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RULES AND REGULATIONS OF HERBAL MEDICINES IN INDIA

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ABSTRACT

Herbal remedies are a fundamental aspect of alternative medicine. Herbal medicine is becoming increasingly popular nowadays. Herbal remedies are commonly used in various medical systems like Ayurveda, homeopathic, Siddha, Unani, and other regional systems to treat human ailments. The types of products made from medicinal plants vary from country to country and encompass dietary supplements, herbal foods, and traditional remedies. In order to identify changes to laws and new adherence to regulatory bodies, a comprehensive review of literature was carried out on regulations for herbal medicinal products in Europe and India. The European Medicines Agency (EMA) Committee on Herbal Medicinal Products (HMPC) alongside other committees is establishing guidelines for safety, nonclinical studies, clinical effectiveness, and product quality. Regulations pertaining to medications and beauty products. Rewrite the text using the same language and number of words.

INTRODUCTION

Herbal drug compounds and herbal preparations are defined as follows in terms of herbal medicinal products:
A medication is considered a herbal medicinal product if it contains either individual herbal substances, herbal preparations, or a mixture of both as its active components.
Herbal medicines are utilized all around the world.. Herbal treatments are often viewed as both safe and successful remedies. Botanicals, botanical components, seaweed, mushrooms, and lichen are commonly seen as herbal elements, often in their natural state or partially processed.
Ayurveda, Siddha, homeopathy, and Unani are commonly used as traditional forms of medicine in India. India plays a major role in exporting medicinal plants. The Indian forest contains numerous fragrant and healing plants used in the pharmaceutical industry. Around 8,000 herbal remedies have been classified within the AYUSH systems in India. This consists of processed exudates, tinctures, powdered plant material, extracted juices, and essential oils.
Regulations in India:
In addition to allopathy, herbal treatments play a notable role in various Indian medical practices like Ayurveda, Yoga, Unani, Naturopathy, Siddha, and Homeopathy. Laws like the Central Council of Indian Medicine Act, Research Councils, Department of

AYUSH, and D&C Act 1940 (Amendment) regulate herbal medicine in India. The Indian Council of Medical Research, also known as ICMR, is responsible for medical research in India Council of Scientific and Industrial Research, and the AYUSH department collaborate to create novel drugs in India and accomplish the objective of secure and efficient AYUSH products for acknowledged illnesses.

Herbal drugs come under Drug and Cosmetics act 1940, and Rules 1945(D & C ACT). As per rule Ayurveda, A medication, whether taken internally or applied externally, that is used for diagnosing, treating, alleviating, or curing any disease or disorder in humans or animals and is produced following the specified formulas in acknowledged texts of Siddha, Ayurveda, and Unani medical systems found in the First Schedule, is classified as a Unani or Siddha drug.

The D&C Act broadens authority over licensing, formulation composition, manufacturing, labeling, packaging, quality, and export. Schedule "T" of the act outlines the GMP requirements for manufacturing herbal drugs. The Traditional medicine national policy was implemented in 1940. Additionally, there are several national research institutes, with the initial one being the Central Council of Indian Medicine, founded in 1970. The regulation of herbal medicine at the national level began in 1940 with the release of the Drugs and Cosmetics Act; regulations for herbal medicines are somewhat similar to those for traditional pharmaceuticals. Herbal medicines fall under regulations for both prescription and over-the-counter medications, as well as dietary supplements. [3]

Schedules for Herbal Products in CDSCO

Part of Act / Rule	Chapter / Part	Nature of Activity
Drugs & Cosmetics Act 1940	Chapter IV-A (section 33-B to 33-N)	Provides provisions related to *Ayurveda, Siddha* and *Unani* Drugs
Drugs & Cosmetics Act 1940 - Schedules	The First Schedule	List of scheduled books
	The Second Schedule	Standards to be complied with by imported drugs and by drugs manufactured for Sale, Stocked or Exhibited for Sale or Distributed
Drugs & Cosmetics Rules 1945	Part XVI (Rule 151-160)	Manufacture for sale of *Ayurvedic* (including *Siddha*) or *Unani* Drugs
	Part XVI-A (Rule 160 A - 160 J)	Approval of institutions for carrying out tests on ASU Drugs and Raw material used in their manufacture
	Part XVII (Rule 161)	Labelling Packing and Limit of Alcohol in ASU Drugs
	Part XVII (Rule 161-B)	Shelf life and date of expiry for ASU Medicines
	Part XVIII (Rule 162-167)	Government analysts and Inspectors for ASU Drugs
	Part XIX (Rule 168-170)	Standards of ASU Drugs
Drugs & Cosmetics Rules 1945 - Schedules	Schedule A	Different types of forms, particularly 24D, 24E, 25D, 25E, 26D, 26E, 26E-1, 47, 48, 49
	Schedule B-1	Fees for the test or analysis by Pharmacopeial

