



REVIEW ON HERBAL MEDICINE: EFFICACY, SAFETY, REGULATION IN MODERN PHARMACY

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Abstract: herbal medicinal products Is a complex mixture of organic chemicals; from raw or processed parts of plants; Includes leaves, stems, flowers, roots, and seeds. Under current law, herbs are considered dietary supplements Therefore, dietary supplements and manufacturers Grow, sell and market herbs without prior demonstration Ensure safety and efficacy where appropriate Medicine. Ayurvedic herbal medicine is complex Mixtures obtained from organic sources require significant effort to ensure this Constant and sufficient quality. Insufficient data Most factories have safety regulations that ensure quality, effectiveness, and safety. Of The idea that herbal medicine is safe and has no side effects is wrong. Plant It contains hundreds of ingredients, some of which are highly toxic. Digitalis and digitalis are considered to be the most cytotoxic herbal anticancer agents. Pyrrolizidine alkaloids, etc. However, there are no harmful botanical effects. Although therapeutic drugs are less common than synthetic drugs, However, well-controlled clinical trials have confirmed this to be the case. It's really effective. Domestication, production,

and Biotechnology research and genetic improvement of medicinal plants; There are great alternatives to using plants harvested from the wild. Advantages of achieving stable high quality Ingredients important for efficacy and safety

Ayurvedic Herbal medicine. Numerous of moment's synthetic medicines began from the factory area, and only about 200 year's ago our pharmacopoeia was dominated by herbal drugs. Medical herbalism(i.e. the medicinal use medications that contain simply factory material) went into rapid-fire decline when pharmacology established itself as a leading branch of rectifiers.

Key words: herbal medicinal products, efficacy, safety, regulation, modern pharmacy , plant products .

Introduction:

Herbal medicine has been used since In ancient times, it was used as medicine A variety of diseases. Medicinal plants exist Has played an important role in global health. Even though Huge advances are observed in modern medicine Cinema in recent decades, plants still play a role Make important contributions to health care. I- The dicinal tree is distributed throughout the world, but They are more abundant in tropical countries.

In recent years, global and domestic Interest in plant-based products has increased significantly. Especially in the US. Of Not just due to general trends Not only natural products but also more products available Evidence of safety and effectiveness Of herbal medicine. Aside from that, Advanced knowledge of composition I got it through an introduction. New analytical techniques. The current, But there is still a large international one.

Differences in the regulatory status of herbs Medical products Modern edicine is not just a theory, but is scientifically proven with the results of actual experiments and hypotheses. Alternative medicine uses proven chemical formulas to target only specific areas, thereby providing rapid relief from specific symptoms. Additionally, modern medicine is so advanced that it can treat many identified problems and actually prevent many potentially deadly viral infections and genetic diseases. According to the World Health Organization

Zation (WHO) (5), poverty and For example, lack of access to modern medicine

65-80% of world population Life in developing countries mainly depends on: Mainly focused on plants for primary health care. The current Especially major pharmaceutical companies Show new interest in Study of higher plants as a source of new things For lead construction and development Standardized phytotherapy Proven efficacy, safety, and quality (2.6-9).

As a rule, these are herbal medicines Very popular in developing countries, A long tradition in the use of medicine Even in plants and some developed countries Germany, France, Italy etc.

Guidelines for the United States (if applicable) For registration of such medicinal products (7- 15).This review highlights the current display Improving safety, efficiency, and safety knowledge Quality Assurance, Marketing and Regulation Clinical aspects of botanical medicine.

Need of the study:

India has a rich history of traditional medical systems based on six systems, of which Ayurveda is the oldest, most widely accepted, practiced and thriving indigenous medical system. Other related medical systems in India include Unani, Siddha, homeopathy, yoga, and naturopathy. Most of the stories are The only medicine I had was Chinese herbal medicine. Even recently In 1890, 59% of his registered products were from the United States Pharmacopeia.

