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ANALYZING THE IMPACT OF THE BUSINESS LICENSING EASE POLICY FOR DRUG AND FOOD MSME BUSINESS ACTORS: A CASE STUDY IN EAST KALIMANTAN PROVINCE FROM 2018 TO 2023 Ratih Wulandari*1, Pranandari Kenyowulan², Marheni Juwitaningsih³, Akhmad Kamaluddin Jaffar⁴

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Abstract: The limited number of products registered with the Indonesian FDA by MSMEs is primarily attributable to their ignorance of the procedures involved in obtaining product authorization. The Samarinda provincial office of the Indonesian Food and Drug Administration has launched the "Si Jebol" program, which assists MSMSEs in obtaining product authorization. This study aims to determine how the policy of ease of business licensure for pharmaceutical and food micro, small, and medium enterprises (MSMEs) affected product authorization in the province of East Kalimantan from 2018 to the first semester of 2023. This research methodology employs a descriptive qualitative analysis of secondary data obtained from the Samarinda annual reports of the provincial office of the Indonesian FDA. The findings indicate that the convenience of business licensing policy, which was executed by the Provincial office of the Indonesian FDA in Samarinda, effectively stimulates the issuance of product authorization permits. The obstacles encountered by MSMEs during the registration process for product authorization may serve as the foundation for future policies designed to assist MSMEs. Additional research on the challenges encountered by micro, small, and medium enterprises (MSMEs) is crucial in order to establish intervention strategies that the provincial office of the Indonesian FDA in Samarinda can implement.

Keywords: Indonesian FDA, Product Authorization, East Borneo, Policy, Micro Small and Medium Enterprise (MSME)

Abstrak: Kurangnya pengetahuan pelaku usaha tentang tata cara mendapatkan izin edar menginisiasi program Sertifikasi Jemput Bola "Si Jebol" BBPOM di Samarinda yang merupakan serangkaian kegiatan untuk mempermudah pelaku usaha dalam mendapatkan izin edar. Tujuan dari penelitian ini adalah untuk menganalisis dampak kebijakan kemudahan perizinan berusaha bagi pelaku usaha UMKM obat dan makanan terhadap jumlah izin edar produk di provinsi Kalimantan Timur dalam periode tahun 2018-2023. Metode penelitian ini menggunakan analisis kualitatif pendekatan deskriptif terhadap data UMKM dalam periode tahun 2018 sampai dengan semester I tahun 2023 dengan menggunakan data sekunder berupa dokumen laporan tahunan BBPOM di Samarinda. Hasil analisis menunjukkan bahwa kebijakan kemudahan perizinan berusaha yang dilaksanakan oleh Balai Besar POM di Samarinda memberikan dampak positif terhadap peningkatan jumlah izin edar produk yang diterbitkan. Adapun temuan kendala yang dihadapi pelaku usaha dalam mendaftarkan izin edar produk, dapat menjadi dasar

pengambilan kebijakan selanjutnya. Kajian lebih lanjut mengenai kendala yang dihadapi pelaku usaha UMKM penting dilakukan sebagai dasar penetapan kebijakan intervensi yang dapat dilakukan oleh Balai Besar POM di Samarinda.

Kata Kunci: BPOM, Izin Edar, Kalimantan Timur, Kebijakan, UMKM

I. Introduction

Micro, Small, and Medium Enterprises (MSMEs) dominate domestic economic activity; the President of the Republic of Indonesia has designated this as a particular concern in the direction of MSME development policies for Cooperative Modernization and Upgrading. MSMEs are enterprises that are capable of being operated by households, organizations, and other small businesses. In Law of the Republic of Indonesia No. 20 of 2008, the government specifies its definition more precisely by dividing the types of categories according to the quantity of assets under management. (Muhammad Idris, 2023).

