



REGULATORY FRAMEWORK AND CHALLENGES IN THE DISTRIBUTION OF HERBAL MEDICINES IN INDONESIA

Violeta Mashary

Fakultas Hukum Dan Bisnis Digital Universitas Kristen Maranatha

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Abstract

Traditional herbal medicine, known as jamu in Indonesia, has long been part of the cultural and healthcare practices in Southeast Asia. This study aims to explore the role of governmental legal instruments in enhancing the sustainability and global promotion of jamu as a valuable national heritage. Using a qualitative descriptive method, the study analyzes primary and secondary legal sources, including Presidential Regulation Number 54 of 2023 on the Development and Utilization of Herbal Medicine. The regulation signifies the Indonesian government's commitment to preserving and developing jamu following its recognition as an intangible cultural heritage by UNESCO on December 6, 2023. The findings reveal that the regulation provides a legal foundation to optimize the benefits of jamu, prevent misuse, and promote sustainable development of traditional herbal practices. However, the research suggests that further efforts are needed to build a broader movement for public awareness, encourage the regeneration of herbal practitioners, and utilize jamu as a soft diplomacy tool to introduce Indonesian herbal culture globally. By strengthening legal support and public engagement, jamu can be positioned not only as a traditional remedy but also as a strategic national asset contributing to health, cultural identity, and international recognition.

Keywords: Regulatory Framework, Challenges, Dissemination Of Herbal, Medicine

Abstrak

Obat herbal tradisional, yang dikenal sebagai jamu di Indonesia, telah lama menjadi bagian dari praktik budaya dan kesehatan di kawasan Asia Tenggara. Penelitian ini bertujuan untuk mengeksplorasi peran instrumen hukum pemerintah dalam meningkatkan keberlanjutan dan promosi global jamu sebagai warisan nasional yang bernilai. Dengan menggunakan metode deskriptif kualitatif, studi ini menganalisis sumber hukum primer dan sekunder, termasuk Peraturan Presiden Nomor 54 Tahun 2023 tentang Pengembangan dan Pemanfaatan Obat Tradisional. Peraturan ini menunjukkan komitmen pemerintah Indonesia dalam melestarikan dan mengembangkan jamu setelah pengakuannya sebagai warisan budaya takbenda oleh UNESCO pada 6 Desember 2023. Temuan penelitian menunjukkan bahwa regulasi ini memberikan dasar hukum untuk mengoptimalkan manfaat jamu, mencegah penyalahgunaan, dan mendorong pengembangan berkelanjutan praktik pengobatan tradisional. Namun demikian, penelitian ini merekomendasikan perlunya upaya lebih lanjut untuk membangun gerakan yang lebih luas dalam meningkatkan kesadaran publik, mendorong regenerasi peracik jamu, serta memanfaatkan jamu sebagai alat diplomasi lunak untuk memperkenalkan budaya herbal Indonesia ke kancah dunia. Dengan memperkuat dukungan hukum dan keterlibatan masyarakat, jamu dapat diposisikan tidak hanya sebagai obat tradisional, tetapi



juga sebagai aset strategis nasional yang berkontribusi pada kesehatan, identitas budaya, dan pengakuan internasional.

Kata kunci: Kerangka Regulasi, Tantangan, Diseminasi Obat Herbal, Jamu

I. INTRODUCTION

Indonesians have generally used medicinal plants to prevent, inhibit, and cure various ailments by consuming herbal concoctions. Local knowledge about the properties of various medicinal plants is a legacy of our ancestors, and empirical evidence has proven its efficacy and safety. Traditional Indonesian herbal medicine, practiced for centuries, remains highly popular for maintaining health and treating illnesses, as it is believed to be superior to chemical drugs. This traditional medicine is commonly known as jamu. Historically, traveling jamu sellers carried the concoctions they sold, often referred to as "jamu gendong" (traditional herbal medicine).

Knowledge of traditional jamu recipes has been preserved and passed down orally from generation to generation. This aligns with the World Health Organization (WHO) definition of traditional medicine: "a body of knowledge, skills, and practices based on indigenous beliefs and experiences, whether explicable or not, used in health care, prevention, diagnosis, improvement, or treatment of physical and mental illness."