		Laboratory for Indian Medicine or the Govt. Analyst
	Schedule E-1	List of poisonous substances under ASU Systems of Medicine
	Schedule FF	Standards for Opthalmic Preparations
	Schedule T	Good Manufacturing Practices for ASU Medicines
	Schedule Y	Requirements and Guidelines for permission to import and / or manufacture of new drug for sale and to undertake clinical trials
	(Proposed) Schedule Z	Requirements and Guidelines for permission to manufacture of ASU Drugs for sale or for clinical trials. [9]

Ministry of AYUSH

The establishment of the Ministry of AYUSH on November 9, 2014 aimed to ensure the effective growth and distribution of AYUSH healthcare systems.

Objective of AYUSH

- ✓ The main objective is to improve the level of education at Indian System of Medicine and Homoeopathic Universities and Colleges across the entire country.
- ✓ To strengthen the current research institutions and ensure a one-time research program on diseases that can be identified
- ✓ Additionally, it has a duty to regulate the quality of drugs by establishing pharmacopeia standards, overseeing the operations of the Indian Medicine Pharmacopeia Laboratory, and monitoring the operations of Indian Medicine Pharmaceutical Company Limited.[10]

Drug Development Process of Herbal Medicines

The following steps are generally involved in the drug development process for herbal medications:

• First, the bioactive ingredient is isolated and modified synthetically.

• Secondly, safety and efficacy evaluation.

• The third step involves the regulatory approval of a therapeutic agent for new drugs.

• Most recent medication clinical trials.

The medication goes through preclinical, safety, and biological activity research after it has been standardized. The appropriate appendices contain the standardization procedure for each of the formulations.

1-Identification and Prioritizing the R&D needs

2- Literature Survey

3- Hypothetical Rationale Formulation

4- Drug development Initiation (Quality Control, Quality Assurance)

5- Biological activity, Stability studies, pre-clinical studies (With Standard Protocols)

6- Integrated Protocols for Clinical trials development (GCP & traditional methods)

7-Clinical Trials of new drug (With Standard Procedure and approval of Regulatory Authorities) [6]

Clinical Trials of Herbal Medicines

- ✓ According to Good Clinical Practice guidelines, herbal medicines are tested in human trials after testing on animals. Clinical testing will be necessary for the integration of medicinal plants
- ✓ Following the protocols set by the DCGI office for allopathic medications was a requirement. This is unrelated to the protocols set by Ayurveda, Unani, or Siddha experts for testing their medicines in clinical trials, which can later be used in their hospitals..

Stages of clinical trials:

Phase I studies: Herbal medicines may not require phase I trials as they can likely be safely administered to a small group of closely monitored clinical participants in phase II trials. In most cases, phase I studies last for a few months.

Phase II studies: This step includes assessing the range of dosage for sick individuals (100-300). This phase helps plan large therapeutic trials by determining appropriate dosage ranges and outlining dose-response connections. It is crucial to verify tolerance at this point. Both the literature review and the protocol's requirements need to focus on a comprehensive evaluation of the clinical safety parameters. Phase II studies may include several hundred participants and span from several months to one year.

Phase III Studise : This stage of the trial includes thorough safety and effectiveness tests and occurs after the collection of phase 2 data on dosage levels. This phase involves the participation of approximately 1000 to 3000 volunteers with the specific illness, located in clinics or hospitals. Patients are carefully monitored to evaluate the impact of the herbal medicines and detect any possible adverse reactions. The trial has confirmed the drug's safety and effectiveness at this point. This phase could take nearly three years. [14]

Good Clinical Practice guidelines for herbal drugs and products in India for conducting clinical trials.:

- ➢ The Guidelines for Good Clinical Practice for herbal drugs and products in India must be followed during clinical trials..

- Current plants and traditional remedies used must be documented in literature of a reliable traditional medicine system and manufactured following Good Manufacturing Practices outlined in the literature to ensure compliance. Including phase 1 clinical trial studies is not necessary; what is important is that the substances being tested are part of Indian System of Medicines and are described in their texts. It is important to establish if the toxicity of the substances in animals has been decreased. Toxicity studies are not necessary for the phase 2 clinical trial unless a report indicates toxicity or specifies when to administer the supplement.