The Covid-19 pandemic, which emerged in late 2019, is a significant challenge to the Indonesian economy, comparable to the severe economic catastrophe seen in 1997. Micro, Small, and Medium Enterprises (MSMEs), crucial contributors to the country's economy, were also impacted by the Covid-19 pandemic, leading to a considerable decline in employment opportunities. In December 2020, the government allocated a minimum of Rp123.5 trillion and offered its primary incentives to commercial entities impacted by the Covid-19 pandemic (Rosmery E, 2021). Indonesia successfully navigated the economic crisis created by the Covid-19 outbreak by implementing a range of measurable strategic measures and aligning with MSMEs (Micro, Small, and Medium Enterprises).. The Covid-19 epidemic had a considerable effect on the viability of MSMEs, as it caused a decline in the country's economy. According to data from Katadata Insight Center (KIC), a significant 82.9% of MSMEs were affected by a decline in growth, while only 5.9% enjoyed an increase in growth. Data study indicates that the primary challenges encountered by MSME business operators during the epidemic primarily revolve around their incapacity to settle debts and the hurdles they experience in securing finance assistance. Consequently, the government implemented strategic measures such as debt restructuring programs, capital aid, and other forms of financial support (Haryo L, 2021). The financial challenges encountered by MSME business operators can result in job termination, necessitating focused attention from relevant stakeholders, particularly the government. Additional challenges encountered encompass the acquisition of raw materials, a reduced client base, hindered distribution, and diminished production capacities (Maryanto, M., et al. 2022). The government plays a crucial role in implementing

capacity development initiatives for MSME business actors by giving priority to enhancing labor capacity (HR), capital capacity, and optimizing technology utilization in both the production process and product marketing (Ma'ruf, M., et al, 2021).

According to data from the Ministry of Cooperatives and Small Businesses, Indonesian micro, small, and medium enterprises (MSMEs) make up 99% of all business units in the country. These MSMEs contribute 60.5% to the country's GDP and account for 96.9% of national employment. These statistics highlight the significant role that MSMEs play in driving the Indonesian economy. To enhance the competitiveness of MSMEs and effectively implement the President's development agenda, it is crucial to foster collaboration among all relevant stakeholders, considering the strategic significance of MSMEs and the challenges they encounter. The government's procurement policies, both at the central and regional levels, require a minimum of 40% of goods and services to be sourced from Micro, Small, and Medium Enterprises (MSMEs) and domestic cooperatives. These policies are a concrete manifestation of government support and are in line with the implementation of Article 97 of the Job Creation Law (Lasmi Ariyanti, 2023).

The government has established a goal for the development of Micro, Small, and Medium Enterprises (MSMEs) in the year 2024 as part of the National Medium-Term Development Plan (RPJMN) for the period 2020-2024. The success rate is determined by assessing various indicators, such as the national entrepreneurship ratio of 3.9%, the contribution of MSMEs to GDP amounting to 65%, the increased proportion of SMEs engaged in partnerships reaching 11%, the ratio of MSME loans to total banking loans reaching 22%, a growth rate of 4% in entrepreneurship, the establishment of 30 new IKM centers outside Java, and the achievement of distributing People's Business Credit valued at Rp 325 trillion.

MSME business players frequently encounter the challenge of business license, which is a technological barrier. Business licensing is crucial, particularly in the context of market liberalization during the period of globalization. Micro, Small, and Medium Enterprises (MSMEs) can endure the challenges posed by the Covid-19 pandemic by leveraging the government's simplified licensing policy and streamlined processes for managing business and product legality. This includes obtaining permits from regulatory bodies such as National Agency of Drug and Food Control, ensuring halal certification, and securing patent rights (Alfianto, D., & Lambelanova, R, 2021). The Job Creation Law, passed in 2020, seeks to untangle multiple overlapping regulations by implementing significant reforms. To attain the objective of developing micro, small, and medium enterprises (MSMEs), Minister of National Development Planning and Head of Bappenas, Suharso Monoarfa, emphasizes the necessity of

a Draft Implementation Regulation (RPP). This regulation is also a requirement stipulated by the Job Creation Law. The purpose of this is to expedite the enhancement of MSME data collection by means of a unified database, the establishment of MSME criteria, the simplification of business licenses, integrated management, and the advancement of business incubation (Bappenas, 2021).

