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## **Effectiveness of Disposable Medical Device Procurement in Increasing the Acceleration of the Use of Domestic Products in RSUD Bali Mandara**

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### **ABSTRACT**

*During the early days of the Covid-19 pandemic, there were a number of medical device vacancies that impacted health services. This situation urged the government to fulfill the need for domestic medical devices. This is what underlies the establishment of Presidential Instruction No. 2/2022 concerning Acceleration of Increased Use of Domestic Products. The purpose of this research is to analyze the regulation of the procurement of disposable medical devices in order to increase the acceleration of the use of domestic products and analyze the factors that influence the emergence of obstacles in the implementation of Presidential Instruction No. 2/2022 at RSUD Bali Mandara (Bali Mandara Regional General Hospital). This research applies empirical legal research methods, using statutory, conceptual, and sociological approaches. The implementation of the regulation to purchase domestically produced disposable medical devices at RSUD Bali Mandara is conducted by adhering to Presidential Instruction No. 2/2022, with the aim of increasing the use of domestically produced disposable medical devices in the hospital environment. However, during its implementation at RSUD Bali Mandara, there were several obstacles related to the purchase of domestically produced disposable medical devices. These obstacles include limited stock, users concerns regarding quality, and price differences that make domestic products more expensive compared to the imported products.*

**Keywords:** *Domestic Production, Medical Device, Presidential Instruction No. 2/2022*

## INTRODUCTION

Every individual has the right to a prosperous physical and mental life, a suitable place to live, and a safe and healthy living environment. In addition, Article 28 H Paragraph 1 of the 1945 Constitution guarantees everyone the right to obtain healthcare services. In order to achieve optimal levels of public health, the government is responsible for providing integrated and comprehensive health operations, which include both individual and public health programs. This is accomplished through the provision of health service facilities.<sup>1</sup>

In accordance with Health Law No. 17/2023, a hospital is defined as a health care facility that organizes individual health services in a comprehensive manner, consisting of preventive, curative, rehabilitative, and/or palliative services, through inpatient, outpatient, and emergency services.<sup>2</sup> Hospitals must comply with the criteria under Law No. 44/2009 concerning Hospitals in Article 7 Paragraph 1. These requirements include those related to location, construction, infrastructure, human resources, pharmaceuticals, and the devices.<sup>3</sup> The hospital strives to enhance various health service facilities, including medical devices, to attain service effectiveness.

There were several medical device shortages in the early stages of the COVID-19 pandemic, which affected healthcare services. The government is under pressure to address the inadequate supply of domestic medical devices and lessen reliance on imported ones due to this precarious circumstance.<sup>4</sup> Following the COVID-19 pandemic in Indonesia, the Ministry of Industry reported that over 25% of the approximately 500 medical device products could have been manufactured within the country. This indicates that the majority of Indonesia's medical device raw materials are still imported.<sup>5</sup>

In order to decrease reliance on imports, the government nevertheless promotes the use of medical devices produced within the country. There were 891 businesses producing medical devices in 2021. When compared to 2015, there were only 123 businesses registered, which was a huge increase. However, Indonesia's local demand for medical devices has not yet increased despite the

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<sup>1</sup> Weppy Susetiyo and Anik Iftitah, "Peranan Dan Tanggungjawab Pemerintah Dalam Pelayanan Kesehatan Pasca Berlakunya UU Cipta Kerja," *Jurnal Supremasi* 11, no. 2 (2021): 92–106, <https://doi.org/10.35457/supremasi.v11i2.1648>.

<sup>2</sup> Pemerintah Pusat Indonesia, "Undang-Undang (UU) Nomor 17 Tahun 2023 Tentang Kesehatan" (Jakarta, 2023), <https://peraturan.bpk.go.id/Details/258028/uu-no-17-tahun-2023>.

<sup>3</sup> Pemerintah Pusat Indonesia, "Undang-Undang (UU) Nomor 44 Tahun 2009 Tentang Rumah Sakit" (Jakarta, 2009), <https://peraturan.bpk.go.id/Details/38789/uu-no-44-tahun-2009>.

<sup>4</sup> Dinas Kesehatan Provinsi NTB, "Workshop Peningkatan Penggunaan Alat Kesehatan Dalam Negeri, Implementasi Intruksi Presiden Untuk Menunjang Pelayanan Kesehatan," Dinas Kesehatan Provinsi NTB, 2022, <https://dinkes.ntbprov.go.id/berita/workshop-peningkatan-penggunaan-alat-kesehatan-dalam-negeri-implementasi-intruksi-presiden-untuk-menunjang-pelayanan-kesehatan/>.