As an archipelagic nation covering approximately 1.3% of the Earth's surface, Indonesia is one of the 12 Centers of Biodiversity. There are approximately 28,000 plant species, including 400 edible fruits, which serve as a source of genetic diversity in breeding programs. Furthermore, Indonesia has approximately 7,500 medicinal plant species, or approximately 10% of the world's medicinal plants. However, only 940 plant species have been identified. Indonesian forests contain more than 9,606 biopharmaceutical species, 350 of which are known to have medicinal properties. The community uses approximately 1,000 types of traditional medicinal raw materials, 74% of which are wild plants growing in local forests. In general, traditional or natural medicines can be identified as medicines that use raw materials derived from nature. Furthermore, traditional medicines are classified into three types: herbal medicines, standardized herbal medicines, and phytopharmaceuticals.

As recorded in history, UNESCO designated jamu as an intangible cultural heritage at the 18th Session of the Intergovernmental Committee for the Safeguarding of the Intangible Cultural Heritage. In addition to being Indonesia's cultural and natural wealth, jamu also holds strategic economic value. Herbal medicine production itself involves many parties from all walks of life, from farmers and workers to marketing staff. This contributes to the local economy, and some herbal products have gained popularity in the global market.

Currently, because herbal medicine has significant economic and clinical potential, its use is gaining popularity worldwide. Most people who choose traditional medicine believe it is more natural and safer. Therefore, herbal medicine is now sought after not only by the older generation but also by the younger generation, and is sought by all age groups and across educational and socioeconomic levels. Herbal medicine has a very broad market reach. In fact, demand for medicinal plants, both in Asia and on other continents, is increasing significantly.

In line with the significant benefits of herbal medicine as Indonesia's medicinal heritage, the government has issued legal regulations to protect this heritage, as stipulated in "Presidential Regulation of the Republic of Indonesia Number 54 of 2023 concerning the Development and Utilization of Herbal Medicine."

However, amidst the increasing popularity of herbal medicine, there has also been the emergence of illegal herbal medicine producers. Herbal medicine itself has standards governed by national law and is supervised by the Food and Drug Monitoring Agency (BPOM). These regulations are strictly regulated in "Regulation of the Food and Drug Monitoring Agency of the Republic of Indonesia Number 34 of 2018" concerning Guidelines for Good Manufacturing Practices for Medicines. This regulation was specifically created to ensure the safe consumption of any medicine or food sold throughout Indonesia. In short, the BPOM has a similar function to the Food and Drug Administration (FDA). Without a permit from the BPOM, food or medicine is unfit for consumption.

This paper explores the potential of herbal medicine (jamu) in Indonesia's tourism sector, focusing on how it can be leveraged to create sustainable tourism initiatives and legal protection for the authenticity of herbal medicines.

II. THEORETICAL STUDY

Indonesian Food and Drug Monitoring Agency (BPOM) Regulations on Guidelines for Good Manufacturing Practices (CPOB)

Law No. 36 of 2009 concerning Health and its amendments require pharmaceutical companies to implement measures to ensure that pharmaceutical products and medical devices, including medicines, are safe, efficacious, standardized, and affordable. The production, storage, processing, promotion, and distribution of medicines must be carried out in accordance with quality standards. Produced and distributed medicines must comply with the provisions stipulated in the Indonesian Pharmacopoeia or other applicable standards. Any party intentionally producing or distributing medicines that do not meet safety, efficacy, and

quality standards will be subject to criminal sanctions of up to 10 years in prison and/or a fine of up to 1 billion rupiah. If the violation is committed by a legal entity, the company's permit and legal entity status may be revoked.

Law No. 8 of 1999 concerning Consumer Protection guarantees consumers' rights to compensation in the form of a refund, replacement of similar goods, medical treatment, and/or compensation. Related Regulations on Medicines by BPOM:

1. Regulation of the Head of BPOM No. HK.03.1.33.12.12.8195 of 2012 and its Amendments

Companies, including MSMEs producing pharmaceutical products, are required to ensure compliance with Good Manufacturing Practices (GMPs). Violations will result in administrative sanctions, such as warnings, temporary suspension, or revocation of certificates/permits.

