

Phytopharmaceuticals: A Green Revolution for National Health

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Abstract

Phytopharmacology is a sustainable economic strategy that focuses on the use of natural ingredients in medicinal preparations. These phytopharmaceuticals have been scientifically proven safe and effective through rigorous testing. In the context of a green economy, phytopharmacology aims to improve health while reducing dependence on synthetic drugs that harm the environment. It is distinct from herbal and traditional medicine, offering a significant opportunity for widespread use in health services, particularly in national health insurance programs like BPJS Health. The research method is normative juridical with statutory, conceptual, comparative, and case approaches. The use of phytopharmacology in developed countries is a cheaper and more effective alternative for diseases like hypertension and diabetes. The government has established a Phytopharmacology Formulary as a reference for health services, but Phytopharmacology has not been integrated into the National Formulary of Medicines for the JKN program due to a lack of regulation. The Health Law provides a framework for improving health services, public protection, and regulating health workers. Therefore, incorporating phytopharmacology into the National Formulary of Medicines is crucial for improving access to health services and increasing efficiency and transparency in health financing. The government must provide support, facilities, and clear regulations to oversee phytopharmacology development and use.

Keywords: Phytopharmaceuticals, Drug, Health Law, Economy, Green Revolution

I. Introduction

Green revolution and phytopharmaceutical are two related concepts in the effort to improve public health. The green revolution in phytopharmacology is the concept of using natural medicines that have been scientifically proven for safety and efficacy through preclinical and clinical trials and have been standardized. Both concepts have an important role to play in public health, phytopharmacology offers a cheaper and more effective alternative for several diseases, such as hypertension and diabetes. The appeal of consumer awareness and well-being did not happen overnight. Research shows that since ancient times, nature has been used as a major source of medicine, with humans seeking cures from plants for their ailments. The traditional use of medicinal systems such as Ayurveda in India and traditional Chinese medicine has shown the great potential of phytopharmaceuticals, which provide important chemical and biological substances in medicine. (Dilrukshi Jayawardene et al., 2021) This is evident from the continued use of plant-based medicines in modern medicine, which is highly valued by the general public and healthcare providers from both a moral and commercial perspective. As much as 45% of pharmaceutical products are derived from nature, with almost a quarter of these derived from plants. The development of natural medicines, especially from plants, is on the rise, and their market value is expected to reach \$5 billion by the end of 2020. (Porras et al., 2021)

Despite the scope and application advantages of compounds isolated from plant-based crude extracts, the study is neglected in developing countries, particularly in sub-Saharan African countries, where traditional medicine is still a significant force rather than modern pharmaceuticals. As a consequence, calling upon sectors needs more scientific evidence to appreciate the worth of plant-based crude compounds. So far, due to the lack of scientific evidence, the pharmaceutical sector has used plant-based organic chemicals to make pure material for commercial benefits. The modern pharmaceutical industry, after isolating and characterizing, uses phytochemicals from plant-based crude compounds. However, it is unmanageable and time-consuming to treat different diseases with a single-crude extract using pure material in the modern pharmaceutical industry. Indigenous herbal preparations or crude raw herbals prepared from medicinal plants have traditionally been a valuable source of pharmaceuticals in Ethiopia. They contain a variety of bioactive compounds that can be utilized in various applications such as pharmaceuticals, cosmetics, and for industrial use. In other parts of the world, the application of crude plant-based phytochemicals and medicinal compounds possessing various physiological activities is commonly used, particularly in developing countries. According to WHO, 85% of people in developing countries depend on herbal medicines and traditional methods of treatment. (Alkhamaiseh & Aljofan, 2020) These types of treatments are not widely acceptable due to reasons such as the lack of quality controls, lack of promotion programs, and the presence of other external factors.

The government's efforts to increase self-reliance in the pharmaceutical sector include the development of phytopharmacology. Phytopharmaca development can be a cheaper and more effective alternative for several diseases due to the easily accessible natural medicinal raw materials in Indonesia. Although there is much potential for the development of natural resources and related regulations available, phytopharmaceutical development is still limited in Indonesia. Currently, there are 22 phytopharmaceuticals already produced in Indonesia, according to data from the Ministry of Health. (Kementerian Kesehatan Republik Indonesia, 2022) Phytopharmacology is a type of medicine derived from natural materials, according to Health Law Number 17 of 2023. (Undang-Undang Republik Indonesia Nomor 17 Tahun 2023 Tentang Kesehatan, 2023) Phytopharmaceuticals have been scientifically proven safe and beneficial by conducting preclinical and clinical trials. In addition, the raw materials and finished products have been standardized. Phytopharmaceuticals have been scientifically proven safe and beneficial by conducting preclinical and clinical trials. In addition, the raw materials and finished products have been standardized. Kompas.id reports that 95% of Indonesia's medicinal materials are still imported. Ironically, Indonesia has many natural resources. Phytopharmaceuticals that are already in circulation have proven benefits and can compete with conventional drugs. (Kompas.id, 2024) Health workers and health facilities can refer to the phytopharmaceuticals formulary that has been released by the Ministry of Health in 2022 when using phytopharmaceuticals.