<sup>5</sup> Natalia Endah Hapsari, "Peluang Bisnis Lewat Produk Alat Kesehatan Dalam Negeri," *Republika*, 2023, <https://ekonomi.republika.co.id/berita/ruko60478/peluang-bisnis-lewat-produk-alat-kesehatan-dalam-negeri>.

industry's relatively rapid growth. Through a variety of policies that support domestic businesses, Indonesia may reduce the number of imports.<sup>6</sup> The government has a role in ensuring that the health sector's budget collects funds and benefits the citizens. This serves as the foundation for Presidential Instruction No. 2/2022, which aims to accelerate the use of domestic products and those produced by micro, small, and cooperative businesses in the wake of the success of the national movement "Proudly Made in Indonesia" in the implementation of government procurement of goods and services.

RSUD Bali Mandara (Bali Mandara Regional General Hospital) is one of the hospitals owned by the Provincial Government of Bali. RSUD Bali Mandara started operating in October 2017 and is classified as a Class B hospital based on its hospital type. The domestic medical devices have been supplied by RSUD Bali Mandara. However, as the table below indicates, it is also known that in 2023, the RSUD Bali Mandara will continue providing imported medical devices from abroad. This suggests that the requirements stated in Presidential Instruction No. 2/2022 for the implementation of the RSUD Bali Mandara's disposable medical device procurement program are not being implemented.

**Table 1.** Procurement of Imported Disposable Medical Devices at RSUD Bali Mandara in 2023

No.	Types of Disposable Medical Devices	Name of Items	Code of Imported Medical Devices
1	Medical Mask	Masker N95 3M	AKL 21603514296
2	Syringe	SYRINGE (PISTON SYRINGE), 3 ML TERUMO	AKL 20902806418
		SYRINGE (PISTON SYRINGE), 5 ML TERUMO	AKL 20902806418
		SYRINGE (PISTON SYRINGE), 10 ML TERUMO	AKL 20902806422
		SYRINGE (PISTON SYRINGE), 20ML TERUMO	AKL 20902806419
		SURFLO IV CATH SR+OX1451C3-14G (TERUMO)	AKL 20902806423
		SURFLO IV CATH SR+OX2419C3-24GX3/4 (TERUMO)	AKL 20902806423
		SURFLO IV CATH SR+OX2225C3-22GX1 (TERUMO)	AKL 20902806423
		SURFLO IV CATH SR+OX1832C3-18GX1/4 (TERUMO)	AKL 20902806423
3	Antiseptic / Disinfectant	Presep Antiseptik	AKL 20903321928
4	Surgical Suture	Optime 2/0 ½ TP	AKL 21603221829
		Optime 3/0 3/8 RC	AKL 21603221829
		FILAPEAU(PETER SURGICAL) 3/0, 3/8 RC 20 mm,90 cm	AKL 21603222172

Source: The Pharmacy Installation of RSUD Bali Mandara (2023)

<sup>6</sup> Kurniatun K., "Akselerasi Penggunaan Alat Kesehatan Dalam Negeri," Kementerian Kesehatan Republik Indonesia, 2023, <https://www.badankebijakan.kemkes.go.id/akselerasi-penggunaan-alat-kesehatan-dalam-negeri/>.

Research on the effectiveness of Presidential Instruction No. 2/2022 in increasing the acceleration of the implementation of domestically produced disposable medical devices in hospital environments has never been explored by legal researchers, both in the theoretical and practical fields. Prior research has solely addressed certain subjects pertaining to government procurement of goods and services, medications, and medical devices; however, none of these research have examined the effectiveness of these matters. Based on the background of the research that was described above, this research aims to determine the procurement arrangements for disposable medical devices in order to accelerate the use of domestic products at the RSUD Bali Mandara and identify the factors that influence the emergence of obstacles in the implementation of Presidential Instruction No. 2/2022 in increasing the use of domestically produced disposable medical devices at the RSUD Bali Mandara.

## **RESEARCH METHODOLOGY**

The type of research applied in this research is empirical legal research. Empirical legal research includes both research on legal identification and research on legal effectiveness.<sup>7</sup> In order to address the issues in this research, researchers applied statute, conceptual, and sociological approach. The primary source, which was the researcher's direct observation of the research topic, provided the primary data. Field information from informants and respondents at the Bali Mandara Regional Hospital, located at By Pass Ngurah Rai Sanur Street No. 548, Sanur, Denpasar, Bali, served as the primary source of data for this research. The primary and secondary data are then processed using qualitative descriptive analysis. In order to obtain a meaning of the topics being discussed, this procedure entails gathering data in a systematic and consistent manner, which is then qualitatively examined. Subsequently, all of the processed data is correlated with legal theory, principles, and the perspectives of legal experts in order to draw conclusions on the research findings. These conclusions are then presented in the form of a description that explains whether the research's objectives are fulfilled.