2. BPOM Regulation No. 2 of 2022

The pharmaceutical industry is required to submit various reports to the Head of BPOM. If a product is launched before obtaining approval, administrative sanctions may be imposed, including warnings, severe warnings, or suspension of distribution permits.

3. Minister of Health Decree No. 193/KAB/B.VII/71

Regulates mandatory packaging and labeling of drugs distributed in Indonesia. Violations may result in criminal sanctions, drug confiscation, and administrative sanctions.

BPOM's Role Based on Presidential Regulation No. 80 of 2017

BPOM is tasked with overseeing the food and drug sector. In carrying out its duties, BPOM Regulation No. Law No. 21 of 2020 outlines the following functions of the BPOM:

1. Supervising products before and during distribution.
2. Taking action if regulatory violations are found.
3. Issuing distribution permits and certificates that meet safety, efficacy, and quality standards.
4. Conducting investigations and gathering intelligence related to product oversight.
5. Imposing administrative sanctions in accordance with regulations.

Presidential Regulation No. 54 of 2023 concerning the Development and Utilization of Herbal Medicine

This regulation aims to maximize the potential of herbal medicine as a traditional heritage and an important part of the national health system. The main focuses of the regulation include:

1. Preservation of Traditional Knowledge

Preserving traditional recipes and techniques for making herbal medicine as a cultural heritage.

2. Quality Control

Implementing strict quality standards to ensure the safety and effectiveness of herbal medicine products.

3. Promotion of Innovation

Supporting research and development to create new formulations and modern herbal medicine applications.

4. Market Access

Increasing access to domestic and international markets to encourage economic growth in the herbal medicine sector.

This regulation balances traditional values with modern needs and encourages investment, research, and international collaboration. It also strengthens Indonesia's position as a global leader in traditional medicine.

Mochtar Kusumaatmadja's Theory of Development Law

Mochtar Kusumaatmadja states that cultural factors significantly influence law enforcement in multicultural Indonesia. Law is used as a tool of social engineering to encourage development. The ideas of Roscoe Pound and McDougal have significantly influenced development law theory, which links social change with legal change.

III. RESEARCH METHODS

This research method uses a normative juridical research method, namely a method used in legal studies to analyze and interpret legal norms, principles, and rules. This method involves examining applicable laws and regulations, judicial decisions, and legal doctrines to understand their meaning, application, and implications in the legal system. The approach chosen by the author is a conceptual approach. The data analysis used by the author is descriptive qualitative data analysis. This research focuses on secondary data such as positive law and legislation relevant to the research topic. The secondary legal sources used by the author are written literature and research results related to this field.

IV. RESEARCH RESULTS

Herbal concoctions as a diplomatic tool to introduce Indonesian herbal culture to the world

The tourism sector is a major economic driver in many countries. Herbal plants have emerged as a valuable asset in tourism, becoming a distinctive attraction that attracts visitors from around the world. Furthermore, herbal plants have the potential to create jobs and increase local incomes. Examples of the use of herbal plants in tourism are numerous, from hotels and spas that integrate these plants into products and therapies, to travel agencies offering tours to aromatic and medicinal plant plantations.

Within the Mediterranean cultural heritage, aromatic and herbal plants are important commodities in tourism, offering high added value. The integration of these plants into tourism is a promising trend with great potential. Through appropriate policies and investments, aromatic and medicinal plants can play a significant role in promoting sustainable tourism initiatives.

Mediterranean countries have agro-climatic conditions favorable for the cultivation, processing, and harvesting of aromatic and medicinal plants, as well as rich cultural traditions and practices passed down through generations. Therefore, the customs, techniques, and traditions that shape the identity of rural communities and serve as tourist attractions need to be preserved.

In Italy, a project focused on the sustainable cultivation of aromatic and medicinal plants in rural areas. This sector was chosen for its potential for cultural exchange and knowledge. The project also introduced tour packages that fostered tourism based on medicinal and aromatic plants. A national law paved the way for the establishment of Wine and Food Routes (WFRs) in Italy. These routes connect communities and business groups within specific geographical and historical regions. WFRs unite high-quality wines, specialty food products, businesses, and tourism operators under one brand, offering various tourist routes that traverse the same region.

