



(Research/Review) Article

Strategy for Penetrating Global Regulatory Barriers: A Case Study of Non-Tariff Measures for Biopharmaceutical plant MSMEs in Lumajang

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Abstract: A MSMEs in Indonesia has recently contributed to national exports by 15,7% compared with Thailand that has reached 29 %, so substantial revision are required to make sure that increasing contribution which ultimately will give positive impact toward the economy overall, because almost 90 % of human resource work in MSMEs sector with nature resource and other plentiful resources. The main problem that is commonly found by MSMEs is to optimize the available resources as well as fulfill the required standards that have established and required regulation in order to ensure the resulting product is accepted by the market and to comply with the regulation that has been established by the regulator. Indonesia as the second biggest country in the world has biodiversity certainly offers benefits that hard to imitate by other country in producing biopharmaceutical plants product, therefore it offers competitive potential in the global market, however market penetration by MSMEs biopharmaceutical plants sector commonly discontinued regarding with technical barriers to trade (TBT). This study is based on a case study that aims to analyze main challenges in fulfillment of international certification and to formulate adaptation strategy for MSMEs. By conducting through a descriptive qualitative method with case study approaches, the result of study indicates that high compliance costs, registration procedural complexity from the source and destination country, as well as the inconsistency of raw material quality became the main barriers. The proposed strategy including group certification model, CPOTB standard harmonization, and the utilization of integrated government assistance schemes will provide real contribution in assisting MSMEs fulfilling global market requirements.

Keywords: MSMEs; Biopharmaceutical plants; Global Regulation; Certification; Standardization'

1. Introduction

Health market products based on nature (biopharmaceutical plants) are expected to continue growing along with global back-to-nature trend. Indonesia as the second largest mega biodiversity country in the world has more than 30,000 herbal species. Nonetheless, MSMEs contribution to biopharmaceutical plant product export remains low compared with neighboring countries such as India or China or even Malaysia. The main barrier is no longer on raw material quality intrinsically, instead of the fulfillment of non-tariff measures (NTMs). Global regulations such as the European Union Medical Agency (EMA) or US FDA applying safety standards, efficacy, and strict quality. For MSMEs with limited export regulation knowledge, these requirements commonly become impermeable barriers without the right strategy. The core of the issue is the readiness of MSMEs for exporting not only limited to funding, but also to overcome the impact of trade restrictions that caused by non-tariff measures (Fliess & Busquets, 2006; Chia, 2013; Sithamparam et al., 2017). As part of their initiative to go international, MSMEs commonly encountered a substantial barrier. These barriers are complex in nature and may originate from company internal itself or even from a wider business environment, a place where the MSMEs operate, including barriers from trade policy. On the other hand, a lot of MSMEs that receiving supplies from non-standardized agricultural producers since pursuing high-volume orders, which often leads to unfavorable conditions for the MSMEs that will exporting biopharmaceutical plants raw material. The inconsistency supplies also become a common barrier encountered by them (Fliess and Busquets, 2006). One of the findings is that the majority of MSMEs surveyed assess that the barriers related

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with internal capacities and access as barriers is the most significant in the internationalization process, while barriers related with business environment (including trade policy) are considered as less important. However, there has been a change in perception when MSMEs response is analyzed based on their activity level on the international market. Inactive exporters tend to be concerned about financial and access, meanwhile a company that has export experience conversely, they tend to be more concerned about their operational business environment. However barriers that related with financial, access, and internal capacities hinder the progress and MSMEs internalization, trade tariff barrier and non-tariff can have a highly damaging impact for MSMEs since those barriers are commonly beyond of their control and hard to deal with. Even though the trade barriers are not only impacting on MSMEs and commonly not specifically addressed to MSMEs because these barriers are typically encountered well by big as well as small companies, MSMEs are the most vulnerable and require an open environment as well as transparency to operate.

One of the conclusions is that the majority of MSMEs evaluate the barriers related with internal capability and access as more significant barriers to the internationalization process compared with barriers related with the business environment. Specifically, when invited to evaluate the barrier based on the extent to which those barriers prevent their capability for accessing international market, MSMEs that participate in that survey consider the "internal" company issues as more significant barrier in accessing international market compare to barrier from domestic environment and foreign/the host country where the company operates, including the policy barrier (tariff and regulation). However, apparently there is a difference between companies in export activity. Inactive exporters tend to consider the financial and access barrier, while exporting companies tend to prioritize issues that are related with the overall business climate, including trade barriers. The difference between inexperienced and experienced exporters is also found in other studies that experienced companies in the international market tend to consider their uncontrollable barriers (Moini, 1997).