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<sup>7</sup> Ellyne Dwi Poespasari, Trisadini Prasastinah Usanti, and Soelistyowati, "The Settlement of Adopted Children Status Regarding The Inheritance of Adoption Parents in Toraja Community," *YURIS (Journal of Court and Justice)* 2, no. 1 (2023): 40–53, <https://doi.org/10.56943/jcj.v2i1.240>.

## RESULT AND DISCUSSION

### **Arrangements for Procurement of Disposable Medical Devices at RSUD Bali Mandara**

Improvements in procurement of goods/services can be achieved by giving priority to purchasing domestic products, thereby encouraging innovations in policies related to demand for procurement of goods/services. Coercive measures are implemented to ensure that the procurement of goods/services can run effectively and efficiently, both in the process and in the results, by encouraging the use of domestic products. This action is reflected in the adoption of Presidential Instruction No. 2/2022 concerning the Acceleration of Increasing the Use of Domestic Products and Products of Micro Businesses, Small Businesses and Cooperatives to support the Proudly Made in Indonesia National Movement. Implementation of Presidential Instruction No. 2/2022 in government procurement of goods/services creates a legal foundation that applies previous laws and regulations to maximize the use of domestic products. Regarding the use of domestic products, this instruction confirms that:

1. Establish and modify policies or laws and regulations to accelerate the increase in the use of domestic products and encourage Micro Enterprises, Small Enterprises and Cooperatives.
2. Prepare, allocate and realize the procurement of government goods/services using domestic products in Ministries/Institutions and Regional Governments.
3. Prepare, allocate and realize at least 40% (forty percent) of the budget for goods/services to use domestically produced products for Micro Enterprises, Small Enterprises and Cooperatives.
4. Establish the Increasing the Use of Domestic Products Team (P3DN Team) in Ministries/Institutions and Regional Governments.
5. Develop a strategy roadmap to increase the use of domestic products and products from Micro Enterprises, Small Enterprises and Cooperatives, including a roadmap to increase the number of domestic products into 1,000,000 (one million) products displayed in electronic catalogs.
6. Make use of domestic products with a Domestic Component Level (TKDN) of at least 25% (twenty five percent) if there are domestic products with the sum of the TKDN value and the Company Benefit Weight (BMP) value of at least 40% (forty percent).
7. Encourage the accelerated display of domestic products and Micro Business, Small Business and Cooperative products in sectoral or local catalogues.

8. Include mandatory requirements for using domestic products and products produced by Micro Enterprises, Small Enterprises and Cooperatives/Artisans in all cooperation agreements.
9. Eliminate requirements that inhibit the use of domestic products and products of Micro Enterprises, Small Enterprises and Cooperatives in Procurement of Government Goods/Services.
10. Providing price preferences in Government Procurement of Goods/Services for purchasing domestic products with a TKDN value of at least 25% (twenty five percent) in accordance with statutory provisions.

Presidential Instruction No. 2/2022 is considered a breakthrough to increase the use of domestic products in the context of procurement of goods/services by the government. Increasing targets for the use of domestic products shall be accompanied by efforts to improve the ecosystem, thus, it can meet internal needs. Presidential Instruction No. 2/2022 is expected to encourage every government institutions to accelerate the use and development of domestic products, especially from micro enterprises, small enterprises and cooperatives, as well as supporting the achievement of the Proudly Made in Indonesia National Movement in the implementation of government procurement of goods/services. In addition, this instruction provides direct instructions from the President to the Governors, the Regents, and the Mayors to direct Regional Apparatus Organizations (OPD) to purchase domestic products through local catalogs or online shopping platforms.

Based on Law No. 44/2009 on Hospitals, the Government and Local Governments are responsible in providing hospitals in accordance with public needs. Meanwhile, according to Law No. 23/2014 concerning Regional Government, government affairs shall be related to basic services. Therefore, the RSUD Bali Mandara Technical Implementation Unit (UPTD) was established to provide services to the wider community around Bali, based on Pancasila, and in accordance with human and ethical values, professionalism, benefits, justice, equal rights, anti-discrimination, equality, patient protection, patient safety, and social function in society.

Procurement of goods/services at RSUD Bali Mandara, including disposable medical devices, is conducted at the Procurement Installation. According to the Regulation of the Director of RSUD Bali Mandara, Bali Province No. B.37.188.4/81970/HHP/RSBM concerning Guidelines for the Implementation of Goods/Services at the RSUD Bali Mandara, Bali Province, the Procurement Installation is a unit formed by the Budget User/Authorized Budget User (PA/KPA) to implement the procurement of goods/services at the RSUD Bali Mandara.

