

# The Strategic Role of the Indonesian FDA in Empowering Micro, Small, and Medium Enterprises in the Drug and Food Sectors: A Review

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## Abstract

This review examines the evolving role of the Indonesian Food and Drug Authority (BPOM) in empowering Small and Medium Enterprises (SMEs) within the pharmaceutical and food sectors. While significant strides have been made in recent years, challenges remain. These include discrepancies between regulatory objectives and the practical capabilities of SMEs, particularly in navigating complex regulatory frameworks. While digitalization initiatives and technical assistance programs have shown promise, their impact is often hindered by resource limitations and resistance to change among stakeholders. This review underscores the critical need for a balanced approach that effectively integrates regulatory oversight with targeted support for SME growth. Fostering an ecosystem that encourages innovation and ensures regulatory compliance necessitates a multi-stakeholder approach, demanding more sustainable and effective coordination among government agencies, industry associations, and academic institutions. The success of BPOM's empowerment efforts hinges on adopting flexible, technology-driven, and results-oriented strategies. Future endeavors should prioritize long-term evaluations of existing programs, develop robust metrics to assess their effectiveness and explore innovative approaches to address the evolving regulatory landscape in the digital era.

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## INTRODUCTION

Micro, Small, and Medium Enterprises (MSMEs) constitute a cornerstone of the Indonesian economy, particularly within the drug and food sectors. These sectors significantly contribute to the nation's Gross Domestic Product (GDP), accounting for approximately 60%, and provide employment to a substantial portion of the manufacturing workforce, exceeding 97%<sup>1</sup>. However, ensuring the safety and quality of products manufactured by these MSMEs remains a significant challenge. Compliance with the stringent regulations set forth by the Indonesian Food and Drug Authority (*Badan Pengawas Obat dan Makanan* or BPOM) is crucial for market access, consumer safety, and public health. Recent data suggests that only 45% of MSMEs in the drug and food sectors currently meet these regulatory requirements<sup>2</sup>. This significant compliance gap necessitates urgent attention to address the specific challenges faced by MSMEs in adhering to regulatory standards and to facilitate their growth and development within the Indonesian market.

As the national regulatory authority, BPOM operates under a dual mandate: ensuring the safety of consumer products while promoting domestic industry growth. Over the past decade, BPOM has undergone a paradigm shift in its regulatory approach, transitioning from strict oversight to a more empowerment-oriented strategy<sup>3</sup>. This shift reflects a growing

recognition that overly rigid regulatory frameworks can stifle MSMEs growth and innovation, particularly given the limited resources and technical capacity of many MSMEs to meet complex regulatory requirements.

Numerous studies have highlighted the challenges MSMEs face in complying with BPOM's regulations. Mahardhika *et al.*<sup>4</sup> identified the complexity of licensing procedures, high compliance costs, and limited access to testing facilities as significant barriers for MSMEs. Similarly, Wahyudi *et al.*<sup>5</sup> emphasized the need for a more adaptive, risk-based regulatory approach to accommodate the diverse capacities and operational scales of MSMEs. These studies underscore the necessity of balancing regulatory stringency with support mechanisms tailored to the specific needs of MSMEs.

On the other hand, BPOM's empowerment initiatives have demonstrated promising results in certain areas. Programs offering technical assistance and simplifying licensing procedures have led to a 15% increase in MSMEs compliance rates over the past three years<sup>6</sup>. However, these initiatives remain limited in scope and have yet to benefit a majority of MSMEs, particularly those located in remote regions or with limited resources.

The digital transformation presents both opportunities and challenges in the regulatory landscape for MSMEs<sup>7</sup>. The implementation of BPOM's electronic licensing system has expedited product registration processes, making it easier for compliant MSMEs to navigate regulatory requirements. Nevertheless, this digital shift has also exposed a divide among MSMEs, with smaller and less technologically equipped enterprises struggling to adapt<sup>8</sup>. The situation has been further exacerbated by the COVID-19 pandemic, which disrupted supply chains, strained resources, and altered the regulatory environment for businesses<sup>9</sup>.

