represented by 1 company, this is as mandated by article 13 of the minister of health regulation number 62 of 2017 concerning distribution permit medical devices, in vitro diagnostic medical devices and household health supplies. And in article 44 of the same regulation, it is stated that the import of Medical Devices can only be carried out by companies that already have PAK permits and distribution licenses for imported

Medical Devices. This is regulated in the context of orderly trade in the importation of medical devices, because if all companies can import from one particular brand it could result in un controlling of the imported medical devices and will have an impact on the community.

#### *B. Follow-up actions taken by the Directorate of Medical Devices and Household Health Supplies Supervision*

The Directorate of Medical Devices and Household Health Supplies Supervision in supervising imported medical devices circulating in the community, of course, cannot carry out this supervision alone. Apart from strengthening from an internal perspective such as making regulations, of course this must be supported by external parties including strong coordination with other ministries / agencies such as the directorate general of customs and excise. Thus, the Directorate of Medical Device Supervision still does not have standard rules for the supervision of medical devices and household medical supplies. So far, in carrying out duties and imposing sanctions, they are only armed with the old regulations which are still not rigid and the technical instructions that have been made. This of course can result in legal vulnerability which has the potential to result in the weakness of a supervisory action carried out by the directorate of medical device supervision.

#### 4. CONCLUSION

This study has been successful studied. Here, violations committed by business actors who import medical devices not as the owner of the distribution permit are serious violations besides harming the distribution permit owner, this also affects the safety of the public from these medical devices. As a measure of anticipation and protection, the Directorate of monitoring of medical devices and home health supplies ladder as an institution in charge of carrying out government tasks in the field of medical device supervision. Follow up the case finding of medical devices that are not imported as the owner of the distribution permit by giving a strong warning sanction to the business actor and ordering to re-export / destroy and / or hand over the product to the owner of the distribution permit.

The Directorate of Medical Devices and Household Health Supplies Supervision in supervising and examining the circulation of medical devices circulating in the territory of Indonesia carries out post-market supervision, namely supervision that is carried out after the product is circulating on the market, this is aimed at keeping the products circulating in the market following applicable regulations, including imported by an official

company. Strong cross-sector cooperation with the directorate general of customs and excise, among others, needs to be strengthened and the making of regulations for the supervision of medical devices needs to be formalized immediately. Thus, the giving strict sanctions against business actors who import medical devices not as the owner of a distribution permit need to be regulated in a minimum regulatory mechanism at the level of a ministerial regulation, so that the legal standing of the government, in this case the directorate for the supervision of medical devices and household health supplies, is strong. Apart from giving written sanctions, the follow-up steps such as re-export / destruction or delivery of products to the distribution permit owner should also be regulated. There is a need for strong cross-sector cooperation with the directorate general of customs and excise to carry out profiling and blocking actions against importing business actors who commit similar violations. Thus, the cooperation agreements between agencies, namely between the directorate for the supervision of medical devices and household health supplies and the directorate general of customs and excise need to be drafted immediately to strengthen the supervisory coordination program and criminalization can be an alternative that can be imposed on the perpetrators who violate the importation, although it must be the last resort for the punishment and prioritizes administrative action.

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