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Review Paper

Review: Potency and Problem in Development of Self-reliance of Traditional Drug Raw Material in Indonesia

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Abstract

The use of herbs for health purposes has been practiced for thousands of years, long before the discovery of synthetic chemical drugs. Indonesia is widely recognized for its vast biodiversity, boasting approximately 30,000 plant species, equivalent to 75% of the total plant species worldwide, earning it the title of a mega-centre of global biodiversity. This highlights Indonesia's enormous potential in the traditional medicine industry, with the capability to compete on a global scale. However, several challenges hinder the development of traditional raw materials and the production of traditional medicines. These include herbal raw materials that fail to meet quality standards, a non-conducive business climate, limited technological advancements in the extraction and production of raw materials, uneven distribution of third-party laboratories across Indonesia which making it difficult for small and medium-sized industries to access product testing facilities, the exclusion of traditional medicines from the National Health Insurance (JKN) program, and a lack of empirical evidence for many plants with potential as traditional medicines. To address these challenges, intensive support and synergy from the government and legislative bodies are essential to enact policies that accelerate the growth of the traditional medicine industry. Additionally, strong collaboration with business actors, academics, and community organizations is crucial to fostering self-sufficiency in traditional medicine raw materials.
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Keywords: Self-reliance Industry, Traditional Drug Raw Materials, Herbs

1. Introduction

Herbs are natural ingredients widely used for medicinal purposes, health supplements, and food supplements. According to the WHO, traditional medicine is defined as the combination of knowledge, skills, and practices based on theories, beliefs, and experiences originating from different cultures, whether explainable or not, used for health maintenance and the prevention, diagnosis, improvement, or treatment of physical and mental illnesses. Traditional medicine encompasses herbs, herbal ingredients, herbal preparations, and herbal finished products containing plant parts, other plant ingredients, or combinations thereof as active ingredients. In some countries, herbal medicines may also include natural organic or inorganic active ingredients not of plant origin, such as animal or mineral ingredients [1].

The use of herbs for health purposes has been widely practiced for thousands of years, long before the discovery of synthetic chemical drugs. The preference for herbal medicine can be attributed to several factors, including the belief that herbal medicines have fewer side effects than conventional medicines, or are even considered side-effect-free. Herbal medicines are also easily accessible without a doctor's prescription, rooted in strong traditions, particularly in rural areas, and are considered a more affordable and safer alternative for treating degenerative diseases that require prolonged treatment [2].

The practice of using herbs is widespread across various countries, particularly those rich in biodiversity.

Indonesia, renowned for its vast biodiversity, is home to approximately 30,000 plant species—equivalent to 75% of the world's total plant species—making it a global biodiversity mega-center [3,4]. Research conducted by the Research and Development Agency of the Ministry of Health (RISTOJA) identified 10,047 traditional herbs used by Indonesians to treat 74 types of diseases. The most common indications include cough, fever, diabetes, diarrhea, hypertension, back pain, skin conditions, open wounds, and pre/postnatal care. These practices involve around 19,871 medicinal plants, 16,218 of which have been identified to the species level, encompassing 1,559 unique species or types [5]. This data underscores Indonesia's immense potential in the development of traditional medicine.

Other Asian countries renowned for their use of herbs in traditional medicine include China (Traditional Chinese Medicine), Japan (Kampo), Korea, India (Ayurveda), Iran (Persian Medicine), and indigenous tribes in the Americas. Traditional Chinese Medicine is reported to utilize 12,000 types of materials, predominantly plant-based, while India similarly employs thousands of plant materials in its traditional medicinal practices [2,6,7,8,9].

The use of herbs is typically based on tradition and generational knowledge, deeply rooted in specific ethnic or cultural practices. However, with the increasing public awareness of product quality and safety, herbal medicines have evolved rapidly. Product development has advanced to improve quality, efficacy, and safety. Herbal products that were initially basic formulations have now been developed into Standardized Herbal Medicines and, subsequently, phytopharmaceuticals that undergo clinical trials, akin to the development of chemical drugs.

