SAFETY AND REGULATORY ISSUES OF TRADITIONAL MEDICINE ON GLOBAL MARKET

SUBHA RANJAN GANGULI (M.Sc), Research Scholar, Dept of **Chemistry,** CMJ University, Jorabat.
DR HARSH SHARMA, Research Supervisor, Deptt. of **Chemistry,** CMJ University, Jorabat.

ABSTRACT

Traditional remedies are commonly utilised in underdeveloped nations, and their popularity is quickly spreading over the world. There is a lengthy history of traditional medical practises that have been passed down from one generation to the next. Traditional medicine's quantity and quality, safety and efficacy, has become a global issue, highlighting the need for harmonised international standards. Herbal treatments are a $83 billion industry worldwide and are expected to develop between 10 and 20 percent every year with the major global participants being Germany, Asia, Japan and Europe. Due to the widespread belief among customers those natural goods are less likely to induce side effects, traditional remedies have a lower adverse effect rate. Use poisonous herbs, overdose, drug–herb combinations and individual sensitivities are the most prevalent causes of herbal product-related adverse effects. A growing number of people are using herbal remedies without consulting a medical professional, which has raised concerns about their safety. Traditional goods are plagued by a variety of quality difficulties, including incorrect processing, adulteration, misidentification, the absence of one or more herbs in a product, replacement, the addition of prescription medicines, contamination, and variations in active ingredient. Researchers must do scientific research to determine if a drug is safe, effective, and appropriate for use. Traditional and complementary treatments' safety, quality, and efficacy are regulated differently in different nations, and many countries do not have a formal system for registering traditional and complementary therapies. Use of chromatographic fingerprinting and appropriate manufacturing practises in the harvesting and processing of traditional medicines can substantially improve the quality control of these medicines. Clinical trials and preclinical safety-efficacy testing of traditional or complementary medicine necessitate rigorous research. The availability of finances for research is a serious concern. We must ensure the credibility of traditional and complementary therapies by promoting spontaneous reporting, creating active pharmacovigilance and clinical safety monitoring systems.

Keywords: Traditional medicines, Safety, Global Market, Quality

1. INTRODUCTION

Traditional medicine is becoming increasingly popular across the world, not only in impoverished nations. Convention on International Trade in Endangered Species (CITES) defines traditional medicine as "the sum total of the knowledge, skills and practises based on ideas, beliefs, and experiences unique to various cultures, whether explicable or not." There is a wide range of supplementary or alternative medical techniques that originate in a country's unique culture and are generally not part of the dominant health care system. Traditional medicine, on the other hand, has a lengthy history of practise based on the transmission of knowledge from generation to generation. WHO Director-General Dr. Margret Chan noted that "for many millions of people, herbal medicines, traditional treatments and traditional practitioners are the main and sometimes the only source of health care." At the International Conference on Traditional Medicine for South-East Asian Countries in February 2013. This is care that is near to home, easily accessible, and reasonably priced. ' It's also widely accepted and trusted across cultures. Various nations and locations have different traditional medical practises that are affected by their history, culture, custom, geography, and personal beliefs and values. There has been no establishment of worldwide standards or adequate procedures for evaluating the quality of traditional medicines throughout the course of centuries. There must be appropriate evidence of its safety and efficacy in light of the current tightly controlled pharmaceutical age. Concerns about safety, effectiveness, and quality have arisen as a result of the widespread use of traditional medicine. Access to quality health care for the whole population will be made possible by traditional medicine's demonstrated

quality, safety, and effectiveness. Traditional and complementary medicine must be made available to the public in a way that is both reliable and affordable, and many nations have realised this. Traditional medicine's safety and effectiveness evidence are woefully inadequate to fulfil the requirements required to sustain its widespread usage over the world. International standards for harmonising traditional medicine are being urged by all of these areas of traditional medical practise across the world.

