Understanding the Benefits and Risks of Herbal Medicine

THERE ARE NO HERBAL GENERIC DRUGS. CONSUMERS NEED TO KNOW THE BENEFITS AND RISKS OF USING HERBAL MEDICINES BY UNDERSTANDING THE INGREDIENTS OR THE COMPOSITION OF THE EXTRACTS USED, AS WELL AS THE STAGES OF THE PRODUCTION PROCESS.

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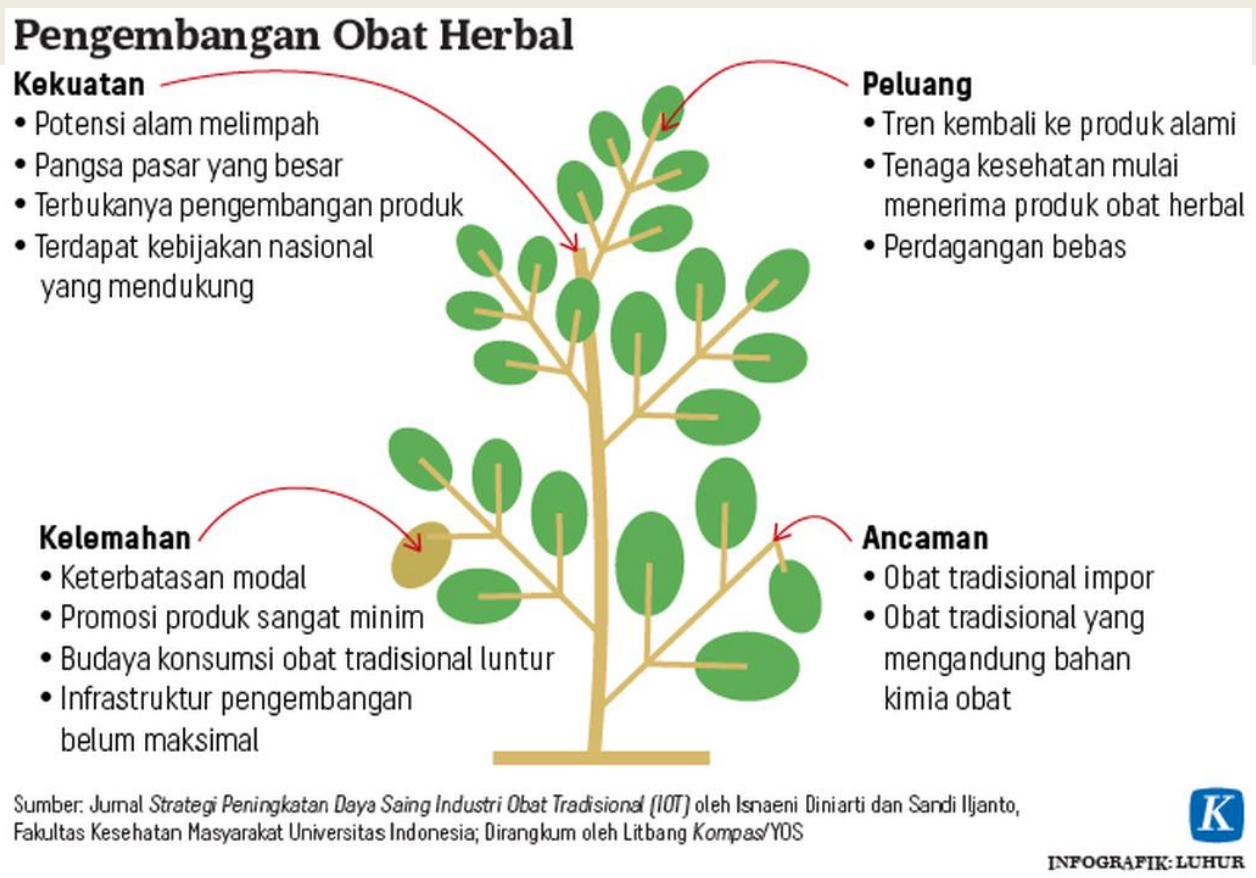

By: Michael Heinrich
The global use of herbal medicines has increased rapidly in recent years. Many consider this natural remedy a safer option than chemical treatments due to its organic composition. However, it is very important for consumers to be careful in making decisions regarding the selection and use of herbal medicines.

Herbal products are basically composed of complex combinations of natural ingredients that exhibit multifaceted effects. Each herbal medicinal product on the market in Indonesia and other countries will differ depending on the agricultural medicinal plant cultivation, harvest handling and processing, as well as the drug manufacturing process from formulation to product storage. **So, are there herbal generics? No.**

The exact composition of these products can vary widely, influenced by factors such as the sourcing and quality control of raw materials, preparation methods, and careful analysis of the consistency of the final product. Given the many brands available in the market, it is very important for consumers to be smart in choosing and using herbal products, especially preventing switching from one herbal product to another without documented proof of equivalence or equivalence tests.

