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Pharmacy Practitioners' Experiences in Developing Herbal Products for Alternative Therapy: Quality Control and Regulation in Indonesia

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ABSTRACT

The increasing demand for herbal products as alternative therapies has raised concerns about their quality control and regulatory frameworks in Indonesia. While the development and use of herbal medicines are growing, there is limited understanding of the practical challenges faced by pharmacists in ensuring the quality and compliance of these products. This study aims to explore the experiences of pharmacists in developing, formulating, and evaluating herbal products, focusing on the regulatory and quality control issues they encounter. We used a phenomenological approach to examine these challenges through in-depth interviews with 15 experienced pharmacists in the field. The findings highlight the significant difficulties practitioners face, including inconsistent raw material quality and unclear regulatory guidelines, which complicate the standardization and evaluation of herbal products. These results provide valuable insights into the practical and regulatory gaps in the herbal medicine sector, suggesting the need for clearer guidelines and better training for professionals. Additionally, the findings underscore the importance of establishing robust regulatory frameworks and targeted educational programs to enhance practitioners' competencies and improve the quality of herbal medicines. This study contributes to the understanding of the intersection between science and traditional medicine and offers recommendations for improving regulatory practices and quality control standards in the industry.

INTRODUCTION

The development and evaluation of herbal products as alternatives in healthcare have gained significant attention worldwide, particularly in regions like Indonesia, where traditional herbal medicine plays a vital role in the healthcare system (Abdallah dkk., 2020). Herbal medicine, often viewed as a natural and safer option compared to synthetic pharmaceuticals, is increasingly sought after by consumers who prefer more "natural" treatment modalities. This growing interest has spurred the expansion of the herbal product industry, but it has also brought to the forefront challenges related to product quality, safety, and regulation (Bonini dkk., 2024)."

"Despite the popularity of herbal remedies, there remains a gap in understanding the challenges pharmacy practitioners face in developing and regulating these products. Many studies focus on technical aspects, such as chemical analyses and clinical outcomes, yet the subjective experiences of practitioners navigating regulatory and quality control issues are underrepresented. This study seeks to address this gap by exploring their lived experiences, shedding light on the practical and regulatory complexities they encounter."

"Modern technology and scientific advancements have enabled improvements in the quality of herbal products (Chapman dkk., 2020). However, challenges such as inconsistent raw material quality, unclear regulatory frameworks, and the integration of traditional and scientific practices persist. While research on herbal medicine efficacy continues to grow, the practical perspectives of

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those directly involved in product development remain underexplored. This research aims to fill that void by adopting a phenomenological approach to uncover the experiences of pharmacy practitioners."

"Previous studies often emphasize measurable outcomes, such as product efficacy or consumer satisfaction, but fail to address how practitioners interpret and respond to challenges in their work. By focusing on the lived experiences of practitioners, this study aims to provide insights that are both meaningful and actionable for the improvement of policies and practices in the herbal product industry."

"The findings from this study will not only address the gaps in existing literature but also contribute to a more nuanced understanding of the dynamics between traditional practices and modern scientific standards. The study highlights the need for clearer regulatory guidelines, enhanced training programs, and a more integrated approach to addressing the challenges faced by pharmacy practitioners in developing herbal products.

RESEARCH METHODS

Study Design

This study adopted a phenomenological approach to explore the experiences of pharmacy practitioners in developing and evaluating herbal products in Indonesia. Phenomenology was chosen as the research design due to its emphasis on understanding individuals' lived experiences and the meaning they ascribe to those experiences (Hung dkk., 2019). This approach was particularly relevant to the research questions, as it allows for an in-depth exploration of the subjective experiences of pharmacy practitioners involved in herbal product development, which cannot be fully understood through quantitative methods alone. By focusing on these lived experiences, phenomenology provides rich, detailed insights into the complexities of quality control, regulatory challenges, and the integration of traditional and scientific approaches in herbal medicine development. A descriptive phenomenological approach was applied in this study to capture and describe the essence of the participants' experiences without imposing pre-existing theories or interpretations. This approach enabled the study to remain close to the participants' perspectives and ensure that the findings reflect the meaning they attach to their experiences.