2. Literature Review

The MSMEs internalization is highly influenced by organization capacity and ecosystem support. The policy that leads to a barrier for the company that aims to sell their product abroad and unsupportive domestic regulation can be a trade barrier either unintentionally when that regulation intended for other purposes (such as health, safety, sanitation, environment, and consumer information) as well as intentionally. Since the characteristic is implicit and commonly inconspicuous, the procedural barrier in trading is hard to documented and resolved. These barriers can come in various forms, depending on the related trade policy field. The form can be the policy implementation procedure, regulatory authority behavior and public administrator, bad administration practice that leads to corruption and discrimination, or the vulnerability of domestic institutions (for instance the law system and legal system).

MSMEs

In accordance with The Constitution of the Republic of Indonesia of 2008 No. 20 about MSMEs define MSME in Indonesia is productive economic enterprise that established individually and called as small enterprise, conducted by personal/individual or business entity, subsidiary or not a subsidiary owned, controlled, or be a part of subsidiary either direct or indirect from small enterprise or big enterprise that fulfill the small enterprise criteria as referred to The Constitution of The Republic of Indonesia. This is divided into three sizes, the first is having a turnover of up to 300 million categorized as micro scale then turnover between 300 million to 2,5 billion categorized as small scale and turnover between 2,5 billion to 50 billion categorized as middle scale. That MSMEs sector has an operational scale and small relative number of employees compared with big companies. MSMEs refers to all forms of productive economic enterprise that have characteristics such as small scale operation and limited budget and typically employs a limited number of employees (Tambunan, 2012) that open work opportunities or work fields as well as increasing revenue. Most MSMEs in developing countries are small-scale. Because of the small-scale, MSMEs has limited access toward a resource that can assist to encounter risk, survive, and conduct a transformation and innovation, and has bargaining power in market for interacting with stakeholders and institutional environment (Dass, 2000). According to Westhead, Wright, Ucbasaran, & Martin (2001) is expected that MSMEs internalization topic has been studied especially from seven

aspect: internalization of time and duration, sustainability and intensity of internalization process, internalization model, domestic environment context and its impact toward internalization, the importance of utilizing external resources for conducting internalization, difference in units of analysis, as well as internalization impact toward SME performance.

Company that conducted internalization incrementally by utilizing resources and knowledge which they had gathered in the domestic market. According to Uppsala theory, a company that aims to internationally expand toward entering a barrier due to 'psychological distance' that leads to the difference of socio-economic and politic between the company's home market and target market. Those factors include the difference of economic and politic, language barrier, culture orientation, and others, that impede the understanding toward business environments in foreign countries (Ruzzier, Robert, & Hisrich, 2006). According to Child & Hsieh (2014), information and knowledge are key elements in MSMEs internalization process in developing countries. (Musteen, Francis, & Datta, 2010) found that fostering various knowledge practices through collaborative networks are significant key determinants in MSMEs internalization process. As stated by Costa, Soares, & de Sousa (2015), shared knowledge as well as gaining information related to the international market through collaborative networks can assist in achieving expansion and rapid international growth. Network model developed by Johanson and Mattsson (1988) as well as Bell and McNaughton (2000) illustrates internalization as the peak of network position in international position.

The Roles of MSMEs

Not only in developing countries, but also in developed countries, recognized widely that micro, small, and middle enterprise has played significant roles in construction process and economic expansion. In developed countries, micro, small, and middle enterprise (MSMEs) have played a very important role. This type of enterprise type does not only absorb more employees compared with big enterprises for instance in developing countries, but the contribution toward expansion or formation of gross domestic product is bigger than the contribution given from big business (Tambunan, 2012).

Non Tariff Measures (NTMs)

NTM is commonly defined as policy steps, other than tariff, that can impact international trade. This term includes sanitary and phytosanitary (SPS) regulations, technical barriers to trade (TBT) regulations, as well as various policy intervention which impacting trade and prices and flow, for instance rules of origin, licensing, price control measures, or distribution restriction (UNCTAD, 2013). Non Tariff Measures or NTM includes various trade policy measures, such as import quota, licensing, and rules of origin. NTM also includes specific product requirements, for instance quality or content requirement, labeling, testing, and certification. Trade barrier related with NTM defined as regulation barrier or any procedural toward company when obeying certain measures. One of the MSMEs internalization activity is conducting product export on the global market or other countries where there are several products which require certification documentaries specifically for products which are related with human consumption as well as product standardization which will export. Company in agri-food sector affected by sanitary and phytosanitary (SPS) regulations, especially that related with certification or quality control where 48% from trade barrier that reported for agriculture product related with conformity assessment procedures in destination market, other than that those product commonly perishable and fragile as well as can bring a disease which can affect that area where the product exist. Therefore, the requirements that must be met are extensive and rigorous.