This applies to products that appear to contain “the same substance”. Likewise the consistency of different batches, i.e. a quality control system that judges that each batch is of comparable composition, is an important requirement. Giving herbal medicines that are not tested has the potential to cause risks and adverse effects on the body.

Indonesia, which is recognized as one of the leading producers and exporters of herbal medicines, is ranked 19th in the world's herbal medicine exporting countries with a market share of 0.61 percent from 2019 to 2019. Biodiversity< /a> Indonesia's abundance, with its astonishing range of 19,871 medicinal plants used as traditional ingredients, means that Indonesia can lead the world in introducing new medicines. Among them, 16,218 plants have been identified, 9,600 plants are known to have medicinal properties, and 200 species as raw materials for the traditional medicine industry.

The considerable interest in herbal medicines among Indonesian consumers can be linked to a cultural tradition deeply rooted in the making of jamu (traditional herbal medicine) passed down from generation to generation. The affordability and availability of raw materials further contribute to the widespread popularity of jamu. Indonesian society places great trust in the knowledge passed down from their ancestors, thus reinforcing their preference for alternative treatments over chemical/synthetic drugs.

To improve the safety of herbal medicine consumption, the Food and Drug Supervisory Agency (BPOM) has implemented a policy which includes the Basic Provisions for Grouping and Labeling of Indonesian natural medicines. Currently, Indonesia has around 12,000 types of traditional herbal medicines, 86 standardized herbal medicines (OHT), and 24 phytopharmaceuticals. Although they have different effects and properties, these three categories are often regarded as traditional medicines with the same effect according to the community.

The uniqueness of herbal medicines

Herbal drug preparations are usually complex mixtures with many potential active metabolites or known compounds so that "bioequivalence" (two products with identical active ingredients) is not possible. Making efficacious herbal medicines requires strong chemical, manufacturing and control (CMC) systems to be documented and carefully followed. As a result, equivalence can be assigned to products or batches because they are sourced equally and manufactured following the strict CMC production system.

For synthetic medicines, the government conducts supervision to ensure that the CMC system can be established and followed by all parties to achieve quality, safety, and product security standards. Although the CMC already exists, it is undeniable that documentation of equivalence in the efficacy and safety of drug use in humans is still needed to support claims.

The active ingredients and manufacturing process of herbal medicine products are very complex, and require strict steps to achieve good quality and consistent composition to have therapeutic properties. Therefore, it is important for herbal medicine manufacturers to be transparent in disclosing complete documentation regarding the composition of the medicine and its manufacturing process. In addition, education about this matter should be expanded to various stakeholders, including drug distributors, doctors, pharmacists, and patients.

AUGUKEYWORD

UNDERSTANDING THE BENEFITS AND RISKS OF HERBAL MEDICINE

Creating efficacious herbal medicines requires strong chemical, manufacturing, and control (CMC) systems to be documented and carefully followed.

Standardization, such as defining detailed profiles of active metabolites or at least strong profiles of relevant marker compounds, presents an opportunity to ensure the success of complex herbal drug development. Hence, a strong CMC system is very important in the manufacturing process to monitor and control various variables that can affect the final product.

The validity of the properties of herbal medicine products is influenced by every variation of the variables of ingredients and production methods. Even the final product of herbal medicine may lose its properties if there are changes in the source of the product or extraction temperature.

The well-defined CMC system establishes standard methods for the manufacture and quality control of herbal medicines, ensuring consistent composition, safety, and efficacy. This includes the identification and quantification of active ingredients and marker compounds, evaluation of impurities and contaminants, as well as establishment of appropriate production processes and analytical controls.

In addition, the results of the final product and the way it is used clinically need to be carefully controlled because herbal medicines have complex biological mechanisms in humans. Product benchmarks, which can be called "specific evidence" natural health products, need to be controlled from the source to the benefits.

UNDERSTANDING THE BENEFITS AND RISKS OF HERBAL MEDICINE

KEYWORD

Challenge

From a manufacturing perspective, the approval of herbal medicines is sometimes based solely on the composition of raw materials and ensuring there are no manufacturing contaminants, such as heavy metals or microorganisms.

Therefore, the chemical profiling or standardization and the methodology followed during production plays a crucial role because the composition of the final product of herbal medicines is highly dependent on the raw materials and all steps of their manufacture. The overall chemical composition of the final product is also determined by several factors, such as the environment in which the plant is grown, the time of day it is harvested, and the method used in the detailed industrial process.