This review aims to comprehensively evaluate the evolution of BPOM's role in empowering MSMEs in the drug and food sectors, focusing on the effectiveness of various regulatory and empowerment initiatives. By synthesizing existing literature, this study seeks to identify best practices and address gaps in current approaches while proposing a framework for balancing oversight and empowerment. Furthermore, this review explores the potential for innovative regulatory models and multi-stakeholder collaborations to address the challenges faced by MSMEs in the digital era.

This study employed a comprehensive literature review approach to analyze and synthesize existing knowledge on the empowerment of MSMEs in the traditional medicine, health supplement, and cosmetic sectors by BPOM. A systematic search was conducted across reputable academic databases, including Scopus, PubMed, and Google Scholar, as well as official government sources such as BPOM reports, national policies, and relevant regulations<sup>10</sup>. The inclusion criteria focused on publications that specifically addressed policies, challenges, and innovative approaches to supervising and empowering MSMEs within these sectors.

The collected data were systematically analyzed using descriptive methods to identify key trends, patterns, and existing gaps in policy implementation. This analysis served as the foundation for formulating strategic recommendations aimed at enhancing the effectiveness of BPOM's efforts in supporting the growth and development of MSMEs in the traditional medicine, health supplement, and cosmetic sectors. To ensure the validity of the findings, the study adhered to rigorous methodological guidelines for conducting literature reviews, prioritizing credible and recent sources.

## DEVELOPMENT OF BPOM REGULATIONS, CHARACTERISTICS OF MSMEs, AND EMPOWERMENT PROGRAMS

### *Development of BPOM regulations*

The BPOM has undergone a significant regulatory shift in recent years, transitioning from a predominantly command-and-control approach to a more collaborative and risk-based oversight model, as shown in **Figure 1**. This evolution is evident in several key developments. For instance, BPOM Regulation Number 22/2020 represents a crucial milestone, streamlining registration procedures for MSMEs by introducing a differentiated risk-based categorization for products<sup>11</sup>. Furthermore, the implementation of the e-registration system in 2018 has significantly improved efficiency, reducing the processing time for distribution permits by up to 40%<sup>12</sup>. While this digital transformation has streamlined processes, challenges related to MSME adoption of the e-registration system persist<sup>13</sup>. These advancements reflect BPOM's ongoing efforts to create a more supportive and efficient regulatory environment for the Indonesian food and drug industry.

Harmonization with international standards has been a cornerstone of BPOM's regulatory framework. This alignment aims to enhance product safety, quality, and consumer protection while facilitating regional and global trade. Indonesia has

adopted a substantial portion of the ASEAN Common Technical Requirements for drugs and food products, demonstrating a significant step towards regional harmonization<sup>14</sup>. However, the implementation of these international standards can pose challenges for local MSMEs. These challenges may include increased compliance costs, difficulty in accessing necessary resources, and the potential for hindering the growth and competitiveness of domestic industries.

Post-market surveillance in Indonesia has witnessed advancements with the implementation of technology-driven approaches by BPOM. The introduction of online adverse drug reaction reporting systems and risk-based food product sampling programs has significantly enhanced surveillance effectiveness<sup>15</sup>. However, a recent evaluation highlighted a critical gap between existing regulations and their practical implementation in the field<sup>16</sup>. This gap is particularly evident at the regional level, where challenges in surveillance capacity may hinder the effective monitoring and control of regulated products.

### ***Characteristics of MSMEs in the drug and food sectors***

Micro, Small, and Medium Enterprises in Indonesia's drug and food sectors exhibit diverse characteristics<sup>17</sup>. A significant portion, approximately 60%, of these businesses fall under the micro-enterprise category, characterized by limited capital, typically below IDR 50 million. Conversely, only 5% of MSMEs in this sector qualify as medium-sized enterprises. This suggests a strong presence of micro-enterprises, which often operate on a smaller scale with limited resources<sup>18-20</sup>. Traditional, primarily manual, production methods remain dominant in the sector. Notably, the adoption of partial automation is extremely limited, with only 15% of traditional drug and food MSMEs utilizing it, underscoring a lack of progress in modernizing production processes<sup>21</sup>. These findings underscore the need for targeted support programs to enhance the competitiveness and sustainability of MSMEs in Indonesia's drug and food sectors.