Herbal products 3, and up to One-third to half of the drugs in use today were original obtained from plants “Traditional” use of herbal medicine refers to significant historical use. And this is certainly true of many products available as “traditional herbal remedies.”

Research methodology : Regulations for herbal medicine vary around the world. Different countries have different approaches, ranging from strict regulations to more lenient frameworks. Many companies focus on safety and quality standards and regulate herbal products as dietary supplements. Always check with your local health authority for specific guidelines.

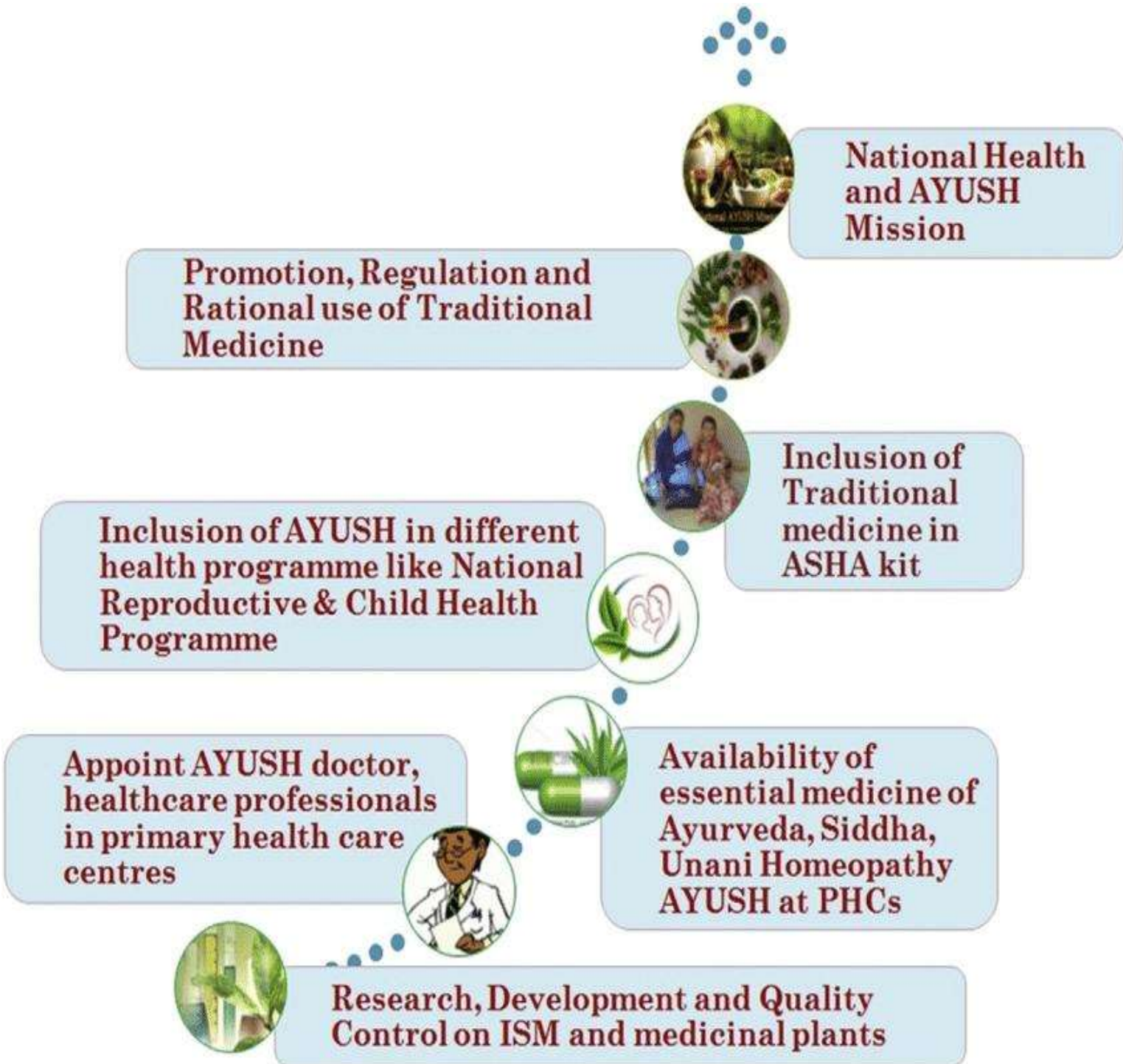
According to the World Health Organization (WHO) Definition of “herbal medicine” Retaining plant parts or plant material in crude oil Or in a processed state as an active ingredient; May contain excipients. Combination with Chemically defined active ingredient or iso Related ingredients are not considered plant-based Medicine (1). Similarly, European media The Sines Assessment Agency (EMA) defines it as follows:

Chinese herbal medicine as medicine Products containing only herbal medicines or Ayurvedic herbal medicine preparations as active ingredients

Perspective. Herbal medicine is a plant or part of a plant In its raw state, it is for a. be used Medical or pharmaceutical purposes Grinding crude drug preparations Or powdered herbal medicines, extracts, tinctures, Fatty oils or essential oils, expressed juices, professional Prepare precipitated resin, rubber, etc.

From ayurvedic herbal medicine and preparations, Production includes separation, purification Concentration or enrichment process (2) Based on EMA and WHO quality Guidelines, herbal medicines or preparations Considered to be active overall Material. From this definition we get: And from the fact

that it is a herbal medicine Films are complex mixtures of substances That significant effort is required to ensure this; appropriate quality.



Regulation of herbal medicine in India: Herbal medicine in India is governed by the Drugs and Cosmetics Act (D&C), 1940 and Rules, 1945, which clearly provide for the regulation of Ayurvedic, Unani and Siddha medicines.

The AYUSH Department is the regulatory authority and stipulates that the manufacture or sale of herbal medicines, where applicable, must be done after obtaining a manufacturing license.

Acts D and C expand controls over the composition, manufacture, labeling, packaging, quality, and export of authorized drug products.

Schedule 'T' of the Act sets out Good Manufacturing Practice (GMP) requirements to be followed by manufacturers of herbal medicines.

Get official pharmacopoeia and recipes for medicines. The first schedule of the D and C Act lists the authorization documents that must be followed for the licensing of herbal products in his two categories: ASU medicines and patented or branded medicines.

In India, traditional medicine is regulated by the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945. It regulates the import, production, distribution, and sale of pharmaceuticals and cosmetics.

In 1959, the Government of India recognized the traditional Indian medicine system and amended the Drugs and Cosmetics Act to include drugs derived from traditional Indian medicine.

No products derived from traditional systems can be manufactured without a license from the national drug control agency.

Proprietary and patented medicines derived from traditional systems must contain ingredients maintained in the recognized records of the above systems as specified in the Drugs and Cosmetics Act .

The government is advised by a special committee and advisory board on Ayurvedic, Siddha and Unani medicines. The Pharmaceutical Committee was established to prepare pharmaceuticals for all these systems.

Regulation of herbal medicine in US:

Herbal products are approved by the U.S. Food and Drug Administration based on claims or end uses as drugs, foods, or dietary supplements. Products used to prevent, diagnose, alleviate, treat, or cure diseases fall under the category of medicines. If the intended use of a herbal product is to affect the structure or function of the human body, it is classified as either a drug or a dietary supplement. According to the FDA, the drug must be marketed under an approved new drug application (NDA). The FDA regulates dietary supplements under the Dietary Supplement, Health, and Education Act of 1994. They do not require assurances of safety and compliance when labeling their products before sale.

The application must meet FDA regulatory requirements. The production of dietary supplements must be carried out in accordance with the current GMP standards for dietary supplements.