The capability of MSMEs to contribute to the domestic economy is not directly correlated with their export capacity, which has never surpassed 19% of Indonesia's overall export value. Research indicates that there are various issues that have an impact, such as difficulties in obtaining export permissions, limitations in finance, inadequate proficiency in the English language, and insufficient access to information linked to exporting (Tambunan T, 2019). Hence, it is imperative for the government to exhibit favoritism by empowering and enhancing legal safeguards for MSME business operators through simplified licensing procedures (Redi A, et al. 2022). The government must implement a set of laws and utilize technology to streamline the licensing procedure in order to support the autonomy of MSME actors (Al Huzni S & Susanto Y.A, 2021).

According to a study conducted by Marthaliana in 2018, over 50 percent of MSME entrepreneurs in Indonesia are women. These women primarily engage in home and small industries that require specialized talents, as well as culinary companies. The government should implement sustainable empowerment initiatives that align with MSME business actors. Enhancing proficiency and comprehension in product marketing, product design, management aptitude, e-commerce usage, business capital support, aid in business plan preparation, and fostering business networks are among the achievable objectives.

The POM Agency, as a non-ministerial government entity, consistently backs President Joko Widodo's initiatives concerning micro, small, and medium enterprises (MSMEs), particularly those in the pharmaceutical and food sectors. In 2018, the POM Agency, in collaboration with seven key Ministries/Institutions, initiated an integrated initiative called "Development of MSMEs for Traditional Medicines, Cosmetics, and Competitive Food". This program aligns with the Nawacita President's agenda to enhance the productivity and worldwide competitiveness of products manufactured by Micro, Small, and Medium Enterprises (MSMEs). The POM Agency offers various forms of support in this program, such as streamlining licensing regulations and reducing bureaucratic processes. They also provide technical guidance to business actors and offer incentives in the form of a 50% reduction in registration fees for processed food products, based on the applicable Non-Tax State Revenue rate (National Agency of Drug and Food Control, 2019).

In light of the implementation of the Job Creation Law No. 11 of 2020 and its associated government regulations, particularly government regulations No. 5 of 2021 regarding the Implementation of Risk-Based Business Licensing, there is a need for more specific laws and regulations that provide detailed explanations about technical implementation. Hence, the POM Agency has issued Regulation No. 10 of 2021, which pertains to Business Activity and Product Standards in the Implementation of Risk-Based Business Licensing in the Drug and Food Sector. This regulation aims to facilitate and expedite the licensing process for Drug and Food MSMEs in Indonesia. The MSMEs operating in the medical and food sectors are considered as priority industries that require support to enhance their contribution to Indonesia's GDP. Consequently, the POM Agency is responsible for developing policies that can have a beneficial effect, particularly in ensuring the continuity of a favorable business environment through licensing regulations for the distribution of drugs and food in Indonesia (Sudewo P. A, 2021). Over the past decade, there has been a consistent growth in the number of MSME business entities in East Kalimantan Province, as evidenced by the expansion of the industrial sector and trade in goods and services. Nevertheless, there are still numerous challenges mostly associated with business capital, business management proficiency, hurdles in product certification, and a deficiency in product marketing expertise. The issue of hurdles in product certification arises from the insufficient understanding of business actors on the procedures for acquiring distribution permits, resulting in a low number of MSME products registered with the POM Agency. In order to effectively supervise the Food and Drug Supervisory Center in Samarinda, it is necessary to take strategic measures. These measures should take into account the available Human Resources (HR) and aim to optimize the integration of innovation with other supporting elements during the policy development process (Afriadi H, 2019).

Since 2019, the POM Center in Samarinda has introduced the "Si Jebol" Ball Pickup Certification program to boost the registration of drug and food MSMEs in East Kalimantan Province with the POM Agency. The POM Center in Samarinda offers extensive support to MSME business owners, including guidance on registration procedures, assistance in designing production rooms, development of SOPs, recommendations for Good Drug and Food Production Methods, and support in the registration process for the Distribution License Number (NIE). This mentoring program offers complimentary laboratory testing services for MSME products that will be registered with the POM Agency. The POM Agency encounters several hurdles in augmenting the quantity of MSME firm participants in the medical and food sectors. Hence, this study was undertaken to ascertain the influence of the leniency of licensing

regulations on the quantity of MSME entrepreneurs who acquire permits for product distribution under the jurisdiction of the POM Center in Samarinda.