- Clinical trials for herbal medicines must wait until they have been standardized to ensure that the markers for the drugs being tested are reliable. Clinical studies using plant medications must adhere to identical regulations regarding informed consent, participants, incentives for joining, information disclosure, and study withdrawal, even for children or people with restricted autonomy. Approval for these trials is necessary from the scientific and ethical committees of all institutes involved. However, it is essential to make sure that an Ayurvedic, Siddha, or Unani practitioner is involved as a co-investigator when carrying out clinical trials for herbal remedies. An allopathic doctor conducting any form of clinical trial would be unethical and inappropriate. [15]

GCP Guidelines contains

- Introduction
- Definitions
- Pre-requisites for the study
- Protocol
- Ethical and safety consideration
- Informed consent process
- Compensation for participation
- Responsibilities of sponsor, monitor and investigator
- Data handling
- Record keeping
- Quality assurance
- Statistics

WHO guidelines:

The WHO guidelines contain a broad discussion on potential harmful residues and contaminants in herbal medicines. It outlines key criteria for assessing the primary pollutants and remnants present in herbal remedies to establish their quality. Moreover, it recommends analytical methods for evaluating these residues and contaminants, both qualitatively and quantitatively.

The objectives of these guidelines are to provide:

a) Quality control for plant preparations, final goods, and raw materials for pharmaceuticals
b) Evaluation of stability and shelf life
c) Safety assessment; record-keeping of safety determined by toxicological research or experience.

The guidelines do not cover the adulteration of herbal medicines. It's worth noting that these steps need to be validated for both the material being examined and the various types of tools. These actions should be added to other WHO publications and papers regarding the safety and quality assurance of herbal medicines.:

1. Authentication (Taxonomical identity, microscopically and histological analysis, stage of collection, parts of the plant collected, regional status, phytomorphological identity, etc.)
2. Foreign matter (soil, insect parts, animal excrement, etc. should not be present in the herbs that are collected).

3. Organoleptic evaluation (taste, look, feel, and other sensory characteristics of the drug)
4. The medication powder contains tissues that are necessary for diagnosis.
5. Values of ash and extraction.
6. Volatile matter
7. Determining the moisture content
8. spectroscopic and chromatographic analysis. When evaluating the TLC fingerprint of herbals (FEH), TLC, HPTLC, and HPLC techniques will yield qualitative and semi-quantitative data regarding the primary active ingredients found in the crude drug as chemical markers. The chromatographic fingerprint can also be used to evaluate the drug's quality.
9. detection of heavy metals, such as arsenic, cadmium, and lead.
10. Pesticide residue: The Food and Agricultural Organization (FAO) and WHO establish limits on pesticides, which are typically found in herbs. When the herbs are being grown, these pesticides are combined with them. Pesticides such as DDT, BHC, toxaphene, and Aldrin primarily cause major adverse effects in humans when combined with crude pharmaceuticals.
11. Microbial contamination: Medicinal plants that harbour molds and bacteria typically originate from the soil and atmosphere. It is evident from an analysis of the mold and E. Coli limits that the methods used in production and harvesting are illuminated. If the crude drugs are taken with the substance known as afflatoxins, there will be severe adverse effects. Either all afflatoxins should be eliminated or they shouldn't exist.
12. Radioactive contamination: Irradiation typically prevents microbial growth in herbals. The plant material may be sterilized by this process, but it's important to consider the radioactivity risk. The International Atomic Energy (IAE) in Vienna and the World [7]

The quality of the raw materials can be tested according to the following format:

- Name of the drug (English, Regional names, Exact botanical nomenclature)
- Part of the plant used
- Area of collection
- Distribution details
- Season of Crop
- Time and year of collection
- Pesticide and insecticides
- Condition of the drug (fresh or dry)
- Form of the drug (powdered or intact or cuttings like etc.

Stability testing of herbal drugs:

This can be a risky situation as the entire herb or herbal product is believed to be the main ingredient, even if the specific medicinal properties of its components are unknown. The key aspect to consider is the stability study and storage conditions of the product. Stability testing is conducted to demonstrate the impact of environmental factors such as temperature, light, oxygen, moisture, additional ingredients or excipients in the dosage form, drug particle size, microbial contamination, trace metals, etc. on the quality of herbal products as time progresses.

Shelf-life

For the suggested shelf-life—typically referred to as long-term stability—stability tests should be conducted on a minimum of three production batches of the herbal products under ambient air conditions. It is possible to generate stability data and predict the shelf-life of herbal products with the aid of contemporary analytical techniques such as spectrophotometry, HPLC, and HPTLC, and by following the appropriate guidelines. This will help to improve the acceptability of herbal products worldwide. The expiration date of herbal medicinal drug products is established similarly to chemically-defined APIs, but the specific attributes of herbal products must be considered. It is recommended that the variation in component of a herbal medicinal product with natural ingredients or herbal drug preparation with therapeutic activity constituents should not go beyond ± 5% during the recommended shelf-life.