FDA regulates the dietary supplement under the Dietary Supplement Health and Education Act of 1994. These don't bear premarket review to insure the safety and labeling compliance of their products with the regulations. The claim must not misbehave with the non-supervisory guidelines issued by the FDA. The manufacturing of dietary supplements should be done as per the current GMP for dietary supplements.

Regulation of herbal medicine in Australia:

Australia's regulatory body, the Therapeutic Goods Administration, regulates herbal products under the complementary medicine category. This category covers Ayurvedic medicine, Traditional Chinese Medicine, and Australian Indigenous Medicine.

Complementary medicines that do not require medical supervision are permitted and must be registered with the Australian Medicines Registry (ARTG) before they can be marketed.

The low risk medicines require to be listed while the medicines for comparative higher risk therapeutic conditions require registration on the ARTG. Only evidence based claims which are entered on the ARTG are allowed.

Regulation of herbal medicine in Canada :

Since January 1, 2004, Health Canada has regulated traditional medicine, including herbal remedies and Ayurvedic medicine, under the Natural Health Products Regulations. The regulations require manufacturers, packers, labelers, or importers to first register with Health Canada before engaging in such activities.

This process involves registering the production site along with the product. Complete data on product composition, standardization, stability, test methods and tolerance limits for microbial and chemical contaminants, safety and efficacy, and characterization and quantification of ingredients by assay or input can be found in the Natural Health Product Directorate (NHPD). The agency requires NHPs to comply with pollution limits and manufacture according to GMP standards.

Regulation of herbal medicine in European Union :

In the European Union, herbal medicines are covered by the Traditional Herbal Medicines Directive (THMPD). This directive introduces a simplification of the registration process for traditional herbal medicines and improves their quality and safety. To qualify, a product must have a history of prior use and undergo efficacy and safety testing before approval. Member states are responsible for enforcing and administering these regulations. Quality control requirements require that product specifications include physicochemical and microbiological testing. Products must meet the quality standards of the relevant

pharmacopoeia. Bibliographical evidence must demonstrate that the product has been in medical use for at least 30 years, of which at least 15 years have been in the European Community.