II. Literature Review

Definition of Drugs and Food

The scope of the Presidential Regulation of the Republic of Indonesia Number 80 of 2017, which pertains to the Food and Drug Supervisory Agency, encompasses drugs, medicinal ingredients, narcotics, psychotropics, precursors, addictive substances, traditional medicines, health supplements, cosmetics, and processed foods.

Distribution License

Based on the Food and Drug Supervisory Agency Regulation No. 26 of 2018, a distribution permit is required for the circulation of Drugs and Food in Indonesia. This permit is granted to manufacturers and/or importers after assessing the safety, quality, and suitability of the products.

In the Indonesian Big Dictionary, policy is defined as a set of concepts and principles that provide guidance and foundation for a strategy in executing tasks, leadership, and behavior (both inside the government and organizations). Public policy refers to the governmental actions undertaken to address societal issues. The activity can be conducted either directly or indirectly through diverse entities that strive to achieve specific objectives in society (Taufiqurakhman, 2014).

The Law of the Republic of Indonesia Number 6 of 2023, which incorporates the Government Regulations in Lieu of Law Number 2 of 2022 concerning Job Creation, defines ease of doing business as the facilitation of job creation through a streamlined, uncomplicated, and expedited business process. This approach aims to stimulate increased investment, empower micro, small, and medium enterprises, and bolster the economy, ultimately leading to the creation of a wide range of employment opportunities for the Indonesian population.

III. Research Methodologies

Qualitative analysis is employed to identify a broad range of potential outcomes, encompassing both factual information and subjective viewpoints, on a given issue. The qualitative methodologies that can be employed encompass interviews, observations, workshops, protocol analysis, and ethnographic studies (Cadle, J., Paul, D., & Turner, P.,

2014). Qualitative analysis employs a distinct methodology in contrast to quantitative methodologies. Although there are similarities in the technique, qualitative analysis primarily emphasizes the examination of text and visuals. The historical roots of qualitative research can be traced back to the disciplines of anthropology, sociology, humanities, and evaluation. Case studies are a viable method for conducting qualitative analysis. The case study is a methodological approach specifically created for qualitative investigation of phenomena across scientific disciplines. It is particularly useful in assessment research, when researchers perform comprehensive analyses of a specific instance, program, event, activity, process, or individuals. Analysis is conducted within a specific timeframe and context, where researchers gather comprehensive information through diverse data gathering techniques over regular intervals of time (Creswell, J. W. 2014).

In this study, the author employed a qualitative case study methodology with a descriptive approach. The author focused on presenting the factual findings of the study, which were derived from the field observations of problems, constraints, and other relevant factors. These findings were processed and presented in a descriptive manner, rather than being subjected to statistical analysis. The MSME data is derived from secondary sources, specifically the annual report documents of the POM Center in Samarinda spanning from 2018 to 2022, as well as the mentorship data for the first semester of 2023. Furthermore, interviews were performed with pertinent stakeholders, including business players and the internal Food and Drug Supervisory Center in Samarinda. The acquired data is subsequently processed and analyzed to ascertain the influence of the ease of doing business policy on the registration of medicine and food business entities that comply with legal requirements in the province of East Kalimantan. The findings of this analysis will serve as a foundation for subsequent actions aimed at augmenting the number of business entities supported in acquiring distribution permits.

IV. Result and Discussion

In accordance with POM Agency Regulation Number 10 of 2021, which pertains to business activity and product standards in the implementation of risk-based business licensing in the drug and food sector, the POM Center in Samarinda initiated mentoring activities in 2021. These activities aim to provide support to micro, small, and medium enterprises (MSMEs) in East Kalimantan, enabling them to progress and advance. The measure of success is the growth in the number of business entities that acquire legal authorization in the form of

distribution permits for items registered with the POM Agency. The specific products being focused on include Traditional Medicines, Cosmetics, and Processed Foods.