The following is the flow of procurement of disposable medical devices at the RSUD Bali Mandara:

1. The procurement of disposable medical devices is carried out after the budget implementation list is issued;
2. The Commitment Making Officer (PPK) registers the general procurement plan (RUP) with the Procurement Installation;
3. Planning for the demand for disposable medical devices is conducted by the Pharmacy Installation in the form of pre-procurement documents;
4. Procurement Actors (PP) use E-Purchasing through E-Catalog to choose suppliers;
5. The selection of suppliers is carried out by the PP in accordance with its authority as stated in the Budget User Authorization Decree No. B.37.188.4/2049/HHP/RSBM.

The government's procurement of goods and services spends a significant amount of money. Being largest purchaser in the nation, the government has to establish procurement policies to both support and facilitate the achievement of economic objectives. Developing policies for empowerment at the small, medium, and large levels is one tactic the government can employ in the sector of procurement. The Indonesian government's procurement decisions are invariably associated with policies designed to increase the use of domestic production. In addition to fulfilling physical development demands and ensuring the availability of goods and services, government procurement of goods and services also serves to accelerate the growth of domestic industry.<sup>8</sup> On Tuesday, December 5, 2023, the procurement officer and the head of procurement installation at RSUD Bali Mandara, Dr. I Dewa Agung Gede Manu, S.H., M.H., were interviewed. Several conclusions were drawn from the interviews:

1. In compliance with hospital policies regarding the purchase of domestically produced disposable medical devices, in accordance with national legal provisions such as Presidential Regulation No. 16/2018 jo Regulation No. 12/2021 concerning Government Procurement of Goods/Services, as well as Regulation of the Director of RSUD Bali Mandara, Bali Province No. B.37.18.4/1970/HHP/RSBM concerning Guidelines for Implementing Goods/Services Procurement at the RSUD Bali Mandara, Bali Province.
2. Supervision of the procurement of domestically produced disposable medical devices at the RSUD Bali Mandara begins at the planning stage, which gives priority to domestic products. Furthermore, in carrying out the selection of products and suppliers, this process must

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<sup>8</sup> Merry Tjoanda, *Kedudukan Pemerintah Dalam Kontrak Pengadaan Barang Dan Jasa* (Yogyakarta: Deepublish, 2023).

adhere to the provisions outlined in the Regulation No.112/2022 of the Head of the Indonesian Government Goods/Services Procurement Policy Agency. According to this regulation, the use of domestic products must be prioritized when the TKDN and BMP value reaches at least 40%. The products handover process is also adjusted to the achievements of domestic products and is structured into the Electronic Procurement System (SPSE) to record the achievements of domestic products.

3. Implementation of the procurement of domestically produced disposable medical devices at the RSUD Bali Mandara follows the established regulations, and refers to the Circular Letter of the Head of the Goods/Services Procurement Policy Institute of the Government of Indonesia No. 8/2023 concerning Implementation Guidelines for Increasing the Use of Domestic Products in the Procurement of Goods/Government Services. In the process of selecting products listed in the e-catalog, priority is given to domestic products with the following criteria: 1) products with TKDN and BMP values of at least 40%, 2) products with TKDN and BMP below 25%, 3) domestic products, 4) imported products (they could be chosen when there are no domestic products available).

Effective procurement must ensure appropriate availability, quantity and time at affordable prices and meet established quality standards. The procurement process is a series of ongoing activities, starting from choosing products, determining the required quantity, adjusting demands and budget, selecting procurement methods, selecting suppliers, determining contract specifications, monitoring the procurement process, up to the payment.

In order to ensure that medical devices meet the desired quality standards and specifications, if the procurement process is conducted by another unit other than the Pharmaceutical Installation, it is necessary to involve pharmaceutical personnel. Based on an interview with the Person in Charge of Planning at the Pharmacy Installation (Komang Widiastuti, S.Farm., Apt.) on December 8 2023, data indicates that in 2022, RSUD Bali Mandara provided 628 items of disposable medical devices from January to December, where 59 items are domestic products. Furthermore, in 2023 from January to November, RSUD Bali Mandara provided 655 types of disposable medical devices products, with 132 types being domestic products. On Wednesday, December 8, 2023, a member of the Bali Province P3DN Team, Dr. Kadek Agus Putra Sastrawan, S.STP., M.A.P., were interviewed. Several conclusions were drawn from the interviews:

1. Before planning the purchase of goods and services, in accordance with applicable regulations, PA/KPA must identify by prioritizing the use of domestic products. In terms of coordination, if it turns out that domestic



products are not available, the purchase of imported products can be considered.