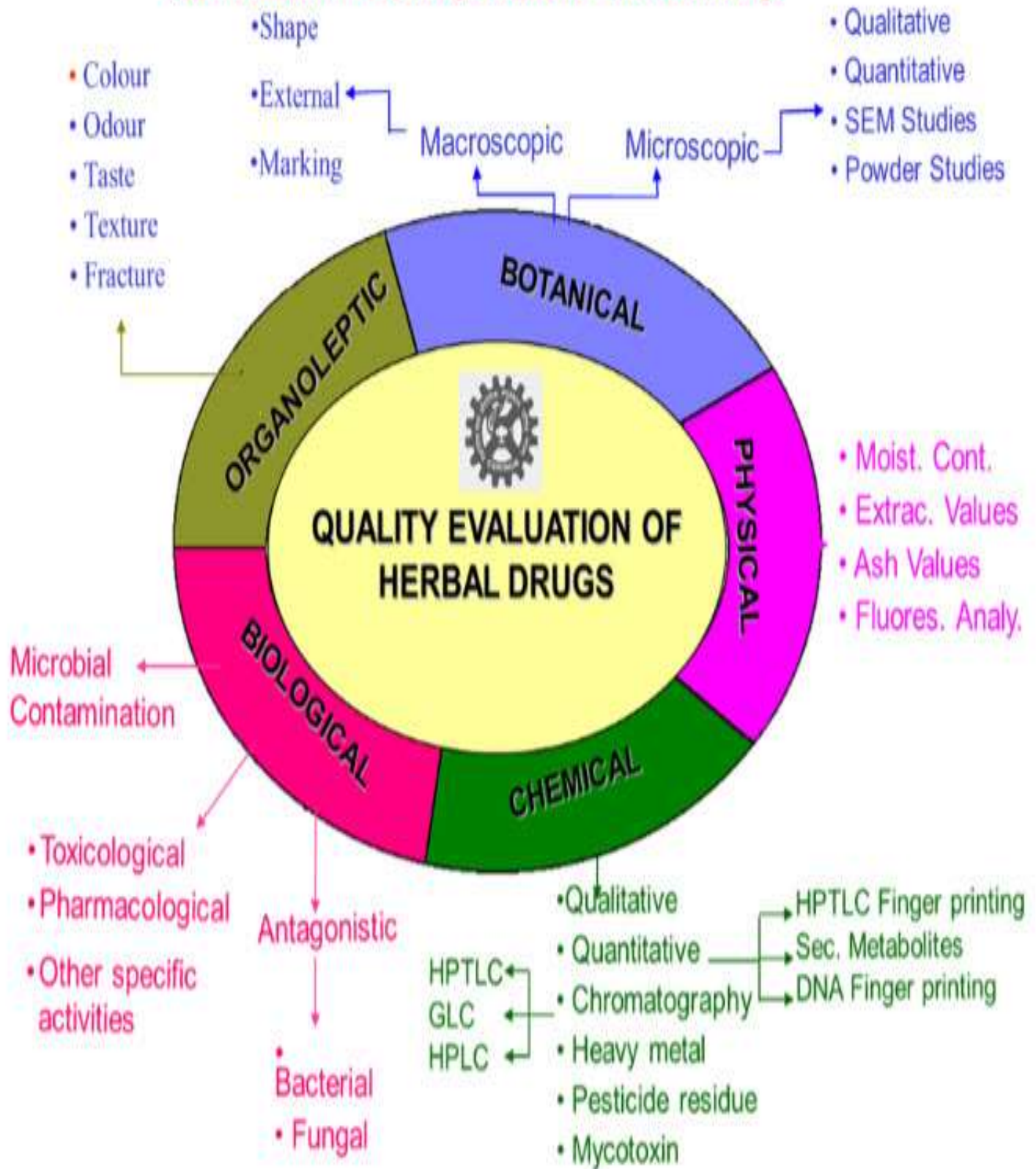
If the product has been available in the community for less than 15 years but would otherwise be subject to the simplified registration procedure under the Directive, an application for registration of traditional use must be submitted to the Herbal Medicines Committee. Will be referred.

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Standardization & Quality Evaluation of Herbal drugs



EFFICACY:

Herbal drug has its origins in ancient time. It involves the medicinal use of shops to treat complaint and enhance general health and good. Some saucers have potent(important) constituents and should be taken with the same position of caution as medicinal specifics. In fact, numerous medicinal specifics are grounded on man- made performances of naturally being composites set up in shops. For case, the heart drug digitalis was deduced from the foxglove factory.

Most plants contain many medicinal ingredients logically active compounds; in some cases he doesn't know Chapter What components are important for treatment? [5]. Many doctors believe that the components dissociate Article : The therapeutic effect is weaker than the effect of the whole plant extract Article Obviously, every case requires evidence. Section Miscellaneous herbal products Chapter Experimental results are better than synthetic ones drugs. One way is to look at whole herbal extracts. As active rules. Optimize regeneration Chapter .

This is often attempted through standardization by key compones corresponding to the main components of the extract (e.g. the Pharmacologically active ingredient or, if that ingredient is unknown, a suitable marker). However, because standardization can only be done for one or two, variations in other ingredients may still remain, which can affect both the effectiveness and safety of the product. Therefore, complete product characterization and quality control are essential for the reproducibility of herbal medicine scientific experiments.



Table 1 : Efficacy data on three selected herbal medicines.

Herbal medicine	Indication	Strength of evidence
Garlic	Hypercholesterolaemia	Statistically significant effect, database clinical relevance.
	Hypertension	Small effect size.
	Cancer prevention	No trial data available.
GINKGO	Intermittent claudication	Positive effect comparable with conventional drug.
	Dementia	Delay in deterioration
	Tinnitus	Uncertain efficacy
PANAX GINSENG	Physical performance	Uncertain efficacy
	Psychomotor performance	Uncertain efficacy
	Cognitive function	Uncertain efficacy
	Immunomodulation	Uncertain efficacy
	Diabetes	Uncertain efficacy
	Herpes simplex	Uncertain efficacy

According to previously available data, this is not possible. Draw general conclusions about the value of treatment.