- a. The distribution permit number (NIE) is a crucial legal need for the widespread marketing of any drug or food product, whether it is intended for domestic distribution within Indonesia or for export to the global market. The POM Agency has implemented measures to ease the provisions and services offered to MSME business actors;
- b. Streamlining the specifications for construction regulations in manufacturing plants;
- c. Staged application of Good Traditional Medicine Production Methods (CPOTB) for UMOT UKOT;
- d. Enforcement of Good Cosmetic Production Methods (CPKB) for Cosmetic Micro, Small, and Medium Enterprises (MSMEs);
- e. Implementing self-assessment of permits for the application of Good Processed Food Production Methods (CPPOB) for Processed Food Micro, Small, and Medium Enterprises (MSMEs); and
- f. Progressive adoption of Risk Management (PMR) for Micro, Small, and Medium Enterprises (MSMEs) in the processed food industry.
 - The relaxation provided by the POM Agency to commercial entities is also obligatory for the POM Center in Samarinda, which functions as the UPT of the POM Agency. Consistent with this policy, the POM Center in Samarinda has intensified its efforts to assist MSMEs by introducing the innovation "Si Jebol" (Ball Pickup Certification) in 2019. This innovation involves certification officers visiting business operators to ensure compliance with product distribution permits. Si Jebol Innovation offers comprehensive assistance throughout the whole process of obtaining a distribution permit, including an initial visit to production facilities to establish production facility plans;
- g. Support in the approval process of floor plans for small and medium-sized enterprises (MSMEs) engaged in cosmetic production;
- h. Providing technical guidance for CPPOB, CPOTB, and CPKB;
- i. Conducting subsequent visits to production facilities in order to oversee the adherence of construction/renovation of production facilities to the approved floor plans;
- j. Providing guidance on preparing SOP documents;
- k. Providing assistance in enhancing Corrective and Preventive Actions (CAPA) to improve the outcomes of audits;
- 1. Complimentary product testing to fulfill the prerequisites for obtaining a permit for product distribution; and

m. Support in obtaining a permit for product distribution registration.

Table 1. Data on the Number of MSME Actors in East Kalimantan Province

MSMEs Based on Business Scale	Year Data					
	2019	2020	2021	2022		
Micro	201.980	297.496	334.483	334.483		
Small Business	8.887	9.151	9.500	9.500		
Medium Enterprises	681	696	598	598		
Total	211.548	307.343	344.581	344.581		

Source: Government of Prov. East Kalimantan, 2023

The data presented in Table 1 provides information on the quantity of MSME business operators in East Kalimantan Province, indicating the magnitude of their business potential and economic worth. Furthermore, the resilience of MSME business operators in weathering the economic crisis is seen in the observed rise in their numbers. According to official data from the Regional Development Planning Agency (BAPPEDA) of East Kalimantan Province, the number of micros, small, and medium enterprises (MSMEs) has experienced a substantial increase. In 2022, there were 344,581 MSMEs in East Kalimantan Province, compared to 211,548 in 2019.

The Central Bureau of Statistics (BPS) of East Kalimantan Province released the Profile of Micro and Small Industries (IMK) in 2019. The survey conducted revealed that there were over 32 thousand firms dispersed over East Kalimantan Province. Samarinda City has the highest concentration of business entities, accounting for 27.7% of the total. Based on industry categories, the food industry is the largest category in terms of market share, accounting for 45.69%. Furthermore, there are an additional 50 IMK enterprises categorized under the KBLI 21 code, which pertains to the pharmaceutical sector, chemical medicinal products, and traditional medicines. The POM Center in Samarinda must effectively manage the abundance of business actors it encounters.

The insufficient funds allocated for MSME assistance directly affects the range of activities and support that the POM Center in Samarinda can offer to MSMEs in the East Kalimantan Region. From 2018 to 2021, the DIPA POM Center in Samarinda did not have a

dedicated budget allocation for MSME facilitation and assistance operations. Therefore, these activities were funded by leveraging money from other initiatives.

In relation to 2022, the DIPA of the POM Center in Samarinda has incorporated measures to support and aid MSMEs, in accordance with the POM Agency Policy. This includes setting a target indicator to increase the number of accompanied MSMEs and the percentage of eligible MSMEs in the East Kalimantan Region. The budget for MSME facilitation and assistance in 2022 experienced a significant growth of 102.54% compared to the previous year, as shown in Figure 1.