In addition, herbal supplement products are complex mixtures of substances with multifactorial effects. Therefore, herbal medicine manufacturers must use a "fingerprinting" approach in their production process.

Also read: Utilizing Medicinal Plants

Fingerprinting is an analytical technique used to produce characteristic profiles of herbal medicinal products based on their chemical composition to ensure the consistency of the herbal medicines produced. This method has also been endorsed by the World Health Organization (WHO) since 1961, which recognizes that medicinal plants contain hundreds of metabolites (compounds), some of which are present in very small amounts.

Thus, identifying the marker compounds of medicinal plants and the products derived from these ingredients is very important for tracking the production process. The content in the processed material must remain consistent to support claims that the documented properties are valid from one batch to the next batch.

Various techniques, such as high-performance liquid chromatography (HPLC), high-performance thin layer chromatography (HPTLC), gas chromatography (GC), mass spectrometry (MS), and nuclear magnetic resonance (NMR), are used in the fingerprinting approach. This method provides complete data on metabolites in herbal medicines, including composition, marker compounds, calculation of active ingredients in supplements, and detection of impurities or contaminants. The fingerprint ensures that other herbal products cannot claim bioequivalence data for existing or circulating products.

The problem arises when patients switch from one product to another without consulting their medical specialists.

For chemical drugs in Indonesia, bioequivalence is used to determine compounds in generic drugs or drugs bearing the OGB logo. This drug is often prescribed by doctors in government-owned facilities, such as health centers, hospitals or pharmacies, because of its affordable price. This practice is regulated in the minister of health regulations to set standards for inexpensive drugs with verified bioequivalence data.

When a drug has bioequivalence data that meets standards, patients can avoid variations in quality that deviate from standard drugs that have been previously patented. This is especially important for patients who are actively taking medication for certain ailments, such as a brain injury or stroke.

Similar to chemical drugs, herbal medicines derived from different processes must in theory first demonstrate bioequivalence, which refers to the biochemical similarity between two drugs that appear to have “the same active ingredient”. However, due to their complexity, herbal medicine products usually have differences in fingerprint which result in differences in the nature of the product.

AUGUKEYWORD

UNDERSTANDING THE BENEFITS AND RISKS OF HERBAL MEDICINE

Researchers from the Indonesian Institute of Sciences (LIPI) present the results of research on the development of Indonesian traditional medicines at the Natural Materials Chemistry Laboratory, Science and Technology Research Center, Serpong, South Tangerang, Banten, Tuesday (30/4/2019).

Issues arise when patients switch from one product to another without consulting their medical specialists. The change in products can result in new drug interactions, changes in safety, or loss of efficacy. The same applies when deciding to combine chemical drugs and herbal medicines.

Furthermore, seeking alternative treatment options based on lower costs should be avoided because cheaper herbal medicines often lack documented bioequivalence and patent data. This can pose a higher risk of adverse interactions when combined with chemical drugs. Searching for products based on the lowest price also exposes consumers and healthcare professionals to additional risks.

The pressure on cheap herbal medicine prices has led to the production of counterfeit products or intentionally ignoring the correct production process, where the ingredients used are not actually the expected medicinal plants, but cheaper and chemically different species. It is very concerning that the risk of counterfeit products is intentionally created to appear as a correctly produced brand. These counterfeit products are likely to be ineffective and potentially dangerous.

One way to address this challenge is with independent, evidence-based certification.

Herbal medicine products are defined as natural health products. Therefore, the final product can vary greatly depending on the complex production process, especially for natural health products that have thousands of different sources. This means that the evidence documentation supporting natural health products can only be in the form of specific products and brands.

Also read: Society Adapts through Traditional Medicine

Empowered by Evidence, an international non-profit foundation, is a specialist organization in natural health, researchers, doctors, and companies who have invested in scientific research for their products. One of these companies is the leading Indonesian company, PT Soho Global Health.

Empowered by Evidence has developed an independent, robust and transparent accreditation standard for assessing specific evidence products. Products that pass this accreditation have established consistency in manufacturing as well as scientific and clinical evidence. Thus, Empowered by Evidence and its many expert members around the world affirm that there is no simple herbal generic drug.

Conclusion

By promoting understanding of production processes, quality control, and the use of herbal medicines, consumers can make smart and informed decisions. Health professionals should also have a comprehensive knowledge of the safety, quality, and efficacy of herbal medicines to ensure the well-being and health of their patients. Certification of the composition and clinical and pharmacological evidence of products held by manufacturers is one important step towards achieving this.

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