Phytopharmacology may have special advantages to be developed domestically compared to chemical drugs as people's tendency to use nature-based products is increasing. Phytopharmacology may serve as a substitute for modern medicine or even as a substitute for certain chemical drugs. As a result, research on phytopharmacology derived from Indonesian natural ingredients has become very important. (Alkhamaiseh & Aljofan, 2020) Phytopharmacology has enormous potential to be accepted in both domestic and global markets. This can be achieved by expanding the use of

phytopharmacology to various health facilities in Indonesia. This includes combining herbal medicine with conventional medicine. This includes combining herbal medicine with conventional medicine. (Dilrukshi Jayawardene et al., 2021) If the use of natural medicines is included in the national formulary (Fornas) of the National Health Insurance program, the utilization of phytopharmacology will be more widely valued. Increasing the utilization of phytopharmacology in health services will greatly contribute to accelerating efforts towards national self-reliance in self-sufficiency in drugs and medicinal raw materials. The research focused on providing recommendations to the government regarding the provision of support, facilities, and clear regulations for the development and use of phytopharmacology in national health insurance services. Therefore, the inclusion of phytopharmaceuticals drugs in the Fornas or list of drugs that can be included in the e-Catalogue and purchased.

II. Method

This research uses a normative juridical method with statutory, conceptual, comparative, case, and constitutional approaches. The research uses primary and secondary legal materials. Primary legal materials consist of laws and regulations, while secondary legal materials consist of journals, books, and articles. The collection technique uses literature study with qualitative method data analysis.

III. Main Heading of the Analysis or Results

Global Green Economy means an economic system that focuses on the sustainable and economical use of natural resources and integrates environmental and social health principles in business and policy decisions. In this context, the use of natural resources must be done in an efficient and sustainable manner, taking into account their negative impact on the environment and society. The Global Green Economy also involves the use of environmentally friendly technologies, reducing greenhouse gas emissions, and raising public awareness about the importance of better environmental management. Thus, this economic system is expected to achieve sustainable growth, improve people's welfare, and maintain environmental quality. (John & Babu, 2021) The global green economy has been organized in Indonesia. Indonesia launched the Green Economy Index (GEI) on 9 August 2022, as an initiative to measure the effectiveness of economic transformation towards sustainable and environmentally friendly development. Indonesia's GEI consists of 15 indicators covering three pillars, namely economic, social, and environmental, which reflect green economic development. The Indonesian government has also set a green economy plan as one of the main strategies for economic transformation in the medium to long term to accelerate economic recovery after the COVID-19 pandemic and encourage the creation of inclusive and sustainable economic development. (Partnership For Action on Green Economy, 2022)

The global green economy is related to the use of herbal medicine. The use of herbal medicine can be part of efforts to improve health and environmental awareness, as well as promote the sustainable use of natural resources. In the context of the green economy, the use of herbal medicine can be integrated into sustainable and environmentally friendly economic development strategies. For example, the use of herbal medicine can help reduce dependence on synthetic drugs that are harmful to the environment and health, and raise public awareness about the importance of

sustainable use of natural resources. (Gollin et al., 2018)

Phytopharmaceuticals are medicinal preparations of natural ingredients that have been scientifically proven safe and efficacious by preclinical tests (on animals) and clinical tests (on humans), the raw materials and finished products have been standardized. Phytopharmaceuticals meet criteria such as being safe in accordance with established requirements, claims of efficacy scientifically proven through preclinical and clinical trials, standardization of raw materials used in the finished product, meeting applicable quality requirements, and types of use claims in accordance with medium and high levels of evidence. (Prajapati et al., 2023) The difference between phytopharmaceuticals and herbal medicines is the testing and standardization process carried out on these products. Herbal medicines, including jamu, usually do not go through clinical trials and are only based on empirical and hereditary use. Meanwhile, phytopharmaceuticals have undergone clinical trials and have higher production standards, and their safety and efficacy have been scientifically proven through preclinical and clinical trials. (Kementerian Kesehatan Republik Indonesia, 2022)