The Indonesian Food and Drug Authority (Badan POM) categorizes traditional medicines into three groups: Jamu, Standardized Herbal Medicines, and Phytopharmaceuticals. This categorization is based on manufacturing processes, dosage forms, and the level of evidence supporting their benefits and quality. Jamu refers to medicinal preparations from natural ingredients used generationally as traditional medicine, in accordance with prevailing societal norms; standardized Herbal Medicines are medicinal preparations of natural ingredients whose raw materials have been standardized and meet safety and quality requirements. Their efficacy claims are supported by scientific or preclinical evidence; and phytopharmaceuticals are medicinal preparations of natural ingredients whose raw materials and finished products have been standardized to meet quality requirements. Their safety and efficacy are scientifically proven through clinical trials [10,11].

Currently, the development of Standardized Herbal Medicines and Phytopharmaceuticals is a key focus of the Indonesian government in efforts to reduce dependence on imported raw materials for conventional medicines.

2. Traditional Raw Materials Needs

The advancement of information technology, which provides easy access to information about the benefits of herbal medicine, along with the increase in research related to herbal medicine and the rising level of public knowledge, has led to a growing use of herbal medicines in the community. The Covid-19 pandemic has also made people more massive to use herbal medicines as an effort to maintain body resistance. This condition is influenced by the inclusion of the use of traditional medicines in the Corona Virus Disease Control Prevention Guidelines (COVID-19) from the Ministry of Health in the 5th Revision of 2020, which include, red ginger, ginger, temulawak, turmeric, kencur, galangal, garlic, wood sweet, lemongrass, moringa leaves, katuk leaves, guava, lemon, lime, and black cumin [12].

Badan POM also announced that during the COVID-19 pandemic, the need for herbal medicine was increasing along with increasing public awareness of the importance of increasing body immunity [13]. In addition, based on Indonesian statistical data in 2021, the average population who self-medication was 63.67%. People generally use over-the-counter medicines to treat themselves, including the use of herbal medicines that can be purchased without a doctor's prescription. The use of herbal medicines in the community is based on several things including relatively affordable prices, a strong belief that herbal medicines have fewer side effects or even have no side effects when compared to chemical medicines and easy access to herbal medicines because they can be purchased without a doctor's prescription and the public's reluctance to visit health facilities due to avoid exposure of covid-19 virus.

The increased use of traditional medicine is occurring not only domestically but also internationally. This trend is evident from a statement by the Minister of Trade, as reported by *Kompas.com*, which highlighted that the export value of Indonesian herbal or biopharmaceutical products during the January–September 2020 period increased by 14.08%, amounting to USD 9.64 million, compared to the same period in 2019. Notably, Indonesia ranked 19th among global exporters of herbal or biopharmaceutical products in 2019, with a market share of 0.61%. During the January–September 2020 period, Indonesia’s biopharmaceutical export destinations were predominantly India (62.30%), Singapore (6.15%), Japan (5.08%), Malaysia (3.75%), and Vietnam (3.17%) [14]. These data underscore the substantial potential of Indonesia’s herbal medicine market on a global scale. Moreover, with the advent of free trade, indonesian herbal medicine products must ensure high quality, proven

efficacy, and safety to enhance their competitiveness and outperform herbal products from other countries.

The demand for traditional medicine products can be met by approximately 900 small-scale and 130 medium-scale traditional medicine industries currently operating. The scale of national production is evident from the number of registered traditional medicine (jamu) products. As of March 2021, the Indonesian National Agency of Drug and Food Control (Badan POM) had registered over 11,000 products, with only 79 categorized as standardized herbal medicines and 26 classified as phytopharmaceuticals [15].

Figure 1 below illustrates the ten largest biopharmaceutical crop productions in Indonesia in 2020, which include ginger, cardamom, aromatic ginger, turmeric, galangal, aloe vera, god's crown (mahkota dewa), noni, Java ginger (temulawak), and lempuyang. These crops are widely used in traditional medicine and as culinary spices. The data highlight ginger and turmeric as the most extensively produced crops in Indonesia, with production of both increasing compared to the previous year.

In 2020, the export value of ginger and turmeric reached significant levels: USD 4.4 million for ginger and USD 9.51 million for turmeric, primarily to India, Japan, Germany, Singapore, and Malaysia. However, Indonesia also imported these two crops, amounting to USD 16.93 million for ginger and USD 2.49 million for turmeric, from Vietnam, Thailand, China, India, Australia, and Malaysia. These figures reveal that although ginger is the most widely produced crop in Indonesia, its import value surpasses its export value [16].