Participants

The participants in this study were pharmacy practitioners with experience in the development, formulation, and evaluation of herbal products. Purposive sampling was employed to select individuals who could provide in-depth insights into the phenomena under investigation. Inclusion criteria required participants to have a minimum of three years of professional experience in the field of herbal product development, either in the pharmaceutical industry, research institutions, or herbal pharmacies. The sample consisted of 8 to 12 participants, ensuring sufficient depth for phenomenological analysis while maintaining manageable data for thematic exploration. Demographically, participants included both male and female professionals, with an average age range of 30 to 50 years. The diversity of their professional backgrounds and experiences provided a broad perspective on the challenges and practices associated with herbal product development in Indonesia. Exclusion criteria included individuals who had no direct involvement in herbal product development or those whose roles were limited to administrative functions.

Data Collection

Data was collected through in-depth, semi-structured interviews designed to encourage participants to share their personal experiences and reflections on the process of developing, formulating, and evaluating herbal products (Karimi dkk., 2024). The interview questions were designed to elicit detailed responses and covered specific topics such as (1) steps and processes involved in herbal product development, (2) personal experiences with quality control challenges, (3) perceptions of regulatory frameworks, and (4) strategies used to address these challenges. Probing questions were also included to clarify responses and encourage participants to elaborate on

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significant points.The interviews were conducted face-to-face at the participants' workplaces or at neutral locations, depending on their preference, to ensure comfort and privacy. Each interview lasted between 45 to 60 minutes and was guided by an interview protocol that focused on three key areas: (1) the development and formulation of herbal products, (2) challenges related to quality control, and (3) the impact of regulatory frameworks on herbal medicine. The semi-structured format allowed flexibility in exploring themes that emerged during the interviews while ensuring that all relevant topics were covered. Data collection was conducted in the Indonesian language and was audio-recorded with the consent of the participants to ensure accuracy in transcriptions. All interviews were conducted in a quiet and comfortable setting to facilitate open and honest discussions.

Data Analysis

The data was analyzed using thematic analysis, a common approach in phenomenological studies to identify, analyze, and report patterns within qualitative data. Thematic analysis was employed in this study to systematically identify key themes that emerged from the participants' narratives. The analysis followed a six-step process: (1) familiarization with the data, (2) generating initial codes, (3) searching for themes, (4) reviewing themes, (5) defining and naming themes, and (6) producing the final report. Each interview transcript was carefully read and re-read to identify significant statements that captured the essence of the participants' experiences. These statements were then coded, and the codes were grouped into broader themes that reflected the core issues identified by the participants. The analysis was supported by NVivo software to organize and manage the data, although the interpretation remained grounded in the participants' own words and perspectives. The goal of the analysis was to uncover the underlying meanings and insights regarding the challenges and practices associated with herbal product development and regulation, ensuring that the findings represented the authentic experiences of the participants.

Ethics

Ethical approval for this study was obtained from the relevant ethics committee, in accordance with international ethical guidelines for qualitative research. Prior to participation, all participants provided informed consent, acknowledging their voluntary involvement and understanding of the study's aims and procedures. Participants were assured of the confidentiality of their responses, and all identifying information was anonymized to protect their privacy. The data collected was stored securely and used solely for the purposes of this research. The study adhered to the principles of ethical research, ensuring that participants' rights were respected throughout the process, and that the findings would be used to contribute to the advancement of knowledge in the field of herbal medicine and pharmacy practice.

RESULTS

Challenges in Quality Control of Herbal Products

A significant challenge identified by the participants was the difficulty in ensuring the quality of raw herbal materials. Many practitioners reported a lack of reliable sources for high-quality raw materials, which often resulted in inconsistencies in the final products. One participant explained:

> "I often have to double-check the quality of herbal raw materials because sometimes there is no guarantee of their quality from suppliers."

This sentiment was echoed by several others, indicating that the lack of standardized supply chains for herbal ingredients created considerable uncertainty for practitioners. The absence of clear, enforceable quality control procedures within the industry was noted as a major barrier to producing consistent and safe herbal products.

In some cases, the absence of stringent controls meant that herbal formulations were frequently subjected to less rigorous evaluation processes. A respondent working in a laboratory setting shared:

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> "In the lab, we take a careful approach to formulation, but sometimes we have to rely on traditional methods to test the quality of the herbs, which are not always scientifically validated."

This reliance on non-standardized methods, such as organoleptic testing (sensory evaluation), revealed a gap in practices that are expected to meet international standards for pharmaceutical products.

Need for Clearer Regulations and Guidelines

A recurring theme across interviews was the confusion and frustration surrounding the regulation of herbal products in Indonesia. Participants described a lack of clarity about the legal frameworks governing the production and distribution of herbal medicines, particularly in relation to registration with regulatory bodies such as the Indonesian National Agency of Drug and Food Control (BPOM). One participant remarked:

> "There is a lot of ambiguity about how to register and standardize herbal products with BPOM. The guidelines are not always clear, and sometimes we don't know whether a product qualifies as a 'drug' or a 'supplement'."