Stress testing:

Identifying the degradation pathway can be achieved by conducting stress tests to identify the degradation product. Most people agree that stress tests are not needed for making herbal drug. Original: The company's profits have been steadily increasing over the past year.

Paraphrased: The company has seen a consistent rise in profits over the last year. A test may not be needed for herbal medications or herbal medication preparations under accelerated or intermediate conditions. Because it is commonly understood that the majority of items do not perform well at 30°C/65% relative humidity (RH), and especially at 40°C/75% RH, this principle should also pertain to final products. Herbal drug substances can be tested at normal conditions of 25°C and 60% relative humidity, with no requirement

for intermediate or accelerated testing. He decided to take a break from work and go on a vacation to relax and recharge. The time period of three months, consisting of months 0, 6, 9, and 12, is excluded when considering intermediate conditions. Because of the different times of harvesting, it can be challenging in some combination product instances to supply the required two batches of each extract at the same time.
The range will remain within ±5% of the initial assay value, unless there is a legitimate reason to increase it to ±10% or more. The higher extent is warranted by the final product's minimal marker amount. Additionally, it is important to take into account the inherent variability in marker content due to factors such as harvesting, biological differences, and climatic conditions. For example, the method's linearity can be tested using 40-160 percent of the expected content of the marker in the extract or product. Due to matrix interference (placebo), low analyte levels, inadequate precision and selectivity (combination products), and stability testing, tolerances of up to ±10% are permissible for the final product. Considering that the marker [12]

Patenting and Regulatory requirements of natural product

Patent:

A patent is a legal monopoly that allows the patent holder to stop others from using their invention without permission for a specific period. It is considered a restrictive right as it solely permits an individual to obstruct others from engaging in activities outlined in the patent, rather than allowing the creation of any new content. Throughout centuries, patents have undergone evolution as a legal concept. Over time, the scope, length, and objective of protection have evolved, making it beneficial for this study to examine how these changes have mirrored those occurring in Southern nations, albeit at a faster pace

Intellectual property rights (IPRs):

The inventor or the company representing the inventor is given sole rights, usually for 17-20 years, to produce, utilize, and promote a new technology or product. IPRs are meant to recognize researchers, innovators, and creators. It serves as the primary driving force behind the rapid growth and spread of the industrial sector. Intellectual property law gives proprietors exclusive rights over various intangible assets like creative works in music

A patent is a limited-time privilege granted by a government to an inventor or their assignee in exchange for revealing an invention to the public. The association of patents with robbery has a lengthy past. When Columbus began his journey to find a new land, he carried official permission from the Spanish monarchy in the form of letters patent. National regulations and global treaties dictate the process of granting patents, the obligations of the patent holder, and the extent of exclusivity provided. These variations are significant. Nonetheless, a patent application typically must include one or more claims that describe the invention, which must be novel, inventive, beneficial, or relevant. In most countries, both
Pharmaceutical companies have been working with indigenous tribal knowledge to discover plants and their components for developing new medications. Researchers can speed up the screening process of plants for valuable compounds by studying the variety of plants used by tribal healers to treat illnesses. By engaging in the practice of "biopiracy," multiple pharmaceutical companies are exploiting traditional knowledge for their own benefit and making significant profits. A trade secret is an intellectual property right that provides more direct protection. It is not limited by time and does not require government registration. It assists in controlling the expensive expenses of safeguarding intellectual property in countries such as India.[17]

Farmers Rights:

Farmers might have limited knowledge about the scientific basis of genetic diversity, yet they understand its crucial importance in farming and the need to promote diversity in agricultural practices. The autonomy of each farmer in selecting, preserving, and caring for seeds for future planting is crucial for turning plant species into crops and choosing the best ones.

Farmers' rights and intellectual property rights:

The basic concept behind intellectual property rights (IPR) on plant varieties is acknowledging human creativity in developing a novel plant type using selection, with or without recombination, which stands out from existing varieties. In contrast to

advancements in other areas, life forms, such as crop varieties, come from existing life forms and are spread naturally. Therefore, developing a new variety involves utilizing existing varieties and possessing the expertise to select a new variety either through alternative methods or by combining existing ones. Equity demands that the innovations in the original source be acknowledged just as much as the advancements in the newly bred plant variations, or genetic resources. The second option is basically a representation of the significantly greater overall intellectual input provided by agricultural communities throughout generations. These communities' intellectual contributions should not be devalued or unrecognized just because they lack institutional support or a strong sense of identity compared to commercial plant breeders. The request for free access to farmer-created varieties without paying royalties for protected intellectual property (IP) can be seen as a contradictory stance on rights, despite the enforcement of IPR on plant varieties. Additionally, farmers are no longer able to freely use seeds under the new exclusive rights granted for IP-protected varieties. This strict ban on patented seed varieties leaves farmers with no flexibility and gives breeders very limited options, depending on the laws.