While quality wine production is the primary driver of Italian WFRs, wine also contributes to the cultural capital of many Italian regions. Therefore, WFRs provide an opportunity for local stakeholders to showcase their cultural identity amidst globalization. Products such as wine and other Typical Italian Products (TIPs) are part of regional heritage, possessing cultural value, and serve as tourist products offering authentic cultural tourism experiences. Several tourist routes developed under the Council of Europe's Cultural Routes

program promote thematic tourism and protect cultural heritage through the exploration of typical products.

The connection to cultural heritage is strengthened when these distinctive products have labels and brands that guarantee their identity. These labels are given to products whose characteristics are closely linked to the region of production, thus reinforcing their cultural value. Italy is also experiencing a growing awareness of the importance of promoting regions through themed tourism routes, such as the Wine Route, which promotes rural areas as tourism destinations. This model arises from the synergy between two important sectors: wine farming and tourism.

The Wine Route was established under National Law No. 268 of 1999, which defines it as a tourist route in regions known for their quality wine production. The goal is to utilize wine regions and their natural and cultural resources to support tourism. Today, the route has been expanded to include typical food products, known as Wine and Food Routes (WFRs). Each region in Italy has its own regulations governing these routes, ensuring proper management throughout the country.

Establishing a strong national brand can significantly benefit a country's international trade. This brand can influence various socio-economic aspects and enhance the tourist experience. Creating a strong destination identity requires collaboration between businesses, communities, local managers, and the government. Innovative integrated marketing strategies are key to enhancing tourism's appeal globally.

The Importance of Government Support for Indonesian Herbal Medicine

Law No. 36 of 2009 concerning Health regulates traditional medicine, although not comprehensively. The government is working to elevate the status of traditional medicine to be on par with modern medicine and make it part of formal healthcare services. Although traditional medicines do not claim curative effects, they must be preserved as part of our cultural heritage.

However, there are traditional medicines and herbal medicines on the market that contain dangerous chemicals that endanger consumers' health. Such products are considered illegal. Unfortunately, due to the large number of MSMEs and weak oversight, these products are widely circulated. Herbal medicines containing chemicals can cause blindness, hearing loss, stroke, heart attack, liver damage, and even death.

Therefore, consumer protection is necessary, both legally and materially. Advances in science and technology have boosted the productivity of the herbal medicine business, but

consumer protection must be a priority. The agency responsible for this oversight is the Food and Drug Monitoring Agency (BPOM), which plays a role in detecting and supervising products, ensuring safety, and imposing sanctions for violations.

BPOM has several functions, including:

1. Preparing program plans
2. Laboratory examinations
3. Quality testing and assessment
4. Field inspections
5. Production facility inspections
6. Investigations
7. Implementing product certification

BPOM also has the authority to issue distribution permits and certificates, conduct intelligence and investigations, and impose administrative sanctions.

The herbal medicine production process is regulated by BPOM Regulation No. 34 of 2018 concerning Guidelines for Good Traditional Medicine Manufacturing Practices (CPOTB). CPOTB ensures the quality of traditional medicines in accordance with applicable standards.

Herbal medicine distribution requires a distribution permit in accordance with Minister of Health Regulation No. 7 of 2012, with the following requirements: meeting safety requirements, complying with CPOTB, complying with the Indonesian Herbal Pharmacopoeia, having a special label, and including complete objective information.

Establishing a herbal medicine business also requires a permit from the Minister of Health, with the requirement that the alcohol content not exceed 1% and that it does not contain chemicals classified as narcotics or psychotropics. BPOM supervision includes regulation, standardization, registration, inspection, sampling, public warnings, and consumer services, with the aim of preventing consumer harm from traditional medicine products.

Discussion

The herbal sector in tourism plays a crucial role in driving economic growth and development. However, the growing environment for aromatic and medicinal plants is not always conducive to the sector's progress. The sector is influenced by various policy areas, such as trade, agriculture, and tourism, which sometimes conflict with each other. This contradiction makes it difficult for the aromatic and medicinal plant industry to function smoothly and cohesively. For example, while government policies may encourage tourism

and exports, these policies can indirectly hinder herbal cultivation and complicate farmers' access to export markets. Furthermore, the lack of a clear and coordinated policy framework creates uncertainty about future regulations, which can impact industry stability. Workers in the sector may also face low wages or poor working conditions due to job insecurity.

