

Standardization of Herbals: Need and Responsibility

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Recent adverse events with Herbal Supplements in countries such as the US, clearly point towards the urgent need for Herbal Standardization and Evaluation of Safety and Efficacy. Plant-based Traditional systems of medicine like TCM and Ayurveda boast of substantial usage data spanning centuries if not millennia indicating safety and efficacy. The opponents of Standardization and state Regulation for herbal products often cite this as the reason to block research based on modern lines. However, most understand why botanicals or Traditional Medicines need to be subjected to modern day scrutiny for product quality, safety and efficacy. This article details the justification, the approaches and the government effort needed for herbal product standardization.

Why Standardization

Substantial original documentation for the more organized systems of medicine still exists. Large expanses of local ethnic medicine, folklore, etc. were passed on to the present generation only by word of mouth. Medical education was personalized to a small group of students or sometimes a single individual. Although several original codified texts like the Charak Samhita exist with specific herbal formulas, the

physicians down the ages took liberty to modify these formulas according to prevailing local conditions or personalized them for individual patients. In course of time, though the name remained unchanged, the formula of the original preparation went through successive changes. This resulted in the same preparation having different compositions as well as different therapeutic indications. Thus any Traditional System of Medicine (TSM) is often crowded with duplication, confusing nomenclature of plants, accidental substitution of herbs, etc. due to these "transmission errors". There is no denying that the TSM that has been passed on to us from earlier generations is vastly different from the original works of the earliest authors. Even in the original works, the means of maintaining finished product quality, safety and efficacy mentioned were at best only subjective in the absence of objective means of evaluation available to modern day science. This only contributed to misinterpretations and distortions.

Socio-economic changes in Herbal Practice

Modern day awareness of the needs for Herbal Standardization and Evaluation have been aptly summarized in the words of Drugs Controller of India, Mr. Ashwini Kumar: "In earlier days, the activity of herb

procurement, preparation and dispensing remained mainly the responsibility of practitioners and was on a one to one relationship between physician and his patients. It was a matter of sacred trust. However, the socio-economic changes in modern times, the technological advances, commercial factors, consumer preferences, changing lifestyles, etc. has influenced the way Herbal drugs are being 'manufactured' and distributed in the country. The Practitioner as well as the Consumer now seek assurance from the manufacturer about quality, safety and efficacy of a readymade Herbal Supplement or Medication.

Changes in physical constitution, social habits and environmental stressors

Though life expectancy may have increased due to advances in medical treatment of life-threatening diseases, the average adult prior to the industrial revolution was much healthier due to the pollution-free environment and simple lifestyle. There has been a remarkable change in the average adult's physical constitution and his natural immunity towards the disease state, the nature and severity of diseases and the dietary and social conditions within which the patient may be consuming the Herbal Supplement. The disease causing agents / factors then and now are also dramatically different. An average person's diet, lifestyle and other social habits, all which play important roles in disease and treatment, are completely different today. Hence the earlier recommendations for herbs for specific disease states may not hold true today unless validated in today's times.

Phenotypic changes in plant species

Plant constituents are greatly influenced due to climatic factors, intra-species variations and

geographical location of their collection and cultivation. The herbs and their properties as described thousands of years ago without doubt must have undergone changes in phytochemical profile in the normal evolutionary process and due to changed environmental and agronomic conditions. Hence the original pharmacological claims of these medicinal plant species need to be revalidated.

Substitution of drugs due to non-availability or scarcity

Some Traditional literature allows the substitution of herbs that were not found easily or scarce in certain regions. In some cases the substitutes have acquired the status of the original herb and are sometimes wrongly attributed with all the properties of the original herb. With passage of time, the herbs that were meant to substitute the original herb in one application start finding use in other applications not recommended by the authors. Hence constant clinical evaluation and validation is a must.

Evaluation of Herbals as Supplements / Concomitant Therapy

In several countries, regulatory authorities have still limited the use of herbals as supplements and not as the first line of treatment. The high cost of regulatory approvals required in placing a botanical drug on the market as the main line of therapy has meant that herbals are often taken as "Supplements" to other allopathic treatment. The possibility of incompatibilities and complications can be ruled out only after safety trials.

Proliferation of Proprietary Formulas over Traditional Generic Formulas

Traditional literature in Ayurveda for example mentions specific herbal cocktails for all disease conditions. The efficacy and safety of traditional formulas has been confirmed by informal system of trials down the ages but the proprietary branded preparations are not prepared as per Ayurvedic texts hence their final efficacy is open to question. Thus there is a need to confirm their efficacy.