Plant breeders Rights (PBR):

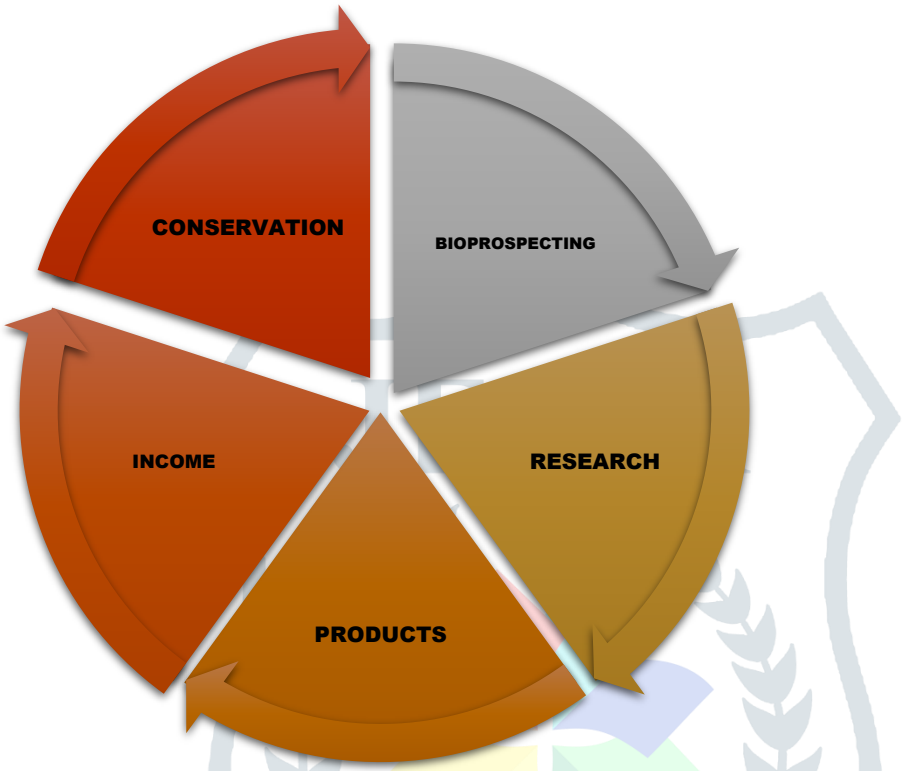
Another term for PVR is plant breeders' rights. The breeder of a new plant variety is given rights that provide exclusive control over the harvested and propagating material of the plant variety for a limited period of time. Breeders who own these rights have the choice to become the sole rights holder; a variety must be new, special, uniform, and steady. Plant breeders have the option to exclude individuals for a set amount of time from using, processing, storing, distributing, selling, marketing, exporting, or importing propagating material of a protected variety through the use of PBRs. Moreover, it allows the breeder to collect royalties from the authorized use of the breeding material and also to grant licenses for these rights to third parties. In some countries, harvested materials may include cut flowers, fruits, or leaves of the protected variety, as long as breeders have a fair chance to claim their ownership rights over the planting materials. In this system of plant variety protection, farmers' rights, along with PBRs, refer to the legal space that farmers have regarding the seed of a protected variety.

Biopiracy: Bio piracy occurs when researchers exploit traditional knowledge or cultures they are studying without permission. Bio piracy is the term used when scientists or research institutions acquire biological resources without authorization. Typically, these resources come from disadvantaged countries or marginalized communities. Bio piracy does not only occur in drug research. It occurs in both industrial and agricultural environments as well. Foreign companies have patented Indian products like Darjeeling tea, tamarind, turmeric, and neem tree for profitable purposes. Pat Mooney coined the term "bio piracy" to describe the unauthorized use of indigenous knowledge of nature for profit without the consent or compensation of the indigenous peoples who own the knowledge. For example, when bio prospectors exploit indigenous knowledge of medicinal plants developed by the indigenous community, they may lose rights to commercial products derived from the technology. This knowledge is then patented by medical companies, even though the knowledge is not new or created by the patent holder. Those who oppose this practice, such as Greenpeace, argue that it widens the wealth disparity between advanced countries hosting biotech firms and less developed countries with rich biodiversity. During the 1990s, many large pharmaceutical companies shifted their focus from natural products to combinatorial chemistry in response to bio piracy accusations.