The discussion of phytopharmacology or herbal medicine in Law No. 17 of 2023 concerning Indonesian Health refers to the definition of phytopharmacology as a natural medicine used for health maintenance, health improvement, disease prevention, treatment, and health recovery. Phytopharmacology has been scientifically proven for safety and efficacy by preclinical and clinical trials as well as raw materials and testing processes that are different from other herbal medicines. Law No. 17 of 2023 on Health also stipulates that phytopharmaceuticals must meet safety and efficacy criteria that have been scientifically proven by preclinical and clinical trials, and standardization of the raw materials used in the finished product. Phytopharmaceuticals must also meet applicable quality requirements and fulfill organoleptic requirements, moisture content, microbial contamination, and others. In Law No. 17 of 2023 concerning Health, phytopharmaca is also regulated as a type of natural medicine that can be used for the treatment and restoration of health. Phytopharmaceuticals must be provided with clear labeling and complete information and must meet applicable safety and quality requirements. In the context of the development of herbal medicine and phytopharmaca in Indonesia, Law No. 17 of 2023 on Health also stipulates that the government must provide support and facilities for the development of herbal medicine and phytopharmaca, as well as set clear and effective regulations to oversee the development and use of herbal medicine and phytopharmaca. (Undang- Undang Republik Indonesia Nomor 17 Tahun 2023 Tentang Kesehatan, 2023) In synthesis, Law No. 17 of 2023 on Indonesian Health regulates phytopharmacology as a natural medicine that has been scientifically proven for safety and efficacy by preclinical tests and clinical trials and fulfills applicable quality requirements. Phytopharmaceuticals must undergo preclinical and clinical trials to scientifically confirm their safety and efficacy. In addition, phytopharmaceutical raw materials must be standardized to ensure product quality and consistency. Phytopharmaceuticals must be provided with clear labeling and complete information and must meet applicable safety and quality requirements. The government is also required to provide support and facilities for the development of herbal medicines and phytopharmaceuticals, as well as set clear and effective regulations to oversee the development and use of herbal medicines and phytopharmaceuticals. (Roihatul Mutiah, 2021)

In synthesis, the development of phytopharmacology in developed countries has been more advanced and more widespread than in Indonesia. Indonesia still has challenges in phytopharmaca development, including regulatory, cultural, and other aspects, and needs to increase the use of local raw materials and develop better extraction processes. The use of phytopharmacology in developed countries in national health insurance services has become a cheaper and more effective alternative for several diseases, such as hypertension and diabetes. (Hermawan Saputra et al., 2022) This is supported by guidelines issued by the Ministry of Health since 1992, but until 2022, not a single phytopharmaca has been included in BPJS Kesehatan. (Kementerian Kesehatan Republik Indonesia, 2022) Thus, the use of phytopharmacology as an alternative to traditional medicine is still in the development stage and needs more research and supervision to ensure its safety and effectiveness in the national health insurance system. (Jamshed et al., 2024) The development of phytopharmacology in Indonesia has been a major focus of the government to address drug imports. Natural raw materials for medicines are widely available in Indonesia, so phytopharmaca development can be a cheaper and more effective alternative for some diseases. The process of phytopharmaca development is not simple and requires analysis, research, and synergistic cooperation between researchers, industry, and universities. Some phytopharmaceuticals that have been produced in Indonesia include immunomodulators, gastric ulcer drugs, antidiabetics, antihypertensives, drugs to improve blood circulation, and drugs to increase albumin levels.

Phytopharmaceutical drugs have not been included in the JKN National Formulary, so many doctors have not been able to prescribe them for JKN patients. The Indonesian National Formulary contains a list of drugs that are needed and used as a reference for writing prescriptions in the implementation of health in hospital settings. Thus, phytopharmaceutical drugs are not included in the JKN National Formulary for several reasons related to cost, market, knowledge, technology, quality, safety, effectiveness, production costs, distribution costs, and marketing costs. (Ariana, 2019) The Phytopharmaca Formulary is used as a reference for the use of phytopharmaca in the implementation of health services. In addition to being a reference for use, it is also used as a reference for healthcare facilities to provide selected phytopharmaceuticals. (Dewi Zebua et al., 2023) By fulfilling these criteria, phytopharmaca can be categorized as a natural medicine that has been scientifically proven safe and efficacious by preclinical and clinical trials and meets higher production standards.