A key characteristic of these MSMEs is their varying production capacities. For instance, a significant range in monthly production output, with food MSMEs producing between 100 and 10,000 units, while traditional drug MSMEs produced between 500 and 5,000 units<sup>22</sup>. Limited access to capital represents a major obstacle for these businesses. Approximately 70% of MSMEs struggle to obtain formal financing, significantly impeding their ability to expand operations, invest in technology, and improve product quality<sup>23</sup>. These characteristics underscore the need for targeted support programs to address the specific needs and challenges faced by MSMEs in the drug and food sectors.

Regulatory compliance poses a significant challenge for MSMEs in the drug and food sectors. Studies have shown that a substantial portion of MSMEs lack a comprehensive understanding of Good Manufacturing Practices (GMPs). Key challenges include limited access to skilled personnel, difficulty in meeting stringent infrastructure requirements, and inadequate documentation of quality systems. This can lead to suboptimal product quality, increased risks for consumers, and difficulties in accessing formal markets<sup>24</sup>. However, there are also positive developments, such as a growing trend in halal certification adoption, indicating a growing awareness of the importance of adhering to regulatory standards.

### ***BPOM's empowerment programs***

Significant improvements in MSME compliance and competitiveness are the result of BPOM's evolving empowerment programs. An evaluation revealed that BPOM's technical assistance programs have reached more than 5,000 MSMEs since 2020, with a certification success rate of 65%<sup>25</sup>. Flagship initiatives like the "Upgrading MSMEs" program launched in 2021 integrate a comprehensive empowerment approach, including training, mentoring, and market access facilitation. The MSMEs participating in BPOM's empowerment programs experienced an average revenue increase of 30% in the first two years after certification. Training programs focusing on the implementation of Good Processed Food Production Methods (GPFPM) and Good Traditional Medicine Manufacturing (GTMM) have improved production standards, although gaps in modern technology adoption still exist<sup>26</sup>.

In terms of market access facilitation, BPOM has developed a dedicated e-marketplace platform for certified MSME products, which facilitated transactions worth IDR 500 billion in 2023. Innovation in empowerment methods is also evident through the "MSME e-learning" program, which has been accessed by more than 10,000 business actors<sup>27</sup>. However, an independent evaluation by Febriani *et al.*<sup>28</sup> highlighted the need for greater customization of programs based on MSME scale and capacity.

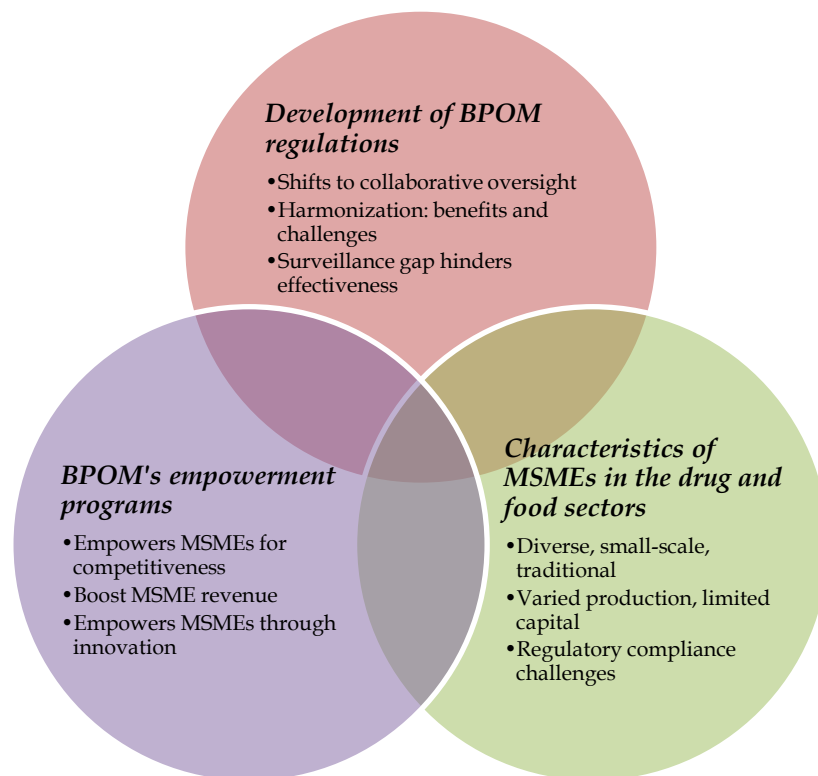


Figure 1. The strategic role BPOM in empowering MSMEs.