The uncertainty regarding regulatory procedures was often described as a hindrance to both the development and commercialization of herbal products. Many practitioners felt that more structured, transparent guidelines would facilitate smoother operations and increase the trust of consumers in herbal products. Another respondent shared:

> "We need a more defined regulatory framework to make sure that we are developing safe products. If the regulations were clearer, it would be easier to navigate the registration process and avoid unnecessary delays."

This theme highlights the crucial role that clear regulatory policies play in advancing the herbal medicine industry in Indonesia, ensuring both safety and efficacy for consumers.

Tension Between Traditional and Scientific Approaches in Herbal Medicine Development

A third theme that emerged from the interviews was the ongoing tension between traditional practices and modern scientific approaches in the formulation and evaluation of herbal products. Several participants noted that while traditional knowledge plays a significant role in the development of herbal remedies, there is often a conflict when trying to align these practices with modern scientific standards for quality and efficacy.

One participant shared:

> "In our practice, we respect the traditional ways, but we are also trying to integrate scientific research into our formulations. It’s challenging because we don’t always have the tools or the framework to test these traditional methods according to scientific standards."

This gap between traditional and scientific approaches created tension, especially when it came to the evaluation of herbal products' safety and efficacy. The participants acknowledged that there is a growing need to bridge the divide between these two approaches to better meet both consumer expectations and regulatory demands.

In summary, the findings from this study underscore the challenges faced by pharmacy practitioners in developing and evaluating herbal products in Indonesia. These challenges include issues related to the consistency and quality control of raw materials, the ambiguity of regulatory guidelines, and the tension between traditional and scientific approaches to herbal medicine development. These findings suggest a need for more comprehensive regulatory frameworks, standardized quality control procedures, and greater integration of scientific methods into herbal product development. These factors are essential to ensuring the safety, efficacy, and reliability of herbal products as viable alternatives in the healthcare landscape.

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DISCUSSION

This study found that pharmacy practitioners face significant challenges in developing and evaluating herbal products, particularly with regard to raw material quality control and the ambiguous understanding of existing regulations (Lee, 2023). These challenges are consistent with findings from prior studies that highlight regulatory uncertainty as a major barrier to effective herbal product development (Pardo et al., 2016; Setiawati, 2019). However, this study extends previous research by uncovering how these uncertainties influence practitioners' day-to-day decision-making and professional practices, emphasizing the interplay between technical, cultural, and social factors. These findings indicate that practitioners' experiences in handling herbal products are not only influenced by technical factors but also by their subjective perceptions of various uncertainties and inconsistencies in the product development process (Locham dkk., 2024). This underscores the necessity for regulatory frameworks that better align with the realities faced by practitioners, a point similarly argued by Palermo et al. (2020).

These findings offer an important answer to the research questions raised in the Introduction regarding how pharmacy practitioners interpret the challenges in herbal product development and how they address the uncertainties related to regulations and quality control (Mohapatra dkk., 2022). The study reveals that, beyond technical aspects, the main challenges lie in uncertainty and the lack of clarity in regulations, which affect how practitioners formulate and evaluate herbal products. This phenomenon suggests that a deeper understanding of pharmacy practitioners' experiences, encompassing professional, social, and cultural factors, is crucial for developing more effective policies and regulations in the herbal industry (Ohtsuka dkk., 2021). Therefore, this research not only enriches the existing literature but also provides new insights that could influence the development of policies and practices in the future.

In the context of theory and previous research, these findings complement and confirm several studies that have highlighted the gap between traditional and science-based herbal product development. Previous studies, such as those conducted by Pardo et al. (2016) and Setiawati (2019), have shown a mismatch between existing regulations and the realities on the ground, which affects consumer trust and product efficacy (Palermo dkk., 2020). However, this study deepens the understanding of how regulatory ambiguity and quality control issues impact practitioners' subjective experiences, an aspect that has been underexplored in the literature. Meanwhile, the theory of science-based herbal product development (Misra et al., 2021) provides a scientific foundation for quality control, but the practitioners' experiences, shaped by this uncertainty, show that their subjective experiences play a critical role in practical decision-making. Thus, the results of this study complement previous research by adding the dimension of human experience, which had previously been insufficiently addressed.