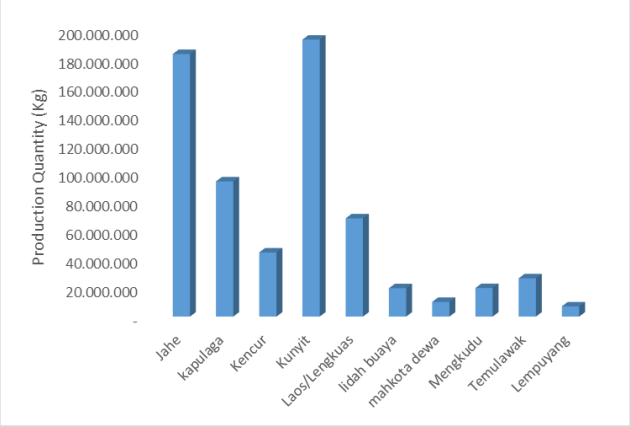

Figure 1. Largest biopharmaceutical crop production in 2020 (BPS 2020)

In this regard, the Indonesian government continues to promote the development and utilization of herbal raw materials to reduce the import of synthetic pharmaceutical ingredients, which currently accounts for 90% [17]. The development of the traditional medicine industry, as an integral part of national economic growth, is a key objective of the Ministry of Health as outlined in the National Traditional Medicine Policy [3]. Furthermore, under the criteria of the National Industrial Development Master Plan (RIPIN), the pharmaceutical industry, including the traditional medicine sector, has been designated as a priority industry within the flagship industries group. The expansion of export-oriented herbal medicine production capacity is expected to increase during the 2015–2024 period [18].

3. Issues

In the development of herbal raw materials and the production of herbal medicines, several issues arise. These include the fact that many traditional medicine raw materials do not yet meet the required standards due to improper post-harvest processing, crop failures, or unfavourable seasonal conditions. Additionally, many medicinal plants remain wild and have not been cultivated. This situation stems from the lack of proper and professional management in the cultivation of medicinal plants, which falls far below the standards of good post-harvest handling practices.

Moreover, the partnership between the government and/or industry and farmers or raw material collectors has not been adequately intensified, resulting in poorly managed harvests. Furthermore, the business climate is not yet conducive, as there is no guarantee of market access or stable pricing for medicinal raw materials. This uncertainty can lead to financial losses for farmers and suboptimal production of high-quality raw materials [2,19].

Another issue relates to raw material extracts, where the design and development of extraction equipment technology remain highly inadequate. This limitation necessitates significant investment costs for purchasing equipment and developing extraction process technologies [2]. According to the Indonesian National Agency of Drug and Food Control (Badan POM), the critical points in ensuring the quality of natural medicinal products lie in several processes, including raw material collection, post-harvest handling, variations in biological materials, unidentified bioactive components, composition complexity, extraction processes, chemical content variability, the presence of chemotypes and chemo-cultivars, the lack of standardized analytical methods or reference standards, and the risk of contamination [20].

These challenges, which remain largely uncontrolled, continue to hinder self-sufficiency in raw materials for herbal medicines.

The exclusion of herbal medicines from the National Health Insurance (JKN) program and the medical system in Indonesia poses a significant obstacle to the development of the traditional medicine industry. Under the JKN program, the public can easily access chemical-based medicines through doctors' prescriptions. However, many Indonesian doctors remain sceptical about the efficacy of herbal medicines in treating diseases. Consequently, the traditional medicine industry must seek alternative market segments to increase product marketing.

Meanwhile, the regulations governing the production and distribution of traditional medicines in certain countries are very stringent, requiring marketed products to meet exceptionally high-quality standards. For example, the European Union's Herbal Directive (EU Directive 2004/24), which came into full effect in 2011, defines Traditional Herbal Medicine Products (THMP) as traditional medicines containing only plants and their derivatives that have been used for at least 30 years, including at least 15 years in Europe. Products that do not meet these criteria must provide clinical trial data on their safety and efficacy. This regulation makes it challenging for traditional medicines from outside Europe to enter the market unless they present substantial scientific data, which requires significant time and investment. Similarly, in the United States, manufacturers must register their products under the Investigational New Drug Application (IND) or the New Drug Application (NDA), both of which have highly rigorous requirements. Meeting these standards requires extensive clinical research, which involves considerable time and financial resources.