Medicinal herbs. There are medical workers -

I used to be careful when recommending herbal medicine.

“Doctors should not prescribe or recommend herbal medicine.

A product whose effectiveness has not been proven...” . However, You must also be reasonably healthy. It informs patients of the need to counsel them responsibly.

Safety, toxicity and side effects:

Because herbs are plants, they are often considered “natural.” Herbs published and recently reviewed, Role of bioactive components of plants Article Effects of pollution and effects of plants and drugs. Information about kidney disease caused by the use of certain drugs pharmaceutical products in China. A special case series of patients identified 105 patients

fed in Belgium Ayurvedic herbal slimming product and innovation Episode Kidney disease from Fangjicao. Forty-three End-stage renal disease developed in patients; Preventive nephrectomy. 18 of the patients Results showed people were diagnosed with urothelial cancer Aristolochia on the formation of DNA adducts This plant contains acid. Another common herbal toxicity.

This drug contains complex pyrrolizidine alkaloids.

Used as a molecule found in certain plants or Accidentally using medicinal herbs (comfrey, (Still available in the U.S.) These alkaloids Causes hepatotoxicity due to unique venous occlusive properties A disease that progresses quickly and can be fatal. Contaminants in plant-based foods can be particularly dangerous.

There is a problem with drugs being imported from Asia. Study test-

As a result of examining the ingredients of 260 Asian patented drugs, 25% of products contain high levels of heavy metals and Another 7% intentionally contained undeclared drugs.

Added illegally to achieve desired effect.

The safety of using most herbs with medications is poorly developed .

Some established herbs are known to interact with pharmaceuticals.

Most of the information comes from ceuticals.

Case reporting rather than systematic investigation .

Because many Chinese herbs have pharmacological properties. Compounds, some medicinal plants will pass Too much toxic effect. For example, ephedra, contains ephedrine, which is widely used in traditional Chinese medicine Medicine has been around for thousands of years and became popular later Electrical Equipment. Toxicant exposure analysis Chapter The control center detected that it is the same as the others plant users 40 times more likely to contract ephedra Section relates to reporting adverse events. 42 visual reviews Episode Ephedra may increase the risk of nausea by 2 to 3 times Chapter Comparison of vomiting, mental symptoms and palpitations Chapter Placebo 43 banned by FDA on April 12, 2004. 7 of the largest ephedra producers shortly after the implementation of the ephedra ban products containing ephedra began to be marketed as “ephedra-free” products, all containing the Citrus aurantium plant. This The Plant, also known as bitter orange, contains synephrine. Has many of the same medicinal properties as ephedra Paragraph 45 of Article will therefore lead to many of the same things. There are .

Use a combination of available herbal products. Episode Citrus aurantium and caffeine have been shown to cause identification. Section Significant increase in systolic and diastolic blood pressure (up to 9 mmHg) and pulse (every 16.7 beats) (min) in healthy adults. The following problems may occur in 46 patients taking this product: Section Increased pulse and blood pressure or symptom of insomnia or Episode Feeling an "emotion"—everything caffeine will cause Additives containing citrus fruit.

Unfortunately, the actual incidence of side effects for most herbs is:

Unknown because most have not been tested in large clinical trials. Because testing and surveillance systems are much less extensive. Review of what is used in medicine. According to the results conducted by the Board of Audit and Inspection, Surveillance system designed to detect adverse reactions to herbal medicines. It is inadequate and probably detects less than 1% of all events.