2. If there is a domestically produced disposable medical device product but the user still prefers to use an imported product due to certain technical reasons that cannot be accommodated by the domestic product, the RSUD Bali Mandara may submit a letter of recommendation for the purchase of imported medical device products to the Bali Provincial P3DN Team. The request will be carefully considered to evaluate the technical reasons included. Should the explanation be justified and proven correct, the purchase of imported products may be made after a careful assessment process.
3. When the product to be purchased is an imported disposable medical device that is part of or an integral part of a medical device in the form of a previously owned machine, the purchase can be immediately made without having to report to the P3DN Team. This is because the disposable medical devices concerned cannot be replaced with domestic products.
4. When the product to be purchased is an imported disposable medical device that is part of or an integral part of a medical device in the form of a previously owned machine, the purchase can be immediately made without having to report to the P3DN Team. This is because the disposable medical devices concerned cannot be replaced with domestic products.

It can be concluded that RSUD Bali Mandara has complied with regulations related to the mandatory use of domestic products by implementing procedures in accordance with applicable regulations. In the context of the procurement of domestically produced disposable medical devices, RSUD Bali Mandara has provided opportunities for suppliers to compete with other products available in the hospital.

According to Soerjono Soekanto's theory of legal effectiveness, success in the implementation of the law is that the law made has achieved its purpose.<sup>9</sup> When people comply with and follow what is mandated by the law or regulation, or when the objectives intended by the law or regulation are achieved, then the law or regulation is considered effective. Nevertheless, related to policies and regulations regarding the procurement of domestically produced disposable medical devices at RSUD Bali Mandara, in accordance with the Regulation of the Directors of Goods and Services Procurement, has indicated its effectiveness even though it is not optimal. This is due to the fact that there is still procurement of

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<sup>9</sup> Hamdi Hamdi, Fitriani Amalia, and Sahrul Sahrul, "The Effectiveness Of Awig-Awig On Merariq Age Maturation In Prevention Of Early Marriage In Kekait Village," *Unram Law Review* 6, no. 2 (October 30, 2022): 224–35, <https://doi.org/10.29303/ulrev.v6i2.246>.

imported disposable medical devices in RSUD Bali Mandara. Although it is not possible to immediately change entirely to the use of domestically produced disposable medical devices in RSUD Bali Mandara, in the future, the use of domestic products is expected to increase.

According to Jeremy Bentham's theory of expediency, the law has the aim of generating the greatest possible benefit for society.<sup>10</sup> Law has a role as a guarantee, equality, and provides benefits to society. Regulations or laws are essentially intended to provide benefits to all members of society who adhere to them as norms that must be obeyed.<sup>11</sup> The implementation of regulations that prioritize the use of domestically produced disposable medical devices provides various benefits to both the Government and the citizens. It can minimize dependence on imported products and increase the competitiveness of domestic products.

Indroharto's theory of authority suggests that there are three kinds of authority derived from legislation, which include attribution, delegation, and mandate.<sup>12</sup> This is also stipulated in Article 11 of Law No. 30/2014 on Government Administration which specifies that authority can be obtained through attribution, delegation, or mandate.<sup>13</sup>

Based on Presidential Instruction No. 2/2022, it is recommended that the Governor orders Regional Apparatus Organizations (OPD) to purchase domestic products through local catalogs or online shopping platforms, where RSUD Bali Mandara is a specialized institution established by the Governor to support the operation of health services in Bali province. In the context of delegation of authority, the Governor of Bali has assigned all OPD leaders in Bali, including the Director of RSUD Bali Mandara as the Procurement Officer (KPA/PA), to prioritize the purchase of domestically produced goods and services, including the procurement of disposable medical devices. This delegation refers to the granting of authority by a government official to another party, where the recipient of the authority becomes responsible for its implementation. According to Article 138 Paragraph 6 of Law No. 17/2023, the Central and Regional Governments are responsible for regulating, controlling, and supervising the production, procurement, storage, promotion, and distribution of medical devices in accordance with their authority. In the context of administrative law, the granting

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<sup>10</sup> Inggal Ayu Noorsanti and Ristina Yudhanti, "Kemanfaatan Hukum Jeremy Bentham Relevansinya Dengan Kebijakan Pemerintah Melalui Bantuan Langsung Tunai Dana Desa," *Sultan Jurisprudence: Jurnal Riset Ilmu Hukum* 3, no. 2 (2023): 183–93, <https://doi.org/10.51825/sjp.v3i2>.

<sup>11</sup> Soerjono Soekanto, *Faktor-Faktor Yang Mempengaruhi Penegakan Hukum* (Jakarta: PT Raja Grafindo Persada, 2019).

<sup>12</sup> Salim H. S. and Erlies Septianan Nurbani, *Penerapan Teori Hukum Pada Penelitian Disertasi Dan Tesis* (Depok: PT. RajaGrafindo Persada, 2013).