Bioprospecting:

It is the process of finding new products to sell that are based on biological resources. Although indigenous knowledge makes sense, bioprospecting has only recently started to apply this knowledge to target screening for bioactive compounds. Natural products or

compounds derived from natural products accounted for one-third of all small molecule new chemical entities approved by the U.S. Food and Drug Administration (FDA) between 1981 and 2010. Although indigenous knowledge makes sense, bioprospecting has only recently started to apply this knowledge to target screening for bioactive compounds. Bioprospecting can include patenting naturally occurring resources that are already widely used, like plant varieties, by commercial entities. It can also involve bio piracy, which is the exploitative appropriation of indigenous forms of knowledge by commercial actors.



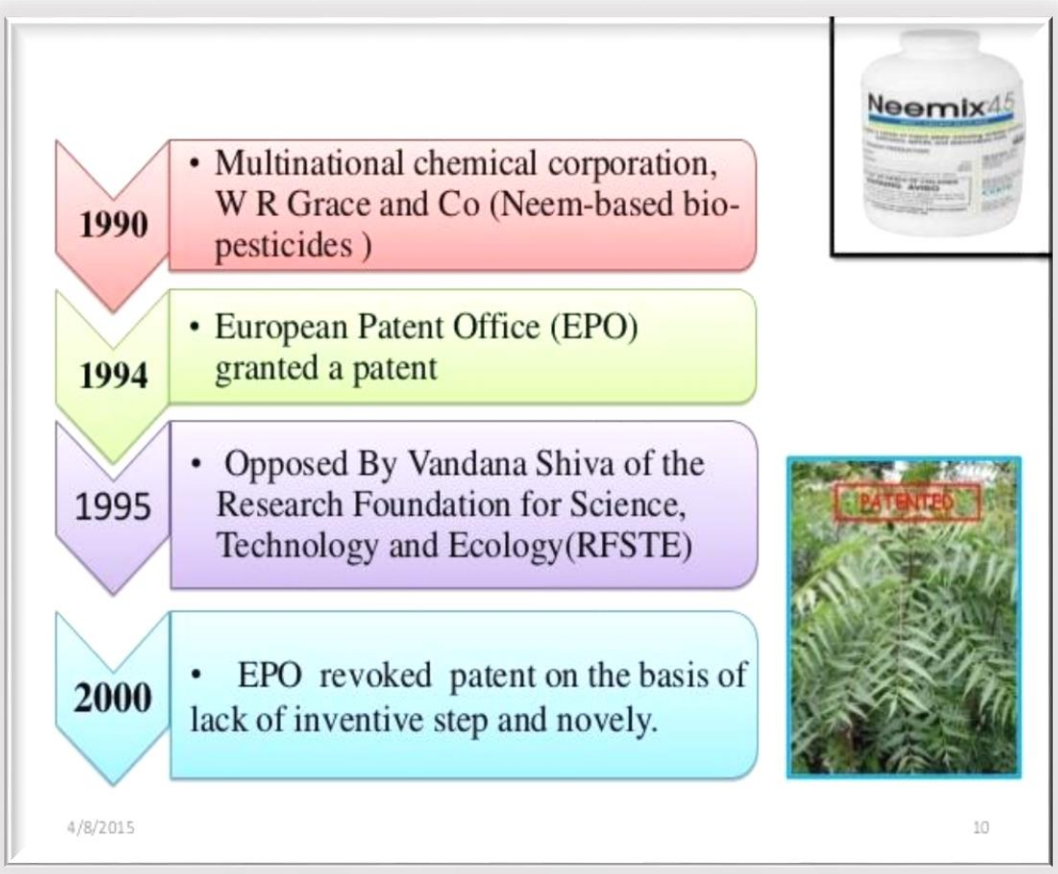
Traditional knowledge (TK):

Having only one definition for traditional knowledge would harm the various types of knowledge held by traditional communities, as the concept is too wide to include them all. There is no simple legal definition that can fully encompass the complex legal and social systems that protect traditional knowledge within indigenous communities. Nevertheless, it is crucial to establish specific demarcation criteria in order to preserve traditional knowledge. The best way to protect is preventing unauthorized use by third parties outside the usual circle. The main emphasis of this form of protection is on the utilization of any indigenous knowledge, whether it be technical, ecological, scientific, medicinal, or cultural, by a traditional community. Based on a report by WHO, approximately 80% of the global population depends on ancient healing methods for treating illnesses. The fundamental aspect of ancestral knowledge is crucial for its main uses in medicine. The indigenous individuals in India traditionally utilize neem for medicinal reasons like first aid, beauty treatments, and managing inflammation and redness caused by different medical issues. This is derived from a medicinal plant called "arogyapaacha".