Explanation of the Findings' Implications

The findings of this study have significant implications both scientifically and practically (Polopalli dkk., 2023). Scientifically, this research makes an important contribution to deepening our understanding of the challenges faced by pharmacy practitioners in the development and evaluation of herbal products. Specifically, their subjective experiences related to raw material quality control and regulatory ambiguity provide new insights into how social, cultural, and professional elements interact in herbal pharmacy practice. Practically, the findings highlight the need for improvements in the education and training of pharmacy practitioners to better prepare them for the uncertainties involved in herbal product development, as well as the need for clearer and more structured policies regarding herbal product regulation in Indonesia. Furthermore, these practitioners' experiences also emphasize the importance of a more holistic understanding of their role in bridging scientific and traditional knowledge in herbal medicine development, which can be applied to professional practice and policy-making in the future.

Study Limitations

While this study provides important insights into pharmacy practitioners' experiences in herbal product development, there are several limitations to consider (Sayed dkk., 2023). First, the

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study uses a limited sample that only includes pharmacy practitioners with at least three years of experience in the field, meaning the findings may not fully represent the entire population of pharmacy practitioners. Additionally, because the study was conducted in Indonesia, the findings may be influenced by local social, cultural, and regulatory contexts, which could differ in other countries. Methodological limitations, such as the use of in-depth interviews that heavily rely on the subjectivity of the informants, also affect the conclusions drawn from the data. Therefore, generalizing these findings should be done with caution, and further research with a larger and more diverse sample in various social and cultural contexts is necessary to broaden this understanding.

Prospective Statements for Future Research

The findings of this study open up opportunities for future research that could explore the relationship between herbal product regulation, professional practices, and consumer experiences. One potential direction for future research is to investigate in more depth how unclear regulations affect consumer perceptions of the quality and safety of herbal products (Trendowski dkk., 2019). Further studies could also focus on developing training models for pharmacy practitioners that integrate scientific and traditional knowledge in herbal product development, as well as strategies for addressing quality control challenges. In this way, this research could serve as a foundation for broader studies on the role of pharmacy in the global herbal product industry, as well as the critical role of regulation in ensuring the safety and effectiveness of herbal products on the market.

CONCLUSION

This study explored the experiences of pharmacists in developing and evaluating herbal products as alternative therapies, focusing on quality control challenges and regulatory uncertainties in Indonesia. The findings reveal significant difficulties faced by practitioners, such as the inconsistent quality of raw materials and unclear regulatory guidelines, which hinder the development of high-quality herbal products. These insights contribute to the growing body of knowledge on the intersection of science and traditional practices in herbal medicine, addressing gaps in previous research regarding the practical and regulatory complexities of the field. By highlighting the need for clearer regulations and better training for pharmacists, this study provides valuable recommendations for improving industry standards Furthermore, it opens several specific avenues for future research that could build on the current findings:

Cross-country comparative studies: Future research could examine how regulatory frameworks in different countries address similar challenges, particularly in regions with strong traditions of herbal medicine, such as India, China, or African nations. This would provide insights into best practices and opportunities for international regulatory harmonization.

Consumer perceptions of herbal products: Studies could investigate how regulatory uncertainties and product inconsistencies influence consumer trust and usage patterns. This research could include surveys or focus groups to explore consumer preferences and their perceptions of quality and safety.

Development of training models: Research could focus on designing and evaluating training programs for pharmacists that integrate scientific standards and traditional knowledge. These models could be tested in pilot programs to assess their effectiveness in improving practitioners' competencies and their ability to navigate regulatory challenges.

Raw material standardization strategies: Further studies could explore innovative approaches to standardizing the quality of raw materials, such as developing digital tools for tracking supply chains or using advanced analytical techniques for quality assessment. Research in this area could involve collaborations between academia, industry, and regulatory bodies.

Economic impact analysis: Research could investigate the economic implications of inconsistent regulations and quality control issues on the herbal product industry. This could include cost-benefit analyses of regulatory reforms or investment in quality assurance programs.

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Integration of traditional and scientific approaches: Future studies could explore frameworks for harmonizing traditional knowledge with modern scientific practices in herbal product development. This might include ethnobotanical studies, the codification of traditional practices, or research into how traditional knowledge holders and scientists can collaborate effectively.

By addressing these specific areas, future research can contribute to a more holistic understanding of the challenges and opportunities in the herbal product industry. It can also help develop actionable solutions that benefit practitioners, policymakers, and consumers, further advancing the field of herbal medicine.

CONFLICT OF INTEREST

This article has undergone an independent and objective review process. The editor handling this article was not involved in the co-authorship of any previous publications with the authors, and to maintain independence, the peer review process was conducted by a different editor who had no direct relationship with the authors.

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