<sup>13</sup> Pemerintah Pusat Indonesia, "Undang-Undang (UU) Nomor 30 Tahun 2014 Tentang Administrasi Pemerintahan" (Jakarta, 2014), <https://peraturan.bpk.go.id/Details/38695/uu-no-30-tahun-2014>.

of authority to a state administrative official is always accompanied by a certain intention, therefore, the use of such authority must be in accordance with the purpose of granting such authority.

The authority related to the procurement of disposable medical devices at RSUD Bali Mandara is given to the Procurement Officer who is responsible for appointing the supplier. The Procurement Officer at RSUD Bali Mandara also serves as the Head of the Procurement Installation, and to hold this position, they must hold a Public Procurement training certificate. The Procurement Officer (PP) is a staff member in charge of implementing various types of procurement, including direct procurement, direct appointment, and purchasing goods/services through the electronic catalog system (E-purchasing). This authority is the position responsibility of the procurement officer who has been appointed by the Decree of the Budget User Authority of RSUD Bali Mandara No. B.37.188.4/2049/HHP/RSBM, dated January 2, 2023.

### **Factors that Encourage and Discourage Presidential Instruction No. 2/2022 at RSUD Bali Mandara**

Medical devices serve a vital role in the implementation of healthcare services. However, although the demand for medical devices continues to increase, the development of the domestic medical device industry has not been consistent with this. In order to overcome this, through Presidential Instruction No. 2/2022, President Joko Widodo ordered the Governors to instruct Regional Apparatus Organizations (OPD) to prioritize the purchase of domestic products through local catalogs or online stores. Based on data from the Government Procurement Policy Institute E-Catalogue (LKPP e-Catalog) for 2019-2020, the 10 most purchased medical devices by the government include injection kits, infusion sets, surgical gloves, IV catheters, gauze and wound dressings, specimen storage and transportation containers, syringes, alcohol swabs, medical masks, and blood sample collection devices. Out of the 19 types of medical devices mostly purchased, 17 are domestically produced, while 2 are still imported products. Nonetheless, the increased use of domestic products, especially in government procurement of goods/services, has not yet reached an optimal level. This is due to the lack of commitment from a number of government agencies in using domestic products. In fact, increasing the use of domestic products has been made a national program.

Based on data from LKPP e-catalog, the expenditure of medical devices for domestic products in RSUD in the Bali Province as of October 2023, RSUD Bali Mandara is ranked 12th out of a total of 15 RSUD in Bali, where the number of transactions for medical devices produced domestically at RSUD Bali Mandara is relatively low at 31.70%. On Tuesday, December 5, 2023, the Head of Procurement Installation of RSUD Bali Mandara, Dr. I Dewa Agung Gede Manu,

S.H., M.H., were interviewed. Several conclusions were drawn from the interviews:

1. The implementation of the procurement of domestic disposable medical devices at RSUD Bali Mandara has followed the established regulations. In addition, there is also a Circular Letter of the Head of the Government Procurement Policy Agency of the Republic of Indonesia No. 8/2023 concerning Implementation Guidelines for Increasing the Use of Domestic Products in Government Procurement of Goods/Services concerning selecting products in the e-catalog by prioritizing domestic products.
2. One of the obstacles in the procurement of domestic disposable medical devices at RSUD Bali Mandara is that the use of domestic medical devices in this hospital is still unfamiliar to doctors, dentists, nurses, and midwives, so they have a lack of comprehension of the advantages of domestic medical device specifications and are still more accustomed to using imported medical device specifications. In addition, the stock availability of some domestic disposable medical devices has not been able to meet the hospital's demands.

A questionnaire distributed to health workers at RSUD Bali Mandara revealed that the quality of domestic disposable medical devices is considered to be acceptable. However, there are still a number of domestic disposable medical devices that are malfunctioning during use, such as handsoons with holes, wound plasters that do not stick well to the skin of patients, masks with easily broken straps, and leaking infusion hoses.

In the theory of legal effectiveness according to Soerjono Soekanto, whether a law is effective can be determined by 5 factors, including the legal system itself, law enforcement factors, facilities that support law enforcement, community factors, and cultural factors.<sup>14</sup> Whether a law is effective can be determined by the first factor, the legal factor itself. Through Presidential Instruction No. 2/2022, President Joko Widodo instructed the Governor to order Regional Apparatus Organizations (OPD) to purchase domestic products through local catalogs or online stores. In regulating the procurement of disposable medical devices in order to increase the acceleration of the use of domestic products at RSUD Bali Mandara, it has been implemented, although it has not been optimized. In terms of regulations, it is quite obvious that in the procurement of goods / services, the Government is obliged to prioritize domestic products. According to Law No. 44/2009 Article 15 Paragraph 1 stipulates that hospitals must ensure the availability of quality, useful, safe and affordable medical devices. Based on the description above, strong regulations are necessary so that there are efforts to

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<sup>14</sup> Soekanto, *Faktor-Faktor Yang Mempengaruhi Penegakan Hukum*.

improve these domestic products related to the trust of users for the quality of domestic disposable medical devices procured in hospitals.