## EFFECTIVENESS, BEST PRACTICES, CHALLENGES AND BARRIERS

### *Program effectiveness*

The effectiveness of BPOM's empowerment programs for MSMEs in Indonesia has shown mixed results. A study by Rohmah *et al.*<sup>29</sup> demonstrated a significant increase in MSME compliance with Good Processed Food Production Practices (CPPOB) standards following the implementation of BPOM's technical assistance programs. This suggests that BPOM's interventions can effectively enhance food safety practices within the MSME sector. However, a study by Secretariat Economic Capacity Building Policy Team, National Team for Acceleration of Poverty Reduction as well as Demographic Institute, Faculty of Economics and Business, Universitas Indonesia highlighted significant geographical disparities in program effectiveness<sup>30</sup>. MSMEs located outside the island of Java experienced limited access to mentoring services, suggesting a need for improved program accessibility and equitable distribution of resources across the archipelago.

The phased certification system introduced by BPOM in 2021 has demonstrated a significant positive impact on the growth of MSMEs. This success can be attributed to the "regulatory ladder" approach, as highlighted by Isnaeni *et al.*<sup>31</sup>. This phased approach allows MSMEs to gradually comply with certification requirements, reducing the initial burden and fostering a more inclusive and supportive regulatory environment. This gradual progression not only facilitates easier entry for MSMEs but also encourages continuous improvement in product quality and safety standards<sup>32</sup>.

Market access facilitation programs, particularly those involving partnerships with modern retail channels, have demonstrated promising outcomes for MSMEs. Research by Mujianto *et al.*<sup>33</sup> found that 35% of MSME participants in such programs successfully entered the national retail market. However, Panuju and Bakri<sup>34</sup> identified a significant challenge: maintaining consistent production and quality to sustain market access. This highlights the need for comprehensive support beyond initial market entry. Baregheh *et al.*<sup>35</sup> emphasized the importance of integrating multiple support programs. Their analysis revealed that MSMEs participating in a combination of technical assistance, phased certification, and market access facilitation programs achieved a higher success rate compared to those receiving support from only one program. This finding underscores the critical role of integrated interventions in enhancing MSME competitiveness and long-term sustainability within the market.



### **Best practices**

A key area of research concerning BPOM's MSME empowerment efforts is the 'mentor-mentee' model, which relies on seasoned MSME entrepreneurs to guide others through the complexities of certification. This peer-to-peer support system provides valuable insights and practical guidance, overcoming the challenges often faced by novice MSMEs. A pilot program implementing this model in East Java demonstrated promising results, with a high success rate in assisting MSMEs in achieving BPOM certification<sup>36</sup>. These findings underscore the importance of fostering collaborative learning and knowledge sharing among MSMEs to enhance their capacity to meet regulatory requirements and thrive in the market.

The implementation of a "regulatory sandbox" system by BPOM, has proven to be a significant catalyst for innovation within the MSME sector. This approach allows MSMEs to experiment with new product development and innovative technologies in a controlled and supervised environment. A study by Handoko *et al.*<sup>37</sup> demonstrated the effectiveness of this system, highlighting that 125 new product innovations were facilitated within a year, with a remarkable innovations subsequently obtaining necessary distribution permits.

Furthermore, cross-sector collaboration has emerged as a crucial component for fostering MSME growth and ensuring regulatory compliance. Partnerships between BPOM, academic institutions (universities), and industry associations significantly increased MSME compliance with food safety standards<sup>38</sup>. This "triple helix" model, as emphasized creates a comprehensive support ecosystem that provides MSMEs with access to technical expertise, resources, and mentorship, ultimately enhancing their competitiveness and sustainability<sup>39</sup>.

The digitalization of the licensing process through BPOM's e-registration platform represents a significant advancement in regulatory efficiency. This innovative approach has garnered international recognition, with a comparative study by Younus *et al.*<sup>40</sup> ranking Indonesia's system third among ASEAN countries for its efficiency and user-friendliness. This digital transformation has led to a substantial improvement in service delivery. Putri observed a remarkable reduction in licensing processing time since the implementation of the e-registration system<sup>41</sup>. By streamlining administrative procedures and minimizing paperwork, this digital platform has not only enhanced efficiency but also improved transparency and accountability within the regulatory framework.