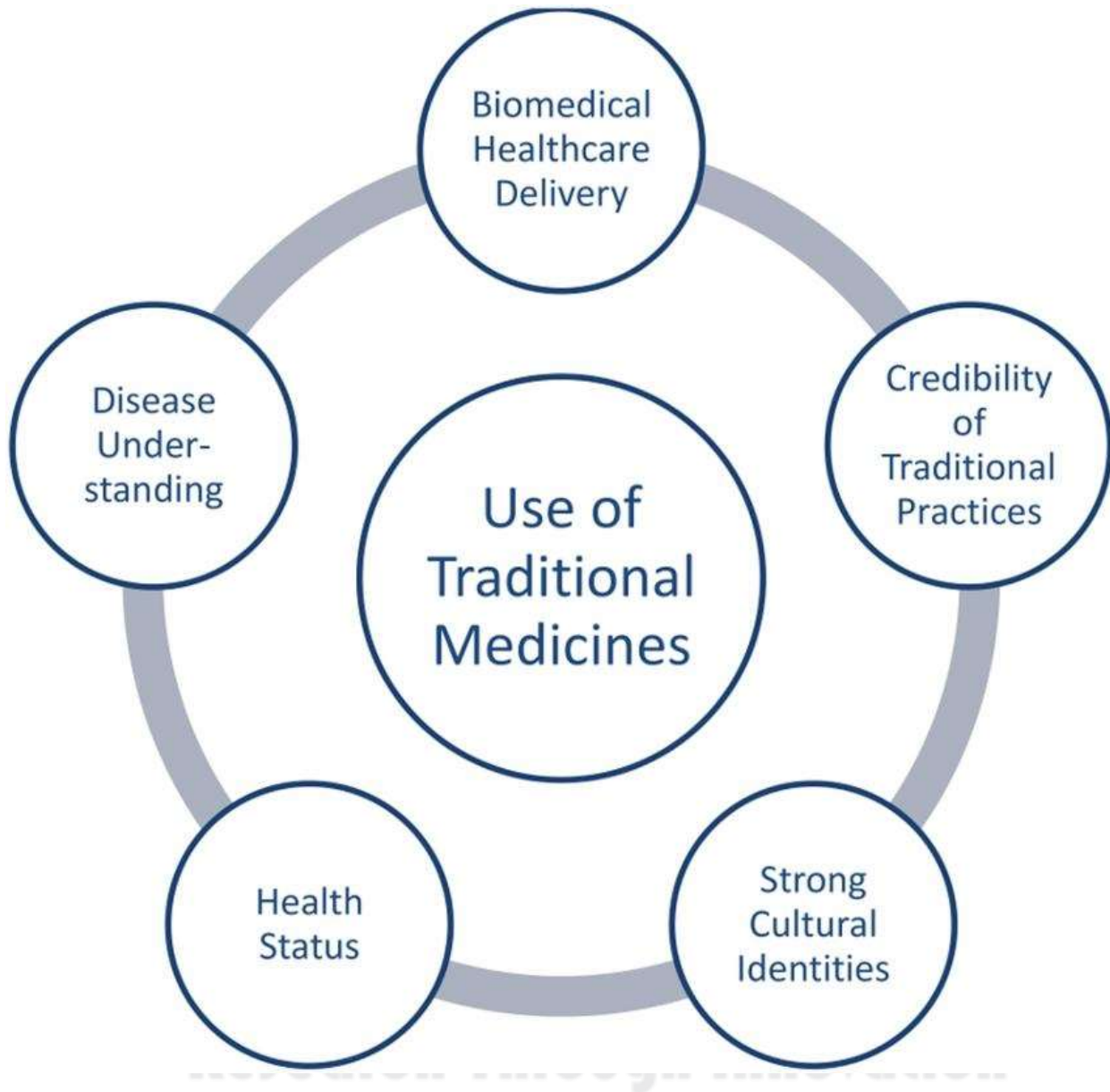
The potential toxicity of some plants is complex. Commonly used trading instructions are incorrect. For Lost only one Search Engine Optimization found Article Benefits of plants are misreported no more effective than placebo) This statement is often confusing. Called "Publication of Scientific Evidence" on the effects of citrus aurantium is used for weight loss regardless of the possibility. There are Illegal and False Herbal Marketing Claims products available. Much more while learning internet marketing. More than half of illegal herbal medicines treat, prevent, Section Special diagnosis or treatment .