The effectiveness of a law can also be determined by how law enforcers implement it. According to Article 73 of Government Regulation no. 29/2018 concerning Industrial Empowerment, the central government formed a National Team for Increasing the Use of Domestic Products, called the P3DN National Team, to monitor the use of domestic products. Based on interviews with sources from the Bali Province P3DN Team, P3DN's job is not as law enforcers in the procurement of goods/services for domestic products, but as supervisors and evaluators regarding the procurement of goods/services carried out by OPDs in Bali Province, including the Bali Mandara Regional Hospital. The law enforcers referred to here are the police, investigators and prosecutors.

Based on a interview with the Head of the Internal Supervisory Unit (SPI) of RSUD Bali Mandara, Drs. Maris Sihombing, Apt., M.Kes., on January 5, 2024, the supervision carried out by SPI in increasing the use of domestic disposable medical devices has been initiated from the planning stage which is adjusted to the demand and quality of domestic disposable medical devices to be procured. The procurement implementation process begins with ensuring that the duties, functions, and responsibilities of the procurement actors are understood, and in receiving the purchased domestic disposable medical devices, it is essential to verify that the goods received are in accordance with the requested specifications, and that the vendor/provider has met the regulatory requirements and standard operating procedures at RSUD Bali Mandara. In addition, this process also includes monitoring until the payment stage between the hospital and the vendor/supplier.

From the description above, it can be concluded that the procurement of domestic disposable medical devices at RSUD Bali Mandara has followed the regulations and standard operating procedures for the procurement of goods/services at RSUD Bali Mandara and has given priority to the procurement of domestic disposable medical devices, although there are still some products that come from abroad. Supervision of this procurement is carried out by SPI which has been appointed in accordance with the Director's Decree No. B.37.18.4/33646/HHP/RSBM regarding the Organizational Structure and Job Description of the SPI at RSUD Bali Mandara, Bali Province. SPI's functions include examining property security, ensuring the accuracy of financial information systems, increasing efficiency and productivity, and supporting the implementation of management policies to improve internal control at RSUD Bali Mandara. Discrepancies in procurement can result in suboptimal use or even not being used at all in healthcare services. Therefore, the hospital must continue to make improvements by evaluating the medical device procurement process, paying attention to every aspect that supports the procurement process starting from the standard operating procedures (SOP), human resources, budget, facilities

and infrastructure, as well as the planning, procurement, and acceptance processes. This aims to ensure that the implementation of the procurement of domestic disposable medical devices at RSUD Bali Mandara becomes more effective and efficient in accordance with applicable regulations.

The effectiveness of a law can be assessed from the means or facilities that support law enforcement. At RSUD Bali Mandara, the importance of facilities that support the role of law enforcement related to the procurement of domestic disposable medical devices in the hospital is confirmed by the appointment of SPI in accordance with the Director's Decree No. B.37.18.4/33646/HHP/RSBM. Based on the results of an interview with the Head of SPI, Drs. Maris Sihombing, Apt., M.Kes., on January 5, 2024 related to supporting facilities at RSUD Bali Mandara are as follows:

1. There is still a lack of improvement in human resource training at SPI regarding auditors.
2. An application program is required that is in accordance with the overall structure and risk management because the application program facilities at SPI are still lacking.

The effectiveness of a law can be influenced by the next factor, the community factor. Based on the results of data obtained from user respondents or health workers in RSUD Bali Mandara, it has been proven that they have used domestic disposable medical devices after completing the trial provided by the vendor or supplier through Integration of Primary Care (ILP). During the trial stage, the users have provided an assessment of the quality of the domestic disposable medical devices. The results of the assessment then become a reference in the procurement process of disposable medical devices by ILP. In the process of selecting disposable medical devices at RSUD Bali Mandara, the participation of the health workers as users of these products has been involved. The users, such as doctors, dentists, nurses, and midwives, have been aware of the regulations that require the use of domestic disposable medical devices at RSUD Bali Mandara. However, the most significant thing is that the use of domestic disposable medical devices in RSUD Bali Mandara still prioritizes the safety and quality of the products.