### **Challenges and barriers**

Despite the positive impact of the phased certification system, MSMEs continue to encounter significant challenges in complying with BPOM regulations. A comprehensive study identified limited capital as the primary barrier, with 67% of surveyed MSMEs reporting difficulties in meeting the required infrastructure standards, such as sanitation facilities and adequate production space. This financial constraint severely limits their ability to invest in necessary equipment and upgrades. Furthermore, a knowledge gap remains a significant obstacle<sup>42</sup>. The majority of MSME operators struggled to understand the complex documentation requirements stipulated by BPOM. This lack of understanding can lead to delays in the certification process, increased costs, and even rejection of applications<sup>43</sup>. Addressing these challenges requires a multifaceted approach that includes targeted financial assistance, capacity-building programs, and simplified regulatory procedures.

Indonesia's vast and diverse geography presents significant challenges for the growth and development of MSMEs, particularly in 3T regions (Frontier, Outermost, and Disadvantaged) areas. A study highlighted a stark disparity, revealing that MSMEs located in 3T regions face significantly longer processing times for certifications, averaging 2.5 times longer than their counterparts in major urban centers. This disparity is further exacerbated by the geographical limitations faced by these businesses<sup>44</sup>. An ethnographic study conducted by Fatimah *et al.*<sup>45</sup> emphasized the critical role of infrastructure and connectivity. Limited access to reliable internet and inadequate telecommunications infrastructure in remote areas pose significant barriers for MSMEs in 3T regions to effectively utilize BPOM's digital services, hindering their ability to navigate the certification process efficiently.

Resistance to change poses a significant obstacle to the successful implementation of the phased certification system. A substantial of MSMEs perceive BPOM regulations as an "additional burden" rather than a valuable tool for improving product quality<sup>37</sup>. This perception is further supported by Gomulia *et al.*<sup>46</sup>, who observed a strong correlation between negative perceptions of regulations and lower compliance rates, particularly among traditional MSMEs. Furthermore, the rapidly evolving market dynamics present unique challenges. The short product innovation cycles prevalent in today's market often clash with the timelines of BPOM's certification process<sup>47</sup>. Discrepancies of this nature can severely hinder

product releases, resulting in substantial financial setbacks, illustrated by the economic damage suffered by innovative food MSMEs due to delayed distribution approvals. These findings underscore the need for continuous dialogue and collaboration between regulatory bodies and MSMEs to address these challenges and ensure the successful implementation of the phased certification system<sup>48</sup>.

## CURRENT TRENDS AND DEVELOPMENTS

### *Digitalization and technology*

The digital transformation of regulatory processes within BPOM has significantly accelerated in recent years, playing a pivotal role in empowering MSMEs. The implementation of BPOM's e-registration system in 2020 has revolutionized the licensing process, resulting in a remarkable reduction in processing time compared to the previous manual system<sup>49</sup>. This digital platform not only streamlines administrative procedures but also enhances transparency and accountability by minimizing human intervention and reducing the potential for corruption within the licensing process. This digitalization effort empowers MSMEs by providing them with easier access to regulatory information, simplifying the licensing process, and ultimately facilitating their growth and competitiveness in the market<sup>2,50</sup>.

Technological advancements have significantly enhanced product oversight for MSMEs. The introduction of a robust tracking and tracing system, facilitated by the integration of QR codes on product packaging, has revolutionized the way consumers and regulators interact with MSME products. This innovative approach empowers consumers to trace the origin of products in real-time, fostering greater transparency and accountability within the supply chain. A study underscored the positive impact of this system, revealing a notable increase in consumer confidence in MSME products. By leveraging technology to enhance traceability and transparency, regulators can effectively monitor product quality, ensure consumer safety, and ultimately contribute to the sustainable growth and development of the MSME sector<sup>51</sup>.