Traditional knowledge is the term used to describe the collective knowledge, inventions, and customs of indigenous and local communities around the world. Oral passing down of traditional wisdom, honed through centuries of practice and tailored to the environmental and cultural factors of the area, is passed on from one generation to the next. Traditionally, it is commonly shared within the community in various forms such as narratives, tunes, traditions, sayings, societal norms, faiths, ceremonies, regional dialects, and farming techniques like the development of flora and fauna. The majority of traditional knowledge is utilized in practical settings, particularly in horticulture, forestry, fisheries, agriculture, health, and environmental management. [12]

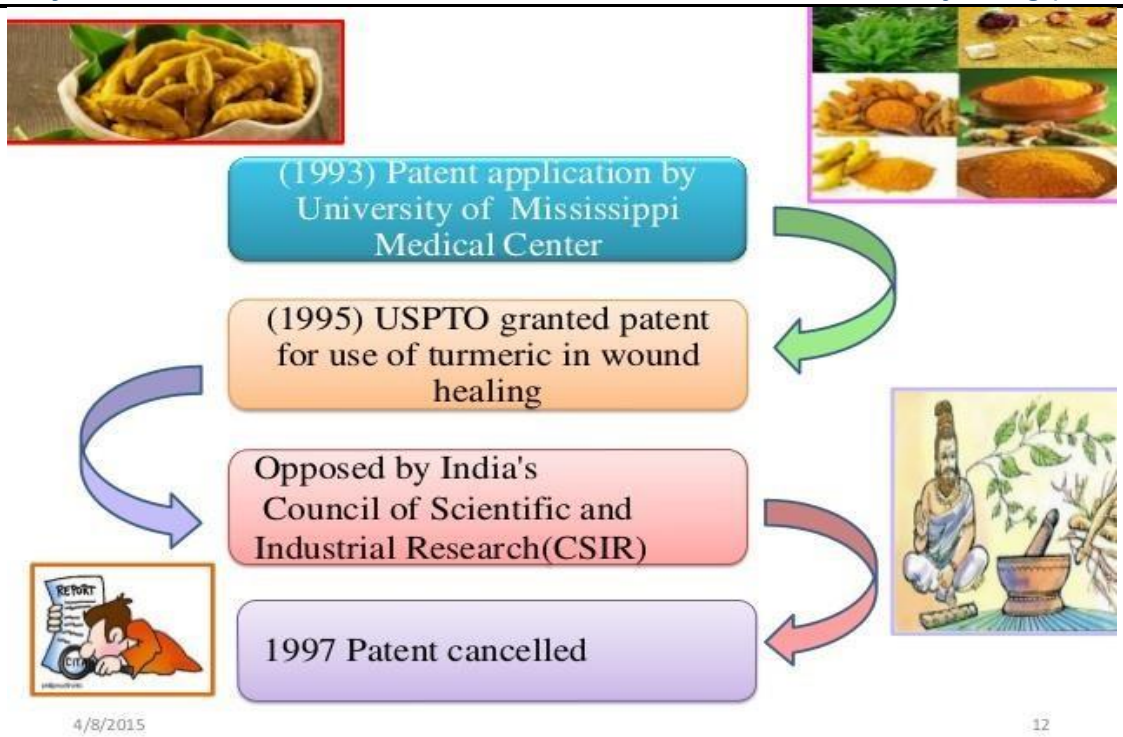
Case study of Neem:

The giant neem tree (Azadirachta indica), a tropical evergreen, can grow as tall as 30 meters and as wide as 2.5 meters. A tree bears a fruit that is yellow or greenish yellow in color and contains a seed inside. The exact birthplace of the tree is not known, but it is predominantly found in India, with an estimated 18 million neem trees. The tree is present in numerous countries. Research has shown that the tree is a popular component in various traditional Indian treatments and medicines, with proven advantages in areas like dental care, pest control, and birth control. Neem trees have become highly popular among Indians due to their extensive growth and many beneficial uses, making them an essential part of their cultural and spiritual heritage. Indian scientists have been researching the Neem tree as a natural pesticide since the 1920s, but it wasn't until 1959 that Westerners, like German entomologist Heinrich Schmutterer, learned of its benefits when he saw Neem trees surviving a locust plague in Sudan. Immediately, he started studying the Neem tree, sparking great interest in the tree's pesticide properties within the western scientific community due to his research. For centuries, Indian farmers have been aware that the Neem tree has the ability to resist locust infestations. Azadirachtin, the main component, can be found in the seeds and, to a lesser degree, the leaves, serving as a safe insecticide for human use. Indian farmers had been using neem seeds as a natural pesticide prior to the discovery of the active ingredient in the late 20th century. Usually, the seeds were crushed, submerged in water or alcohol, and then the resulting mixture was sprayed onto the crops. The rapid decay of the chemical solution, which usually only lasted a few days, restricted the efficacy of this method. W.R. Grace, in partnership with The United States of America represented by The, awarded inventor Robert O. Larsson the initial U.S. patent in 1985 for a storage stable mixture for neem seed extract. The European Patent Office (EPO) was presented with a patent application for the formulation by the Secretary of Agriculture, and after a lengthy evaluation process, the patent was granted to the applicants in 1994. Nevertheless, the EPO restricted the main claim of the patent in comparison to the granted U.S. patent. The adversaries aimed to establish a important legal precedent in their battle against bio piracy by seeking to invalidate the patent based on previous usage and traditional knowledge. The opposition division's decision aligned with their objectives. The claim was denied because it lacked novelty, based on the testimony of a witness who had first-hand experience with the process and could confirm its use among Indian farmers. The Board of Appeal's decision to not confirm if prior art was proven changed the entire focus of the case. They chose the article as the closest prior art based on a scientific study published in a Western journal. Therefore, the assessment of creativity and originality did not rely exclusively on traditional knowledge. The choice was determined by contrasting two scientific papers; the lack of originality was assessed based on the scientific research of the two academicians, not on Indian customary techniques. The board decided to rely on materials for their decision.ssssssss