In Asia, China adopts a different regulatory approach to protect its traditional medicines. The quality standards for raw materials and products must comply with the Chinese Herbal Pharmacopoeia, providing a distinct framework compared to Western countries [2].

According to the Indonesian National Agency of Drug and Food Control (Badan POM), additional challenges in developing herbal medicines include:
(i) the uneven distribution of external laboratories as third-party facilities across Indonesia, which forces micro, small, and medium enterprises (MSMEs) to exert significant effort to fulfil registration requirements;
(ii) the limitations faced by many traditional medicine businesses (jamu MSMEs) in providing testing laboratories, capital, workforce quantity and competency, product innovation, and marketing; and
(iii) Indonesia's abundant herbal resources with potential medicinal uses, but the lack of empirical evidence for many herbs prevents them from being classified as traditional medicines [20].

Moreover, the natural product isolate industry also plays a crucial role in raw material development. Isolates can serve as raw materials for medicines, supplements, food and beverages, or as biomarkers to ensure the quality of raw materials and products. Currently, Indonesia has only one natural product isolate industry, PT Sinkona Indonesia Lestari, which produces quinine-based products. Consequently, the reliance on imported biomarkers remains high.

Nevertheless, the Indonesian government has introduced several regulations and policies to enhance self-sufficiency in herbal medicine raw materials, including:

a. **Government Regulation No. 14 of 2015** on the National Industrial Development Master Plan (RIPIN) 2015–2035, which designates the pharmaceutical, cosmetics, and medical devices industries as key priority industries.

b. **Presidential Instruction (Inpres) No. 6 of 2016** on Accelerating the Development of the Pharmaceutical and Medical Devices Industries.
Under this Inpres, the president specifically instructed 12 government agencies—including the Coordinating Ministry for Economic Affairs, Coordinating Ministry for Human Development and Culture, Ministry of Health, Ministry of Finance, Ministry of Research, Technology, and Higher Education, Ministry of Industry, Ministry of Trade, Ministry of Agriculture, Ministry of State-Owned Enterprises, Investment Coordinating Board, Food and Drug Authority, and the National Public Procurement Agency—to accelerate self-sufficiency and the development of raw material production, medicines, and medical devices to meet domestic and export demands, as well as to restore and enhance industrial activities/capacity utilization.

c. **Minister of Health Regulation No. 17 of 2017.**
To implement the above Inpres, the Ministry of Health developed an action plan for the development of the pharmaceutical and medical devices industries, outlined in Ministerial Regulation No. 17 of 2017. This action plan includes strategies for developing biotechnology products, vaccines, natural/herbal medicines, and chemical raw materials.

d. **Minister of Health Regulation No. 87 of 2013** on the Roadmap for the Development of Pharmaceutical Raw Materials.
This regulation provides an action plan for the development of the pharmaceutical and medical devices industries, focusing on biotechnology products, vaccines, natural/herbal medicines, and chemical raw materials. These products are identified as having significant development potential in Indonesia, targeting greater self-sufficiency in pharmaceutical raw materials.

e. **Economic Policy Package XI (Point 4)** on the Development of the Pharmaceutical and Medical Devices

Industries.

This policy allows foreign ownership of pharmaceutical raw material industries up to 100%, as stipulated in Presidential Regulation No. 44 of 2016. Previously, foreign ownership was capped at 85% under Presidential Regulation No. 39 of 2014. Through this new policy, the government aims to attract greater investment in the pharmaceutical raw materials industry. Other measures include fiscal policies such as exemptions from import duties, Tax Holidays, and Tax Allowances.

f. **Minister of Industry Regulation No. 16/2020** on the Provisions and Procedures for Calculating the Domestic Component Level (TKDN) in Pharmaceutical Products. This regulation aims to increase the domestic component level in pharmaceutical products, thereby advancing the domestic pharmaceutical industry.

4. Conclusion

The development of self-sufficiency in traditional medicine raw materials in Indonesia still faces several challenges, despite the significant business opportunities and high market demand both nationally and globally. As one of the countries with the richest biodiversity in the world, Indonesia has substantial potential to become a leading producer of herbal medicines capable of meeting the needs of both its domestic and global markets. This goal requires intensive support and synergy from the government and legislative bodies to formulate policies that accelerate the growth of the traditional medicine industry. Furthermore, strong collaboration with business actors, academics, and community organizations is essential to achieving self-sufficiency in traditional medicine raw materials.

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