Innovation plays a crucial role in empowering MSMEs within the food industry. The development of BPOM's mobile application exemplifies this, providing access to virtual training programs and online consultations. A study by Qona'ah and Afianto<sup>52</sup> revealed that most of MSMEs utilizing this application experienced an enhanced understanding of food safety standards and regulations. However, challenges remain, as highlighted by Qonita *et al.*<sup>53</sup>, who identified a significant digital divide among MSMEs, with only a minority possessing the technological readiness to fully leverage BPOM's digital solutions. Furthermore, the integration of Artificial Intelligence (AI) and Machine Learning (ML) is revolutionizing food safety oversight. BPOM is actively developing predictive algorithms that utilize historical data to identify potential food safety risks proactively. This data-driven approach allows for more efficient and targeted interventions, ultimately enhancing food safety for consumers<sup>54,55</sup>.

### *Multi-stakeholder collaboration*

Recent years have witnessed a significant shift in BPOM's approach to supporting MSMEs, characterized by increased collaboration with diverse stakeholders. Public-Private Partnerships (PPPs) have emerged as a cornerstone of this strategy, with the government reporting the launch of 15 such programs since it was first introduced<sup>56</sup>. A prime example of successful PPP implementation is the "UMKM Naik Kelas" program. This collaborative initiative, involving BPOM, leading pharmaceutical companies, and industry associations, has demonstrated remarkable success in elevating MSME production standards<sup>57,58</sup>. These collaborative efforts not only streamline the certification process for MSMEs but also foster a more supportive and inclusive regulatory environment, ultimately empowering these businesses to thrive in the market. Research institutions and academic collaborations play a pivotal role in supporting MSME growth within the framework of the phased certification system. The BPOM-University Collaborative Research program exemplifies this by fostering innovation. This program has successfully yielded many technological advancements designed to enhance production quality within the MSME sector<sup>59,60</sup>. Furthermore, research conducted by Pantanowitz *et al.*<sup>61</sup> demonstrated a significant positive correlation between academic-industry partnerships and regulatory compliance. Their findings revealed that MSMEs actively engaged in collaborative research programs exhibited a higher compliance rate with regulations compared to those without such involvement. These findings underscore the critical importance of fostering strong collaborations between academia and industry to empower MSMEs and drive sustainable economic growth within the Indonesian context<sup>62</sup>.

Community initiatives and industry associations are emerging as crucial enablers within the evolving MSME ecosystem. A prime example is the successful implementation of a peer mentoring program facilitated by industry associations<sup>63</sup>. This program, as reported by the Indonesian Entrepreneurs Association or *Asosiasi Pengusaha Indonesia*, significantly contributed to MSME growth, assisting 500 MSMEs in achieving BPOM certification between 2022 and 2023<sup>64</sup>. However, challenges remain, as Koesrianti and Tanega<sup>65</sup> highlighted the need for improved coordination and reduced program overlap among various stakeholders to maximize the effectiveness of collaborative efforts.

Furthermore, a positive trend is observed in the growing synergy between MSMEs and financial institutions. The development of specialized financing schemes tailored to assist MSMEs in meeting BPOM standards has shown promising results<sup>66</sup>. Notably, Bank Indonesia reported an increase in credit disbursements for this purpose in 2023. This financial support plays a crucial role in empowering MSMEs to invest in necessary upgrades, enhance product quality, and ultimately achieve certification<sup>67</sup>.

## IMPLICATIONS AND RECOMMENDATIONS

### *Policy implications*

This review highlights several crucial policy implications for BPOM in effectively empowering MSMEs. A key area for improvement lies in regulatory reform. Utama *et al.*<sup>68</sup> emphasize the critical need for a tiered approach to regulatory standards, allowing MSMEs to gradually comply with requirements based on their individual capacities and growth trajectories. This tiered system fosters a more supportive regulatory environment, encouraging MSMEs to continuously improve their product quality and safety standards. Furthermore, Nugroho<sup>67</sup> underscores the importance of strengthening BPOM's institutional capacity alongside its digital transformation initiatives. This includes investing in human resources development, enhancing technological infrastructure, and ensuring equitable access to information and resources for all MSMEs<sup>69</sup>.

Effective policy harmonization is crucial for the success of the phased certification system. Hidayat *et al.*<sup>32</sup> observed that regulatory fragmentation between BPOM and other relevant agencies can create confusion and impose unnecessary burdens on MSMEs. To address this, stronger cross-sectoral coordination and streamlined regulatory processes are essential. Furthermore, as emphasized by Budiarto *et al.*<sup>70</sup>, sustainable empowerment strategies are vital for the long-term success of MSMEs. These strategies must consider the unique characteristics and limitations of MSMEs, such as limited resources, access to technology, and market knowledge. By providing targeted support, such as access to training, financial assistance, and market linkages, policymakers can empower MSMEs to navigate the regulatory landscape and thrive in the competitive market<sup>71</sup>.