The aromatic and medicinal plant (AMP) sector is growing, but there are gaps and complexities that need to be addressed. Policymakers and the private sector can work together to address the challenges facing this market. Therefore, maximum efforts should be made in brand building and product certification to increase added value and enhance the sector's development. Several steps related to certification in the herbal medicine industry that can be implemented include forest management certification, social certification, organic certification, product quality certification, and product origin certification. These initiatives aim to promote a sustainable approach to forest resource management, improve working conditions and worker well-being, and ensure the production of high-quality products.

Marketing and commercial strategies must be aligned with consumer purchasing trends, addressing challenges such as high product costs and price fluctuations in volatile markets. Therefore, innovative marketing approaches need to be encouraged, particularly in design, packaging, and distribution channels, to meet consumer expectations.

Each country needs to develop effective policies to promote harmonization of herbal harvesting practices while protecting wild plants. Unharmonious or inappropriate practices in herbal utilization can negatively impact the development of this sector. Herbal plant management faces various challenges, including natural resource depletion, overexploitation, unsustainable harvesting practices, and misuse of forest land. Furthermore, it is crucial for organizations involved in wild herbal harvesting to disseminate information and share knowledge with all stakeholders to effectively address these issues.

The government could consider implementing guaranteed minimum prices for herbal products to build trust and encourage new producers to enter the sector. Furthermore, local economic development should be supported through policies focused on sustainability, innovation, and cultural enrichment.

The herbal sector still lacks research on innovative strategies to revitalize and advance the industry. One potential step is to establish a communication network among stakeholders. This network would facilitate the exchange of information and techniques related to sustainable and modern herbal cultivation and harvesting.

Policymakers and stakeholders can collaborate to organize technical courses, training programs, and workshops to enhance technical knowledge and expertise in the herbal and medicinal plant sector. These training programs can positively impact entrepreneurs by improving practical skills, business management capabilities, and developing effective business strategies.

The public and private sectors can also collaborate to strengthen local cultural heritage and traditions, which can have a positive impact on various aspects, such as cooperation between local communities and regional producers (micro-production, investment and production incentives), herbal-themed entertainment activities, the development of innovative tourism packages, the creation of small plots where tourists can learn to grow herbs and understand village culture, and collaboration between schools, institutions, and the industrial sector.

Another step worth considering is establishing community gardens in rural areas focused on herbal cultivation. These gardens would enhance cultural understanding, education, and hands-on learning about herbal cultivation. A comprehensive management plan for these gardens is needed. Additionally, establishing training and education centers for producers and entrepreneurs in the herbal sector could help address issues such as overexploitation, deforestation, and other environmental challenges.

V. CONCLUSION

This study highlights recent advances in the Herbal Medicine sector and its links to tourism, while identifying challenges and limitations that could impact the sector's future innovation, sustainability, and growth. Herbal medicines have significant potential to support the tourism sector by creating products and services that appeal to tourists, while simultaneously creating jobs and improving the quality of life for local communities as part of sustainable tourism development. However, key challenges such as overexploitation and unsustainable harvesting require serious attention. Therefore, a collaborative analysis with stakeholders regarding threats to herbal medicine resources, as well as constraints to production, financing, and marketing, is needed. Key challenges in the sector's development include market development, improving quality of life, research and development, product certification and labeling, and innovation in herbal processing and treatment techniques. The success of businesses in the herbal medicine sector depends heavily on training and access to information on the latest techniques, making training and scientific/technical activities crucial for improving yields and production efficiency. The biggest obstacles faced by farmers in this

study included a lack of knowledge and technological advancements, bureaucracy, limited financial support, limited skilled labor, and cultural, communication, and geographic access barriers. The lack of a database is a major obstacle for policymakers in developing biodiversity conservation strategies. Therefore, further research is needed to support the formulation of a targeted research agenda. While existing regulations represent a significant step forward, challenges in implementation and standardization remain obstacles that must be overcome to maximize the benefits of regulations and realize the full potential of herbal medicine in the Indonesian health system.

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