The opportunities for collaboration between healthcare institutions and the pharmaceutical industry in phytopharmaceutical development are immense. This collaboration can enhance phytopharmaceutical development capabilities by integrating knowledge and technology from both parties. Health institutions can provide information on public health needs and research results, while the pharmaceutical industry can provide technological capabilities and resources to develop safe and effective phytopharmaceutical products. (Singh et al., 2019) Thus, this collaboration can improve the quality and quantity of phytopharmaceutical products developed in Indonesia, as well as increase the nation's independence in the fulfillment of pharmaceutical products.

Drugs can be included in the National Formulary of Drugs through a process of

development, testing, standardization of raw materials, quality testing, submission of distribution permits, document assessment, granting of distribution permits, and use. The government updates the National Formulary of Medicines through the process of submitting changes, determining changes, developing, testing, applying for distribution permits, assessing documents, granting distribution permits, and using them. The National Formulary is updated annually. Thus, factors considered in updating the National Formulary of Medicines include effectiveness, drug availability, drug use policies, disease patterns, other hospital policies, drug quality, treatment costs, availability of facilities, drug product strength, adverse drug reactions, and others. (Mtewa et al., 2020)

In the regulation of the Minister of Health number 21 of 2016, in the event that the drugs and consumable medical materials needed are not listed in the national formulary as referred to in paragraph (5), other drugs including traditional medicines, standardized herbal medicines and phytopharmaceutical may be used on a limited basis, with the approval of the Head of the Regency / City Health Office. Phytopharmacia can be accessed in the Ministry of Health's (MOH) sectoral e-catalog through the Phytopharmacia and Standardised Herbal Medicines (OHT) storefront. In the sectoral e-catalog, the MOH facilitates the use of phytopharmaceuticals and OHT by allowing procuring work units to directly access the storefront. Phytopharmaceuticals have been included in the MOH sectoral e-catalog. In the sectoral e-catalog, the MOH facilitates the phytopharmacology and OHT storefront, allowing procuring work units to directly access the storefront. Phytopharmacia drugs cannot be provided to JKN patients because they have not been included in the National Formulary of Drugs for the National Health Insurance (JKN) program. (Yusriadi & Tinggi, n.d.) This is due to the absence of regulations that stipulate phytopharmacology as equivalent to chemically synthesized drugs, so private health insurers are unable to accept prescription claims for phytopharmacology in hospitals, clinics, and pharmacies.

The use of herbal medicine in the National Health Insurance (JKN) can be integrated in several ways, including: development of phytopharmaceuticals or clinically tested herbal medicines to improve the quality and safety of herbal medicines, which helps to reduce dependence on synthetic drugs as well as increase public awareness about the importance of sustainable use of natural resources; use of herbal medicines in the JKN programme to improve the quality of health services and reduce the cost of treatment, which can improve overall access to health care; development of a herbal medicine scientification programme to improve the quality and safety of herbal medicine, which also supports the sustainable use of natural resources; development of environmentally friendly infrastructure and technology to raise awareness about the importance of sustainable use of natural resources; development of sustainable industries; use of herbal medicines in national programmes to improve the quality of healthcare and reduce the cost of treatment; and development of policy programmes to raise awareness about the importance of sustainable use of natural resources and reduce dependence on synthetic drugs.

The idea for phytopharmacia drugs to be included in the National Health Insurance (JKN) is to include phytopharmacia in the National Formulary of Medicines. The government has created a Phytopharmacia Formulary, but phytopharmacia has not been integrated into the National Formulary of Medicines for the JKN program. As such,

doctors cannot prescribe phytopharmaceuticals for JKN patients as they are not covered by the JKN program. Law No. 17 of 2023 provides a clear framework for improving the quality of health services, and protection for the public, and regulates the authority and responsibilities of health workers. In this context, the idea of including phytopharmacology in JKN can be integrated with the objectives of improving access to health services and increasing the efficiency and transparency of health financing stipulated in Law No. 17 of 2023. Phytopharmacology is not classified as jamu and traditional medicine. With this status, phytopharmacology has a great opportunity to be used massively in health services, especially health services funded by BPJS Health.

IV. Conclusion

The development of phytopharmacology in Indonesia is a strategic step that can support the green economy, reduce dependence on synthetic drugs that damage the environment, and improve the quality of health services to realise the principles of the global green economy. Effective regulation, infrastructure support, collaboration between health institutions and the pharmaceutical industry will accelerate the development of phytopharmacology in Indonesia thereby improving access to quality healthcare and supporting the transformation to an inclusive and sustainable green economy. The development and use of phytopharmacology, which has been proven safe and effective through clinical and preclinical trials, and meets quality standards, should be supported through policies that accommodate phytopharmacology in the National Formulary of Medicines and health sector e-Catalogue.

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