2. GLOBAL MARKET FOR TRADITIONAL REMEDIES

A variety of natural or homoeopathic medicines are employed in complementary and alternative medicine. Plant-based therapeutically active substances are found in the raw materials, preparations, and final products of herbs. Acupuncture, massage, heat, yoga, and meditation are just a few of the treatment options available. The World Health Organization (WHO) estimates that almost 80 percent of African and Asian populations use traditional medicine as part of their basic health care. Cheap and middle-income nations are better able to obtain and adopt traditional medical treatments because of the low cost and ease of availability. Traditional medicine is most commonly used in industrialised nations as a means of disease prevention, wellness maintenance, or as an adjunct to conventional treatment for chronic illnesses. Herbal treatments have a global market value of $83 billion and are expanding at a rate of 10 to 20 percent annually. Herbal pharmaceuticals generate $44 billion in revenue, while cosmetic items bring in an additional $14 billion annually. Germany (28 percent), Asia (19 percent), Japan (17 percent), France (13 percent), the rest of Europe (12 percent), and North America (12 percent) are the leading worldwide participants in the herbal medicine industry (11 percent). An estimated $9 billion in sales are predicted in the Asian market in the near future. Ayurvedic medicine producers hold 30% of the Indian health care market, with other traditional items accounting for the remaining 10%. The Chinese market for herbal and botanical goods is estimated to be at $3.5 billion, and the country has a long history in the field. Around $2.5 billion was reported to be the size of the herbal market in Japan at the time. Herb and botanical sales in the United States were $4.8 billion in 2008, growing at a roughly 4% annual pace. More than half of the herbal raw materials sold in the United States since 1999 have been sourced from China and India. The herbal supplement and herbal medicine business in Europe is valued $7.4 billion at the moment. Germany has a 27 percent share of the European market, followed by France (24 percent), Italy (12%), and the United Kingdom (6%). (9 percent). The UK herbal product sector has been hindered by an uncertain regulatory environment and ongoing legal action linked to the EU Food Supplement Directive. Weight reduction and sports nutrition are two of the fastest-growing categories of herbal medications. As well as vitamin supplements, dietary supplements include items such as guar gum and fibres; fish oil; borage oil; lutein; evening primrose oil; lecithin; aloe vera extract; and chitosan.

3. SAFETY ISSUES OF TRADITIONAL MEDICINE

Functional foods and cosmeceuticals have emerged in the herbal medication industry in the last decade, drastically altering the landscape. Natural and functional foods, such as botanical alternatives to fish-derived omega-3 fatty acids, artificial colouring compounds, and novel kinds of fibre and beauty foods, are currently popular with worldwide consumers. Long product research and development times and medication registration procedures limit the growth and development of the herbal botanical drug business. It is well accepted that traditional treatments have a lower risk of adverse effects than conventional therapies, which may lead some people to select a traditional therapy instead of a conventional therapy in order to prevent side effects. There are risks to using herbal medications, even if the general public may believe that they are safer than conventional drugs because of their perceived naturalness [6]. Using intrinsically poisonous plants, overdosing, drug–herb interactions, and idiopathic responses including allergies are all possible causes of unpleasant reactions to herbal remedies. An further barrier to the public's knowledge of herbal medication toxicity is the lack of a countrywide adverse drug reaction surveillance (pharmacovigilance) system. Over-the-counter use of herbal remedies by consumers, sometimes without knowledge or

guidance from a practitioner, is a major cause of unpleasant effects. Herbal medicine users and practitioners are under-informed about possible side effects, medication interactions, and proper dosage instructions. This is a problem. Adverse drug-herb interaction effects can be avoided by greater patient-provider communication and consumer education.Herbal treatments are less likely to have negative side effects, yet controlled, randomised clinical trials have shown that they can. Many chronic illness patients rely on herbal medicines for a lengthy period of time, and incorrect use might lead to catastrophic consequences. Aristolochic acid from the plant Aristolochia has been linked to renal failure, and Ma huang (Ephedra sinica), which includes ephedrine, has been linked to severe respiratory symptoms and mortality from the long-term use of kava kava (Piper methysticum). Instead of unrestrained abuse, herbal medication should be used with proper dose and treatment course and for adapted syndrome. Overdosage and a lengthy course of therapy both increase the risk of adverse effects. Because herbal preparations are not subject to stringent labelling regulations, many product containers for herbal preparations provide customers with inadequate or confusing information regarding consumption or potential ill effects.

4. QUALITY ISSUES OF TRADITIONAL MEDICINE

A major portion of the world's herbal drug production and manufacture is unregulated, resulting in a lack of quality control. Improper processing, adulteration, misidentification of ingredients, omission of one or more herbs from a poly herbal product, substitution of one herb with another, inclusion of prescription drugs, contamination, and variability in the amount of active ingredient are the primary causes of herbal quality issues. Misidentification, unintentional contamination, or purposeful adulteration can all lead to polluted wild medicinal plants. Quality, safety, and efficacy can all be compromised if chemicals or microorganisms are introduced accidentally during the manufacturing process. High levels of mycotoxins, heavy metals, pesticides, and other microbes are of particular concern to industrialised countries. Unlabeled prescription drugs and substances that might cause blood pressure to increase or cancer have been found in certain natural weight loss products that have been recalled from the USA. Aspirin came from a white willow tree, while paclitaxel was identified in a tree native to the Pacific Northwest called the Pacific yew. Even while many of the pure pharmaceutical medications used today were initially derived from plants, they are no longer extracted from plants but rather synthesised. Pure phytocompound isolation and purification is a difficult and time-consuming task, as well as an expensive one. Until now, the traditional herbal business has relied on a wide variety of different herbs to treat a single disease. For the scientific community, developing a product-specific monograph for the separation, isolation, and identification of poly herbal products is a significant problem. Prescription drugs may be analysed using ordinary analytical procedures, but replacement or omission of a particular herb and bioactive constituent variation can only be determined by a well-specified monograph.