A key factor in encouraging MSME compliance with BPOM standards lies in the implementation of effective incentive policies, including the crucial role of both fiscal and non-fiscal incentives<sup>38,72</sup>. These incentives can significantly improve MSME participation by reducing the financial burden of certification. Examples include subsidizing certification costs, facilitating access to affordable testing laboratories, and providing subsidized mentoring programs to guide MSMEs through the certification process<sup>73</sup>. Furthermore, as emphasized by Supriadi *et al.*<sup>74</sup>, policies that promote innovation and facilitate technology transfer are vital. By empowering MSMEs with access to cutting-edge technologies and knowledge, these policies can equip them with the necessary tools and resources to improve product quality, enhance safety standards, and ultimately achieve successful BPOM certification.

### *Practical recommendations*

Several practical recommendations can be implemented to enhance the effectiveness of BPOM's empowerment programs for MSMEs. Improving existing programs is a top priority. Handoko *et al.*<sup>37</sup> proposed the implementation of a "regulatory sandbox" approach, which would allow MSMEs to experiment with product innovations in a controlled environment, fostering a more flexible and supportive regulatory framework. Moreover, Rudiati<sup>75</sup> emphasized the need for developing user-friendly digital learning platforms. These platforms should be tailored to the specific needs and learning styles of MSMEs, providing flexible access to training materials, technical guidance, and expert consultations. By incorporating these recommendations, BPOM can significantly improve the effectiveness of its empowerment programs, fostering a more conducive environment for MSME growth and innovation within Indonesia's food and drug sector.

Several key strategies have emerged to further empower MSMEs within the Indonesian regulatory landscape. Setiawan *et al.*<sup>76</sup> advocate for innovative empowerment models, emphasizing the crucial role of mentorship programs that connect MSMEs with established large industries. These programs not only facilitate valuable knowledge transfer but also foster mutually beneficial business partnerships. Furthermore, Ibrahim<sup>77</sup> proposes the establishment of regional innovation centers to serve as vital hubs for MSMEs. These centers would provide access to essential resources such as product testing facilities, technical consultation services, and modern technology, empowering MSMEs with the tools and expertise necessary for growth and innovation.

Strengthening the monitoring and evaluation system is equally critical. Utomo<sup>78</sup> advocate for the development of more comprehensive performance metrics that extend beyond regulatory compliance. These metrics should focus holistically on MSME growth, sustainability, and overall economic impact. Recognizing the potential of technology, the significant role of blockchain technology in improving the transparency and efficiency of tracking MSME compliance with BPOM standards. By leveraging blockchain technology, the regulatory process can be streamlined, enhancing trust and facilitating smoother interactions between MSMEs and regulatory authorities.

## CONCLUSION

This review highlights the transformative role that BPOM plays in empowering MSMEs within the food and drug sectors. While significant progress has been made, the analysis underscores a critical gap between the ambitious regulatory objectives and the practical realities faced by MSMEs, particularly in terms of limited resources and resistance to change. While digitalization efforts and technical assistance programs have shown promise, their impact is constrained by structural limitations and the need for more adaptive and evidence-driven approaches. Fostering a balanced approach that integrates regulatory oversight with targeted empowerment strategies is crucial. This requires a multi-stakeholder approach that fosters collaboration and coordination among government agencies, industry associations, and academia. Ultimately, the success of BPOM's efforts hinges on its ability to embrace flexible, technology-driven, and outcome-oriented frameworks, while continuously assessing the long-term impacts of its initiatives and refining its methodologies to effectively measure and enhance their effectiveness.

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## AUTHORS' CONTRIBUTION

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**Funding acquisition:** -

**Investigation:** Mohamad Kashuri

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**Project administration:** Mohamad Kashuri

**Resources:** -

**Software:** -

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**Visualization:** Mohamad Kashuri

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**Writing - review & editing:** Mohamad Kashuri, Taruna Ikrar



## DATA AVAILABILITY

None.

## CONFLICT OF INTEREST

The authors declare no conflicts of interest related to this study.

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