Tough Dietary and Lifestyle restrictions for Effective Therapy

Ayurveda strongly recommends other lifestyle changes in conjunction with herbal medication. Several guidelines in Ayurvedic treatment are either difficult to adhere to in present 21st century lifestyle or are not taken seriously by the patient. The importance of label instructions (eg. "Take with warm milk" or "mix with honey", etc.), dietary restrictions, dosages, etc. need to be studied using modern techniques. Such research can go a long way in improving patient compliance and achieving better results to herbal therapies.

Change in the Consumption pattern of Traditional products

The original recommendations for usage of Herbs and herbal products have undergone mutations in areas of age groups, races, etc. Ginseng is a popular traditional product originating from a certain geographical region where it has been immensely successful on local yellow populations. However, Ginseng has clearly a larger market outside of India and it is consumed by millions people of White / Hispanic / African racial backgrounds. The Traditional Ayurvedic preparation "Chyavanprash" was originally recommended for older men to increase longevity but now even children commonly consume it. Efficacy of traditional products should be established with multi-centric trials spanning the complete or partial spectrum of current human usage.

Over-exploitation of Consumer Sentiment on Herbals

In the last half-century, Natural Ingredients have entered several hitherto untouched areas of our lives. There is now a "Herbal variant" of almost every consumable. Several herbal variants are either

unjustified or have exaggerated claims. Finished product quality control through regulatory legislation is the answer to the problem of spurious and sub-standard "herbal" products with some times exaggerated claims.

Modernization of herb form being administered

Several TSM employ the herb in decoction or extract or tincture form but the majority of medication was still in whole herb form. However, today's herbal products, guided by the pharmaceutical practices of over-purification are sometimes presented in the form of near pure phytochemicals or concentrated extracts which bear little resemblance to the original herb in chemistry, efficacy and even safety. Due to the emphasis on higher and higher actives, the other actives in the plant are often excluded to a point where efficacy suffers and toxicity approaches that of synthetic compounds. Such preparations should be not only tested to confirm efficacy but also long-term safety in humans.

In Self-Interest of the Natural Products Industry

Self-regulation or Governmental control is in the self-interest of the Industry. If the consumer continues to get disillusioned with Herbal products quality due to a few unscrupulous players, then the present rising interest in Natural products will ebb and the entire Industry will be at the losing end.

PRIVATE SECTOR EFFORT

1. Pharmacological (Animal) Screening

The pharmacological screening of plant materials from different ecospheres and traditional formulas from various texts has been going on for years in academia and private sector and must now continue at higher speeds available.

2. Clinical evaluation

Taking potentially active herb candidates to the clinic in phase I and II trials to evaluate novel activities can be the concluding effort in herbal standardization that would lead to a healthy and growing market for herbs.

3. Dose determination and Safety studies

A fresh evaluation of therapeutic and toxic doses should be carried out for even the established uses of common herbs, due to changes over years in patient population, environmental conditions, disease patterns, plant phenotypes, etc.

4. Development of Analytical Protocols for Finished Products

Even as Phytochemical Science and Industry has made some progress on analytical methods for the raw materials, the finished product quality control is still a challenge. Industry has now long used the excuse that Multi-Ingredient Product quality control is a costly process and sometimes unattainable.

5. Privately funded clinical evaluation of branded formulations

Privately funded clinical evaluation of branded formulations has been happening in the past and is only likely to grow as awareness increases amongst physicians and patients alike.

PUBLIC SECTOR EFFORT

1. Government Funding and Support

The Pharmacopoeias often form the basis of quality control in the drug industry of any country. Several countries have already made progress in the compilation of their national Herbal Pharmacopoeias such as the American Herbal Pharmacopoeia, German Monograph E and Indian Herbal Pharmacopoeia. However, this exercise needs to be continued further with added vigor and speed. There is an urgent need for a large collection of cheaply available biologically active compounds.

2. Drug Testing Labs

Smaller players in mostly fragmented Herbal markets of the world cannot be expected to have in-house facilities for testing and product development. Third

party testing facilities, contract research laboratories and other facilitating agencies should be encouraged with easy finance, etc. to meet the needs of the small-scale sector.

3. Health Regulatory Policy

Without a stringently written and implemented regulatory policy on Herbal quality control, there will never be adequate motive for private initiative in this field. Governments should ofcourse first create the public and private infrastructure needed to fulfill the requirements then vigorously implement the existing provisions of health regulations or amend the existing laws to give health authorities more teeth. Private investment in this area will then automatically follow.

4. Consumer Awareness Program

Having the infrastructure and Health Administration in place, a consumer awareness program be launched. This will ensure that private companies tighten up and deliver quality at affordable prices. The consumer is smart but she still needs some training in asking the right questions.

5. International Promotion Program

After having done the good work, the industry and particularly the government can and should tell the whole world about the modern quality standards that their "traditional" medicine adheres to.

Final Fact

Herbal Standardization is a much-needed public and private effort that will help in elevating Traditional Medicine to the levels it deserves internationally.