5. IMPLEMENTING REGULATION ON TRADITIONAL AND COMPLEMENTARY MEDICINE

Legislation and control of traditional medicine are becoming increasingly necessary as the popularity of the practise grows. As a country's improvement in technology progresses so does the variety of herbal treatments available. It is necessary for herbal products to be tested for safety and efficacy, as well as for their dose form and stated indications, before they can be considered medicines. Traditional and complementary therapies' safety, quality, and efficacy are regulated by different laws and policies in different countries. In most poor countries, traditional and complementary medicine is not formally regulated or has a limited regulatory framework, and there is no product registration system similar to that of conventional pharmaceuticals. Traditional medicines can be marketed without providing proof of their quality, effectiveness, and safety, according to a regulatory regulation that is reluctant to enforce it. Ineffective and hazardous items are being sold since there are no controls on quality standards and evaluations for safety and efficacy. For example, the Chinese and Indian governments are promoting traditional medicine as a way to improve

primary health care in rural areas, while Africa is looking to incorporate local traditional resources into basic health care packages, while Europe is requiring licencing and establishing quality control standards. Herbal products are not required to undergo safety or effectiveness testing in the United States since they are classified as foods rather than medicines. An worldwide framework for the evaluation and regulation of traditional medicine goods can reconcile the varied approaches to recognising and classifying these items in countries that lack an established system. A succession of WHO Traditional Medicine Strategies, from 2002–2005 through 2014–2023, have been designed to address these difficulties. An overall plan for establishing government policy, assuring safety, effectiveness, and quality, expanding access to care, and encouraging the use of traditional and complementary medicine is outlined for the years 2002-2005. A primary objective of the current 2014-2023 strategy is to assist Member States in harnessing the potential contribution of traditional and complementary medicines to health, wellness, and patient-centered care while also promoting the safe and effective use of those products, practises, and practitioners through regulatory measures. Three strategic objectives will be used to achieve these goals: To achieve universal health coverage, it is necessary to integrate traditional and complementary medical services, as well as self-health care, into national health systems, while also expanding the knowledge base and developing national regulations to ensure public safety, high quality, and efficacy. For traditional herbal medicines, the Traditional Herbal Medicinal Products Directive (THMPD) is facilitating entry to the market via a streamlined registration system that does not need additional safety and effectiveness studies. In Europe, molecular complexity of plant chemicals is not seen as a problem; rather, it is treated as a single substance. Because of Europe's "doctrine of reasonable certainty" and lengthy history of usage, the time and money needed to approve the safety and efficacy of herbal medicines are lower than the United States. Herbal medicines must meet strict quality, quantity, manufacturing, and labelling rules set by the European Economic Community (EEC). Dry and powdered whole herbs are the most common type of herbal remedies in Japan, China, and India. New applications of traditional herbal medicines were excluded from testing for effectiveness or adverse effects under the 1984 Drug Administration Law in the People's Republic of China. Kampo, a kind of traditional Japanese medicine, is comparable to traditional Chinese medicine. The Kampo medication business in Japan created laws for production and quality control in 1988. There are herb monographs in the Indian Pharmacopoeia (2010), which aims to set quality standards for usage in foods, drugs, nutraceuticals, and cosmetics, among other things. IP treated each plant as containing a single active ingredient, regardless of whether or not information regarding the herb's active ingredients is currently accessible.

6. RESEARCH PROMOTION FOR PROVEN SAFETY AND EFFICACY OF TRADITIONAL MEDICINE

Consumers are attracted to traditional and complementary medicineas it is assumed to be effective and Due to a lack of scientific proof, it cannot be declared with certainty that this product is completely risk-free. A large number of traditional medicine preclinical and clinical research are published in the scientific literature, however the long-term clinical usage of traditional medicine does not typically fulfil international requirements for the clinical trials of new pharmaceuticals. Herbal medicine's effectiveness is likewise dependent on the presence of medicinally helpful or active ingredients, just as it is with conventional medications. To ensure quality, it is critical to identify a plant using its approved scientific name(s), as a single common name may refer to several plant species, which might have potentially harmful repercussions. The quality of herbal medications will unquestionably be influenced by the use of proper manufacturing practises in planting, harvesting, and processing. Polyherbal formulations are often made up of a large number of herbal ingredients outlined in a recipe. The quality, safety, and efficacy of a herbal medicine may thus not be reflected by testing for the content of a single component. The most practical approaches for defining chemical profiles are chromatographic fingerprinting technologies