134.817.000

112.701.000

48.240.000

33.228.440

1.200.000

Anggaran (Rupiah)

2018 2019 2020 2021 2022 2023

Figure 1. Availability of funding for support and aid to Micro, Small, and Medium Enterprises (MSMEs)

Source: Processed by Researchers from the POM Center in Samarinda, 2023

In 2018, there was a lack of socialization and technical guidance initiatives for MSME business actors. In 2019, collaborative technical guidance activities were conducted with stakeholders, specifically the Bontang City Trade and Cooperative Office, which prioritized compliance with rules. The activities conducted involved providing CPPOB technical guidance specifically aimed at processed food MSME firm operators in Bontang City.

In 2020, modifications were implemented in the mentorship strategy as a means of adapting to the Covid-19 epidemic. This circumstance results in a transition of patterns from offline to online. The actions conducted involved providing CPOTB technical guidance through virtual meetings, which were attended by business players and representatives from several regencies/cities.

The CPPOB technical guidance was place in 2021, in East Kutai Regency, in partnership with PT. PAMA PERSADA NUSANTARA. The aim was to support processed food MSME business actors nurtured by the company. Furthermore, in collaboration with the

Berau Health Office, we provided technical support to commercial entities in Berau Regency utilizing the Special Allocation Fund (DAK) from the POM Agency.

The provision of dedicated budget allocations enhances the capacity to offer several forms of support for MSMEs, hence increasing their flexibility in accessing facilitation and assistance. The funds allocated for MSME facilitation and assistance is utilized for a range of activities with the objective of assisting business players in obtaining distribution permits. The activities conducted involve the socialization of distribution permits by the POM Agency, which serves as a platform for communicating business-friendly policies for MSMEs. Additionally, technical guidance is provided on CPOTB, CPKB, and CPPOB to ensure compliance with good production practices. Initial assistance is given through facility visits to aid in the preparation of production floor plans, followed by ongoing supervision to ensure compliance with the specified facility requirements.

The provision of a dedicated budget for the facilitation and support of micro, small, and medium enterprises (MSMEs) at the DIPA POM Center in Samarinda in 2022 and 2023 progressively enhances the facility's capability and capacity to socialize distribution permits throughout all districts and cities in East Kalimantan Province. Annually, two regencies/cities organize socialization activities for distribution permits in order to facilitate communication between Balai and MSME business actors. In 2022, socialization activities for distribution permits will be conducted in the regencies of Kutai Kartanegara and North Penajam Paser. Additionally, socialization activities are conducted virtually in order to broaden the scope of information distribution. The primary audience for virtual technical guidance on fulfilling aspects of CPPOB, CPOTB, and CPKB consists of start-up MSME business actors seeking comprehensive information regarding the implementation of traditional medicine, cosmetics, and food production methods. This guidance is also provided to MSME business actors undergoing the registration process for distribution permits. Socialization of distribution permits has been completed in East Kutai Regency for the first semester of 2023; it will proceed in Berau Regency for the second semester.

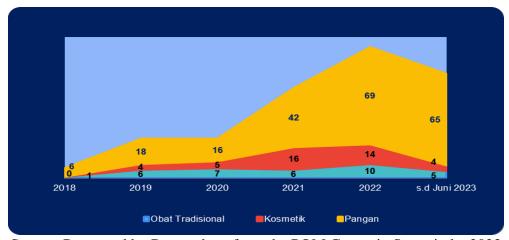
The undertaken initiatives broaden the scope of micro, small, and medium-sized enterprise (MSMEs) as business participants while obtaining distribution permits from the National Agency for Drug and Food Control for all product commodities, including processed foods, cosmetics, and traditional medications. This development represents a favorable breakthrough, as socialization efforts during the preceding period (2018-2021) were concentrated on a single commodity and influenced the evolution of distribution permit assistance from processed food commodities to traditional medicines and cosmetics.