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Use of the traditional medicine

Herbal medicinal product categorization:

1 . Herbal drug with known clinically active principal .



- Senna leave. Sennoside
- Horse chestnut seed aescins
- Milk thistle fruit silibinin
- Kava rhizome. Kava
- Lactones
- Aloe. Aloin

2. Herbal drugs with known pharmacologically active markers:

- Hawthorne leaf Oligomeric With flower Procyanidines
- GINKGO leaf flavono
Glycoside,
Terpene Lactones
- Garlic bulb Allins, allicins
- St John's wort Hyperforin,
Herb. Hypericin
- Asian ginseng Ginsenosides.
- Saw palmetto Fatty acids &
Fruit Their esters.

Other herbal drugs with analytical markers:

- Valerian root. Valerenic acids
- Echinacea herb. Caffeic acids
- Siberian ginseng. Lignan
Glucosides
- Balm leaf. Rosmarinic acid
- Nettle root. Scopoletin

Who should avoid herbal medicine ?

Taking herbal remedies may not be right for you if:

People taking other medications, including hormonal contraceptives such as combination pills

- People with serious medical conditions, such as liver or kidney disease
- People undergoing surgery

Pregnant or lactating women
Children-like all medicine, herbs should be kept out of the reach of children.

If you fall into one of these groups, consult your doctor or pharmacist for advice before trying herbal remedies.

What to look for when buying a herbal medicine:

- If you want to try herbal medicine, look for the Herbal Medicine Label (THR) on the product packaging.
- This means that the medicine meets good safety and manufacturing standards and provides information on how and when to use the medicine.

- **But you need to know:**

THR products are designed for conditions that can be self-treated and do not require medical supervision, such as coughs, colds, or general aches and pains.

2. Using THR products for more serious conditions may be harmful, especially if you delay seeking medical help.

3. Claims for THR products are based on traditional use, not evidence of product effectiveness.

The THR designation does not mean that the product is completely safe for everyone.

4. You can find THR-registered products at your local health center, pharmacy, or supermarket.

Conclusion:

One in five American adults uses herbs. Products from the past year. Unfortunately in most cases. There are approximately 20,000 herbal products in the country. There is little evidence regarding safety and effectiveness. But as one About a third to half of all medicines were original medicines. There is definitely a possibility of discovering benefits as it is derived from plants.

Therapy from the natural environment. Current regulations The use of herbs does not guarantee the safety of commercially available products. False and illegal marketing claims are common Part .

By simply changing the regulations for these products, Significantly improves the correct use of herbs. Depending on the quality of herbal preparations These are key parameters for safety and efficiency. It is important to characterize several components. Determine topics or component groups; Suitable range. Specified component It must be related to safety and effectiveness. And/or indicates an important part.

Herbal preparations.

As with evidence for efficacy, evidence for safety should be considered on an extract-by-extract basis and, at best, only apply to preparations of the same herb with very similar ingredient profiles. However, little is known about the side effects or frequency of use of herbal medicines in general. This

The fact that it contains complex plant extracts It has been shown to be therapeutically active and safe. They also play important roles in:

It has promoted health care around the world.

WHO will review selected medicinal plants And publish a paper on its use .

A comparative paper has been published.

Product approved by the European Scientific Cooperation Tive for medicinal herbs (ESCOP) Both Paperback type is taken into consideration.

Considered in the current European assessment Medicinal herbs by country in Europe, the Middle East, and Africa Herbal medicine working group Jeon. This procedure aims to achieve harmonization.

European herb market. Depending on the quality of herbal preparations These are key parameters for safety and efficiency.

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