like high-performance thin layer chromatography and high-performance liquid chromatography. There should be facilities in the traditional medicine product quality testing system for the detection of any mislabelling, misidentification, variation across batches, and the presence of undeclared components. Traditional and complementary medicine must undergo rigorous research that goes beyond preclinical effectiveness studies, toxicological investigations, clinical trials, and post-marketing monitoring studies. Increased study of traditional medicine need precise scientific proof of both benefits and risks. Traditional medicine research receives far less financing than other branches of medicine. Funding for health care is generally allocated based on the available evidence. In order to recruit top-tier scientists with competence in this currently undeveloped field, research into traditional medicine has to be widely recognised. Adequate funding for research is required to keep this process moving.

7. CONCLUSION

There should be a well-defined regulatory framework for traditional and complementary medicines in every country, including a coordinating agency and a national advisory council, as well as an effective system of pharmaceutical surveillance. Pharmaceutical regulatory systems in place in nations should be modified to include herbal medicines, and regulatory standards in countries that lack them should be established to include pharmaceuticals as well as traditional and complementary treatments. Many pharmacologically active plants are required for herbal medical product registration. More than half of the world's herbal and traditional medicine industry remains untapped. Still to be found are brand-new phytochemicals and uses for already-identified phytochemicals in plants. It is envisaged that phytochemicals that have shown effectiveness and their claim validation would have the greatest impact on future herbal and botanical product development. In order to do this, new products will need to be tested for safety and efficacy, and then they will need to be marketed. The creation of an evidence-based approval system that includes safety and effectiveness assessments will be critical to the credibility of both traditional and alternative medicine. Filling up the gaps in existing research and encouraging future studies will help achieve this goal. A great way to find therapeutically relevant safety problems is to promote spontaneous reporting and adopt active pharmacovigilance. A clinical safety monitoring system and a herbal pharmacovigilance system are both essential to ensuring the safe use of traditional medicines in the community.

REFERENCES

1. Sankaramourthy, Divya & Kavimani, S. & Sudha Rani, Sadras. (2021). Safety and Regulatory Issues on Traditional Medicine Entrusted Drug Discovery. 10.1007/978-981-15-8127-4_28.
2. Mukherjee, Pulok & Harwansh, Ranjit & Bahadur, Shiv & Banerjee, Subhadip & Kar, Amit. (2016). Evidence Based Validation of Indian Traditional Medicine – Way Forward. World Journal of Traditional Chinese Medicine. 2. 48-61. 10.15806/j.issn.2311-8571.2015.0018.
3. Bigoniya, Papiya. (2016). Popularization of traditional and complementary medicine: Urging voluminous effort driving towards scientific evaluation of safety and efficacy. International Journal of Traditional and Complementary Medicine. 1. 14-19.
4. Bhatt, H.A. & Gogtay, Nithya & Dalvi, Shreya & Kshirsagar, N.A.. (2004). Safety issues in Indian traditional medicine. International Journal of Risk and Safety in Medicine. 16. 73-82.
5. Wyk, Anne & Prinsloo, Gerhard. (2020). Health, safety and quality concerns of plant-based traditional medicines and herbal remedies. South African Journal of Botany. 133. 54-62. 10.1016/j.sajb.2020.06.031.
6. Hanssen B, Grimsgaard S, Launso I, Fonnebo V, Falkenberg T, Rasmussen NKR. Use of complementary and alternative medicine in the Scandinavian countries. Scandinavian Journal of Primary Health Care 2005; 23(1): 57- 62.
7. Fraenkel l, Bogardus Jr. ST, Concato J, Wittink DR. Treatment options in knee osteoarthritis: The patient's perspective. Archives of Internal Medicine 2004; 164(12): 1299- 304
8. Newman DJ1, Cragg GM. Natural products as sources of new drugs over the last 25 years. Journal of Natural Product 2007; 70(3): 461- 77.
9. Firenzuoli, Fabio & Gori, Luigi. (2007). Herbal Medicine Today: Clinical and Research Issues. Evidence-based complementary and alternative medicine : eCAM. 4. 37-40. 10.1093/ecam/nem096.
10. Gv, Narasimha & Rg, Dayanand & Pullaiah, Chitikela P. (2018). Traditional Medicine: Safety Evaluation-Need of the Hour. Journal of Natural & Ayurvedic Medicine. 2. 10.23880/jonam-16000152.