Source: Processed by Researchers from the POM Center in Samarinda, 2023

Figure 2. Number Of MSME Business Actors Exposed To Ease Of Doing Business

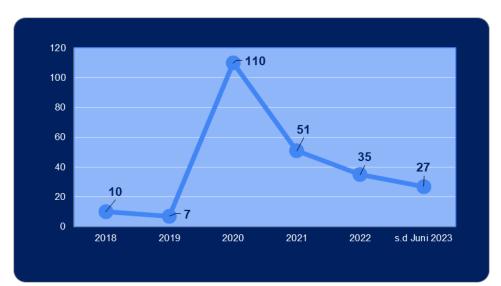
By conducting virtual meetings and engaging in a variety of in-person and district/city-based activities, mentoring success increased by 241.08% among the average number of business actors exposed to ease of doing business from June 2022 to June 2023, as compared to the same period the previous year (Figure 2). Relevant stakeholders, such as the provincial government of East Kalimantan, district and city administrations, and private and state-owned enterprises (SOEs) engaged in Corporate Social Responsibility (CSR), are also engaged in the execution of activities. Involvement of stakeholders can broaden the scope of information dissemination regarding socialization and bimtek activities to MSME business actors, thereby enhancing the efficacy of information dissemination concerning MSME assistance milestone monitoring and ease of doing business.



Source: Processed by Researchers from the POM Center in Samarinda, 2023 Figure 3. Business Actors Who Get MSME Facilitation and Assistance

Consistent with the rise in the number of MSME business actors who continue to request MSME assistance, the number of MSME business actors exposed to the convenience of doing business has increased. In order to facilitate business actors, Si Jebol's innovation has progressed steadily from 2019 to the present. There were 120 business actors that progressed to the stage of assistance for distribution permits between 2019 and 2021. From June 2023 until 2022, there were 167 business actors that maintained their progress to the stage of assistance for distribution permits. Since the introduction of Si Jebol in 2019, the average annual growth rate of requests for distribution permit assistance by MSME business actors has been 108.75% (Figure 3).

This trend indicates a growing sense of urgency and interest among business actors in acquiring a distribution permit. The policy implemented by the POM Center in Samarinda, which prioritizes simplicity of licensing, assistance, and facilitation, has an impact on this. Supporting the compliance of production facility standards by MSME business actors is facilitated by the implementation of this policy. Mentoring provides MSMEs with more comprehensive and individualized guidance. As a government agency, the provision of facilitation brings the POM Center in Samarinda in closer proximity to business actors, who play a crucial role in ensuring that the community has access to secure and high-quality food and medicinal products.



Source: Processed by Researchers from the POM Center in Samarinda, 2023

Figure 4. Number of NIE Published in East Kalimantan

In 2018, business actors in East Kalimantan Province were restricted to distributing a maximum of ten NIE Bottled Drinking Water (AMDK) products per permit. For a total of nine

(9) new NIE, the POM RI Agency granted NIE to one culinary MSME facility and one traditional medicine MSME facility in Samarinda City in 2019 for additional product categories. A number of Bontang City Food and Traditional Medicine MSMEs have fulfilled the criteria set forth by CPPOB and CPOTB in the year 2020. This resulted in the issuance of one hundred ten NIEs in East Kalimantan in 2020, which significantly increased the quantity of NIE products produced in the region. As depicted in Figure 4, the quantity of NIEs published in 2020 demonstrates that East Kalimantan's MSMEs are dependable and capable of enduring the economic crisis brought on by the Covid-19 pandemic.

With a cumulative value of 240 NIE (Table 2), as of June 2023, business entities possessing distribution permits issued by the POM Agency are dispersed among eight districts/cities out of a possible nine districts/cities falling under the jurisdiction of the POM Center in Samarinda. These districts/cities consist of Bontang City, Berau Regency, Kutai Kartanegara Regency, West Kutai Regency, East Kutai Regency, North Penajam Paser Regency, and Paser Regency.