Technical policy refers to a requirement that is related to the product. That policy is legally binding and established by the importing country. That policy defines product characteristic, product specification technical, or production process as well as post-production processing, and includes current administrative regulation, whose compliance is mandatory. Technical requirements include sanitary and phytosanitary (SPS) measures, which are commonly implemented for protecting life and health of human, animal, as well as plants. Conformity assessment refers to the use of measures for determining if a product or process meets technical requirements that have been established in technical policy. Conformity assessment includes controlling procedures, checking, and agreement for instance testing, inspection, certification, and investigation that ensure and monitor that a product has met technical requirements and mandatory standards which are enforced by the importing country (International Trade Centre (ITC), 2015). Therefore, the advantage from natural resource

which not owned by the importing country will not directly become competitiveness or appeal if the requirement in NTM can not be meet and even more easy to negotiate tariff regulations rather than comply with non-tariff regulations which can not be bargained and manipulated since it must be through assessment and inspection from independent third party.

3. Proposed Method

This research methodology is using qualitative approaches that involve in-depth inquiry. The object of study is the MSMEs major barrier in operating international business activities. The respondent required to describe their case related that crisis moment, characteristic, and the consequences (Eisenhardt, 1991). This approach provides context for encountered barriers as well as in-depth understanding related with specific characteristic from the issues encountered especially in comply with non tariff measures related with standardization and biopharmaceutical plants products certification which conducted by practitioners in complying with order as well as ensure the initial standardization that gaining from collected products from the framers or the producers (Loane et al., 2004; Loane and Bell, 2002).

Preparation

In this step, the researcher determine the problem identification: Phenomenon of the issue commonly encountered and reported by MSMEs collectors or suppliers which will exporting biopharmaceutical plants products to abroad starting from the quantity and quality which comply with the standardization from the buyer, then conducting literature study: Non Tariff Measures Theory (standardization, certification) and policies that established by ASEAN Economic Community (AEC) as well as instrument preparation to conduct in-depth interview guide.

Collecting Data

The data collecting process conducted with prior determination of the informants then followed by an interview session and the informant will be raw material biopharmaceutical plants supplier that consists of two collectors for exporting demand and five suppliers as biopharmaceutical plant commodity partner farmers around the Pasrujambe and Senduro subdistrict which is the biggest centra in Lumajang area where producing biopharmaceutical plant products amounting to 2500 ton per year especially cardamom commodity primarily for the export market. The interview was conducted in-depth and structured for two collectors, first with export delivery capability followed by export frequency as well as the standard of material which is exported. After that, document requirements that need to be prepared for export and last are barriers and challenges which are encountered as well as forms of government support in assisting MSMEs to conduct export without any obstacle and effectively. Meanwhile, for five raw materials supplier producers the interview tend to the understanding of standard material that is required by the collector as well as the capability in fulfill the quote committed by the collectors where the harvesting schedule by the farmers or suppliers has managed in a manner that biopharmaceutical plant raw materials is not experiencing any shortages or surplus. However, it is provided in line with demand in these interview sessions, the researcher also directly inspecting the storage facility of raw material as well as seeing the preparing document for export requirements in line with the current regulations.

Processing Data

In this phase, the researcher categorized the obtained data according to sequence or stages in export activity sequence, starting from ordering and barriers then the preparing activity of raw material from the field until delivered to the suppliers or farmers to warehouse. After that, how the categorizing method and selection based on the standard until the packaging activity for delivering as well as the preparing process of standard document and compliance certificate that must be obtained. Furthermore, the data presenting conducted systematically in such was that the flow and correlation whee each of data will provided with further information related with barrier and obstacles which encountered as well as solutions that provided to address this, where it is for ensure the accuracy of data and to address these issues, triangulation was applied by conducting data verification with comparing the interviews of experienced parties in export activity or personal that work in regulator institution and understand the export regulation.

Data Interpretation

The results of the data presentation is followed by an interpretation, which will categorized the barrier and obstacle as well as the result of solution which provided after all data that has interpreted will give whole illustration related with barrier and obstacle that need to be handled, so in further action the barrier in addressing the non-tariff barrier when the export will conduct can minimized or resolve before the export process along with the order from global buyer.