Case study of Turmeric:

The tropical herb turmeric can be found in East India. Turmeric powder is widely utilized in India for a range of uses such as food flavoring, pharmaceuticals, and dyeing. For instance, it is utilized as an anti-parasitic treatment for various skin conditions, as well as a blood cleanser and remedy for colds. It is essential in the making of many Indian dishes. The University of Mississippi Medical Center was granted a patent from the United States in 1995 for turmeric's wound healing properties. The topic at hand was the use of turmeric powder and its application, either orally or topically, for the purpose of wound healing. The topic of discussion was the application of turmeric powder, both orally and topically, for wound healing. Now it has the sole permission to sell and distribute. The USPTO was provided with evidence of prior art by the CSIR in India, who had raised a concern about the approved patent. Despite the widespread understanding that turmeric has been utilized for generations in Indian homes, locating published studies on the use of turmeric powder for wound healing, whether applied topically or consumed orally, was a daunting task. Following a comprehensive examination, a total of 32 citations were discovered in three distinct languages: Hindi, Urdu, and Sanskrit. Consequently, the USPTO invalidated the patent, acknowledging that the utilization of turmeric for wound healing was a long-standing tradition and the assertions in the patent were obvious and foreseeable. As a result, India's traditional knowledge in the Turmeric case was safeguarded. [4]



Regulatory Issues in India

Herbal Drug Regulation in India:

Drug regulation is the public policy response to the evolving needs of the pharmaceutical industry and the requirements of public health. Hence, regulatory control aims to find a "balance" in protecting and promoting public health while helping the industry comply with legal obligations. Regulatory oversight must be tailored to the characteristics of the regulatory space and actors within it, despite clear regulatory objectives, in order to effectively achieve compliance and address non-compliance. This is the basis of the conceptual framework put forward by "Smart or Responsive Regulation". This is because it is necessary to establish a regulatory structure that considers the diversity and intrinsic characteristics of all parties in the regulatory process, as well as the requirements and goals of regulation. The 1940 Drugs and Cosmetics Act includes rules about the manufacturing and oversight of Ayurveda, Siddha, and Unani (ASU) medicines. This legislation created the Drug Consultative Committees (DCC) and the Drug Technical Advisory Board (DTAB), consisting of several appointed members. The DTAB is the top constitutional authority in the country for making decisions on technical drug issues. It belongs to the Central Drug Standard Control Organization (CDSCO), which is part of the Ministry of Health and Family Welfare. The Drug and Cosmetic Act creates the agencies listed below: [16]

CONCLUSION

Herbal medicines are utilized in Ayurveda, Siddha, Unani, and homeopathic systems of medicine in India. AYUSH Department collaborates with ICMR and CSIR to create safe and efficient AYUSH products for specific diseases and to invent new medications. AYUSH department has implemented a certification scheme for AYUSH medication products. India has created rules for conducting clinical trials on herbal medicines, although the registration process is not effectively controlled. Despite the top priority of Indian drug regulators being the quality of herbal medicines, drug producers are finding it challenging to meet the raised standards for these products. The slow development of the Indian herbal industry is primarily due to its fragmented nature, absence of standardization in raw materials and final products, inadequate research and development, slow modernization, limited marketing strategies, weak branding efforts, and low focus on education and human resource advancement. In order to produce safe and successful herbal medicines in India, it is necessary to establish more thorough guidelines for quality control and quality assurance,

along with marker-based criteria, in addition to proper implementation of DCA. The Department has made efforts to address these issues. Measures are being implemented to promote the development of uniform herbal remedies.

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