Table 2. NIE Data Published per Regency / City in East Kalimantan

Provice/Cities	Amount NIE						Total
	2018	2019	2020	2021	2022	s.d Juni 2023	
Samarinda	6	7	72	34	16	3	138
Bontang	0	0	29	8	12	8	57
Berau	3	0	3	0	2	11	19
Kutai Kartanegara	0	0	6	6	0	1	13
Kutai Barat	1	0	0	0	1	3	5
Kutai Timur	0	0	0	1	2	1	4
Penajam Paser Utara	0	0	0	2	0	0	2
Paser	0	0	0	0	2	0	2
Mahakam Ulu	0	0	0	0	0	0	0
Total	10	7	110	51	35	27	240

Source: Processed by Researchers from the POM Center in Samarinda, 2023

Samarinda City is home to the majority of NIEs issued in East Kalimantan Province, exceeding 57%. This figure is consistent with the proportion of business actors residing in Samarinda, which accounts for 27.7% of the total number of business actors in East Kalimantan Province. The vast assortment of products held by a number of business actors with substantial capital also contributes to the high quantity of NIEs that are owned by business actors in Samarinda City. Business actors have the ability to register product variations in accordance with the production facility permits they own when they register a product distribution permit. This enables a single business actor to possess multiple product NIEs. Bontang City, renowned for its empek-empek products, boasts the second highest quantity of NIE. In order to expand the market reach of their products, empek-empek vendors are required to obtain a distribution permit from the POM Agency. The Bontang City Industry and Trade Office actively provides coaching and support to micro, small, and medium enterprises (MSMEs) in Bontang. This includes facilitating collaboration with the POM Center in Samarinda during the distribution permit procedure. The augmentation of distribution permits serves to enhance the quality control, effectiveness, and safety of food and medicinal products that are in circulation within East Kalimantan. Additionally, it demonstrates the competitiveness of domestic East Kalimantan enterprises against foreign products. However, despite acknowledging this, the growing number of wagering business actors that had planned to utilize MSME facilitation and assistance were unable to do so as a result of the onerous quantity of distribution permit numbers. This deficiency can be attributed to the following factors among others:

- 1. The constraints faced by business actors when it comes to allocating funds for the renovation or construction of production facilities to ensure they satisfy the necessary standards for quality production facilities.
- 2. Challenges associated with the recruitment of pharmaceutical technical personnel (TTK), pharmacists, or trained TTK to oversee the production facilities for traditional medicines and cosmetics.
- 3. The capacity of business actors to remunerate the individual responsible for overseeing UMOT and UKOT production facilities is restricted.
- 4. Business actors have restricted aptitude with regard to establishing SOPs.

V. Conclusion

The policy enforced by the POM Center in Samarinda, which functions as the UPT of the POM Agency in East Kalimantan Province, to facilitate business licensing is consistent with POM Agency Regulation Number 10 of 2021. This regulation implements the mandate of Government Regulation of the Republic of Indonesia Number 5 of 2021 regarding the Implementation of Risk-Based Business Licensing. Specifically, it establishes MSME assistance as a Key Performance Indicator Performance Target and a designated special purpose category. The implementation of this policy results in a notable upsurge in the issuance of product distribution permits. A substantial surge in the number of distribution permits has occurred in East Kalimantan Province, which is now distributed among 240 (eight) regencies/cities as opposed to the 10 permits issued in 2018. Among all cities, Samarinda holds the record for the most NIE distribution permits with 138 (one hundred thirty-eight). Nevertheless, there are still a number of obstacles that hinder the registration of product distribution permits by MSME business actors. The results of this investigation may serve as the foundation for the POM Center in Samarinda to develop a new policy regarding the facilitation of product distribution permits for MSME business actors.

On the basis of the findings of the preceding case study, additional research is required to determine the challenges encountered by MSME business actors that have been assisted in meeting the requirements for production facilities. As a foundation for establishing intervention policies that the POM Center in Samarinda may implement, this is a crucial task. Stakeholder engagement may serve as an alternative course of action to surmount the limitations imposed by the limited financial resources of MSME business actors. Concerning the satisfaction of the individual in command of Traditional Medicine and Cosmetic MSMEs, further deliberation is required to ascertain policy relaxations that will aid in the growth of MSME business actors in these industries. It is also crucial to conduct additional research on the constraints that business actors face when developing SOPs so that they can serve as a benchmark when determining strategic measures to promote the autonomy of MSME business actors.

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