4. Results and Discussion

The first interview result with three producers or farmers of biopharmaceutical plant raw material Pasrujambe sub district and two producers or farmers of biopharmaceutical plant Senduro sub district has obtained information related to the readiness to fulfill export requirements. One of the export barriers is bias and the company internal assumption itself. These barriers encountered by the company struggling in innovation, have ineffective management, and insufficient financial resources, between others. Other main determining factors in ensuring the success of export according to Leonidou (2004), these barriers appear because of the influence of resource allocation and direct decision-making. Small enterprises and middle (SME) encountered barriers in fulfilling the export criteria and maintaining reputation in the global market in an institution environment marked with legal uncertainty and minimal policy enforcement (Leonidou, 2004; Morgan & Katsikeas, 1997). The institutional arrangement theory provides information which is appropriately related with this Leonidou (2004). Either internal or external factors can influence export performance, however there are varying impacts depending on specific conditions. To what extent is an organization ready and able to adapt, influenced directly and significantly by internal factors. Conversely, strong internal capabilities enable an organization to mitigate external barrier impact on a larger scale compared with an organization with weaker internal capabilities. There is an export barrier characterized by external, for instance bureaucratic inefficiency, unstable regulation, insufficiency infrastructure, and institutional weaknesses, which also has significant impact; however, those barriers basically serve as conditions that reinforce the existing situation, not as determining factors that work independently (Azyadi & Alaybeyoğlu, 2026). Based on interview results toward those 5 producers the main barrier is the varicosity of consistent quality consisting of form, moisture content to purity levels or the amount of adhering impurities, especially harvest residue soil to additional jobs which burden the brand for meeting the standards as requested by the exporter. Furthermore the permanent continuity of quantity also becomes a barrier whereby producers use traditional methods or the farmers unable to manage harvesting phase in rotation to prevent over or less harvesting. Other than that, there are several contamination fields with chemical material where this biopharmaceutical plant raw material product must be free from contamination or is not allowed to contain chemical material that will lower the quality.

For the next interview with two collectors that will fulfill the export order based on the interview, it explains several points, particularly related with a common product standard is the absence of consistency in quality, ripeness level as well as the lack of documented evidence of the content inside the raw material. From several non tariff policy which places a considerable burden on providing product that will exported that delivered by this collector is the complexity of bureaucracy in certificate processing for instance phytosanitary then there is several countries that requires additional documents that is required including GACC for China then AEO (Authorized Economic Operator) for USA countries. These become requirements that are commonly poorly understood by the MSMEs that will export their product or raw material. Based on the result of interview by all the informant, the main problem MSMEs that will conducting export is the quality and quantity of consistency that has not yet been fulfilled so it cause a lot of barrier which should have been resolved from the beginning, start with monitoring toward commodity cultivation that will exported then certainty from the collector related with the crop yield that will taken for shipping abroad become the main considering from the farmers or producers of raw material. Because of that the need for government intervention for facilitating the existing gap, particularly bureaucracy related with the established regulation, since several standards and certification which required, commonly

burdening the exporters especially for MSMEs so it needs to be simplified and most importantly has socialized to commodity producers that provide raw material not only information to the seller which is not necessarily contributed on quality increase and quality assurance.

5. Conclusions

Based on the result of study that has conducted as well as the analysis and discussion provided, it can be conclude that non tariff barrier that commonly found by the MSMEs who wants exporting more in form of non tariff barrier because it involves many third parties and not necessarily have similar vision for developing MSMEs to upgrade, this is due to the complexity of bureaucracy as well as divergence in objective from each of the field that manage the regulation where there are commonly overlapping regulation across ministries as well as hinders MSMEs to advance and grow. Because of that, it is better if this condition can be realized and provided by the right solution, including simplifying the document and providing training as well as information related with the requirements that need to be fulfilled and completed by the MSMEs before exporting or while looking for buyers from abroad. Obviously, that effort is not only done by themselves since it is cross-ministerial in nature, furthermore, it is also expected that the government role is more active in informing the regulations in export destination countries which ultimately will be more helpful to the MSMEs for upgrading and capable of competing in the global market.

The limitation from this study is the scope and the selected commodity specifically for area and certain industry, this is because covering a wide area needed more time and energy as well as more funding. However, what is presented is a common situation that is encountered by the MSMEs that will conduct an export process, particularly related with raw material or product based on local resources. Furthermore, there are still few MSMEs operating at the international level, since the limitation of networking as well as a lot of MSME which acts solely to collecting the product that will exported, as for those related to buyers is broker who sometimes commonly detrimental MSMEs position with providing a relatively low bid that leading in profit margin that is insufficient to contribute for the MSMEs that will conduct an export.

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