The effectiveness of a law can also be influenced by cultural factors. The implementation of Article 62 of Government Regulation No. 29/2018 will become a habit for public procurement officials once they implement it. Although there is an obligation to include the use of domestic products in documents related to the procurement of goods/services, a culture of compliance in the implementation of the use of domestic products will only be achieved if procurement officials in government agencies are aware of the regulations related to the use of domestic products themselves. According to the respondents' assessment regarding the use of domestic disposable medical devices at RSUD Bali Mandara, the

implementation has progressed relatively well. Nevertheless, there are still some imported disposable medical devices used due to the perceived better quality of imported products. However, domestic disposable medical devices available at RSUD Bali Mandara are still being used by doctors, dentists, nurses, and midwives. Thus, the procurement of domestic disposable medical devices at RSUD Bali Mandara has been adjusted to the demands of the hospital and users, and can be utilized directly in health services at the hospital. Despite this, there is still procurement of imported disposable medical devices at RSUD Bali Mandara for certain medical devices.

The increase in the use of domestic disposable medical devices in accordance with existing regulations at RSUD Bali Mandara has been implemented relatively well. Currently, RSUD Bali Mandara has implemented efforts to increase the use of domestic disposable medical devices through the following actions:

1. Identify and list domestic and non-domestic products in the procurement plan of disposable medical devices;
2. Conduct trials for domestic disposable medical devices by involving users/health workers and pharmaceutical installations;
3. Conduct device demonstrations and reliability tests for domestic disposable medical devices;
4. Evaluate and strengthen communication with suppliers/vendors of domestic disposable medical devices;
5. Improve the quality of domestic disposable medical devices by making written reports and follow-ups from domestic product suppliers/vendors for any further maintenance.

In Jeremy Bentham's utilitarianism theory, the purpose of law is to create the greatest possible benefit for society. As long as there are still doubts from potential users regarding the quality and safety of using domestic disposable medical devices in hospitals, the implementation of Presidential Instruction No. 2/2022 has yet to reach optimality. This is also an obstacle related to the quality of hospital services that cannot provide maximum benefits for customers and patients. The expected implementation of Presidential Instruction No. 2/2022 is to provide opportunities for national industries to increase production capacity and the quality of produced goods and services, so that they can compete independently in the global market. Meanwhile, in an effort to reduce the domestic market's dependence on imported products, Presidential Instruction No. 2/2022 is an additional protection against the potential decline in exchange rates.

The legal foundation for government procurement of goods/services can be found in Article 23 of the 1945 Constitution, which states that "The state budget as a form of state financial management is determined annually by law and implemented openly and responsibly for the greatest prosperity of the Indonesian

people.” Through the allocation and use of budgets to purchase domestic products as a top priority in the procurement of goods/services, various benefits can be obtained, including the empowerment of domestic industries so that they can compete in the global market, strengthening domestic industrial structures, increasing employment opportunities, and optimizing domestic products in the procurement of goods/services by the government.

## **CONCLUSIONS AND SUGGESTIONS**

### **Conclusions**

The regulation of domestic procurement of disposable medical devices at RSUD Bali Mandara is not entirely in accordance with the Regulation of the Director of RSUD Bali Mandara No. B.37.188.4/81970/HHP/RSBM concerning Guidelines for the Implementation of Goods/Services at RSUD Bali Mandara, resulting in regulations and policies implemented at RSUD Bali Mandara still ineffective. Referring to hospital data, the procurement of disposable medical devices at RSUD Bali Mandara is still dominated by imported products.

Several obstacles in the procurement of domestic disposable medical devices at RSUD Bali Mandara include: not all types of medical devices can be produced domestically, especially those requiring high technology that hospitals demand; procurement of medical devices recommended by the Government must include the Domestic Content Level (TKDN), however, some domestic products listed in the e-catalog lack the stated TKDN percentage; products listed in the e-catalog are not always available in stock, causing limitations in procurement; the price of domestic medical devices tends to be higher compared to imported products; users of disposable medical devices (including doctors, dentists, nurses, and midwives) are unfamiliar with the advantages of domestic medical device specifications and are still more accustomed to using imported product specifications; the quality of domestic disposable medical devices is considered inadequate; the procured disposable medical devices must be compatible with existing medical devices in the hospital.

### **Suggestions**

The Ministry of Health of Indonesia and the Health Department of Bali Province are advised to strengthen regulations and conduct careful monitoring to ensure that domestic disposable medical devices meet the necessary quality and safety standards. Meanwhile, RSUD Bali Mandara is encouraged to commit in supporting the use of domestic products in accordance with regulations, conduct the implementation of administrative sanctions for procurement actors and Government goods/services providers in any violations in the procurement process, improve the quality of domestic products by providing written reports and follow-up from domestic product suppliers for improvement, and produce regular reports on the presentation of domestic product uptake at RSUD Bali



Mandara through the P3DN Team which is monitored by the hospital's external auditors, such as the Inspectorate, the Financial and Development Supervisory Agency (BPKP) and the Audit Board (BPK).

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