

Regulatory Requirements for Herbal Medicines

What are Regulatory Requirements?

- These are rules and laws made by government health authorities to ensure that herbal medicines are safe, effective, and of good quality before they are allowed to be sold to the public.
- Herbal medicines, unlike modern pharmaceuticals, are made from plant parts like leaves, roots, bark, flowers, etc.
- Even though they are natural, they can still cause side effects, contamination, or interactions with other drugs. So, proper regulation is necessary.

Why Regulation is Needed

- To protect public health
- To ensure herbal products are safe and not harmful
- To check that they actually do what they claim (efficacy)
- To maintain uniformity and quality of herbal medicines

How Herbal Medicines are Regulated (Steps)



1. Registration or Licensing:

- Companies must get a license from the authority (like AYUSH in India, FDA in the US) before selling herbal products.

2. Good Manufacturing Practices (GMP):

- These are a set of rules for how to make herbal products properly — with clean equipment, proper storage, trained workers, etc.

3. Quality Testing:

- Herbal products must be tested for:
 - Presence of correct herb species
 - No harmful substances like heavy metals or pesticides
 - Proper concentration of active ingredients

4. Labeling Requirements:

- The label must show:
 - Ingredients
 - Dosage
 - Side effects
 - Storage instructions
 - Expiry date

5. Safety and Efficacy Data:

- In some countries, manufacturers must provide scientific evidence (clinical or traditional use data) that the herb is safe and works effectively.

6. Post-Market Surveillance:

- Even after the product is sold, authorities monitor it for any adverse effects or quality issues.

Country-wise Regulatory Examples

- **India:** Regulated under the Drugs and Cosmetics Act, AYUSH department oversees herbal medicines.
- **USA:** Treated as dietary supplements, regulated by FDA and Dietary Supplement Health and Education Act (DSHEA).
- **Europe:** European Medicines Agency (EMA) classifies herbal medicines under Traditional Herbal Medicinal Products Directive (THMPD).
- **China:** Traditional Chinese Medicine (TCM) is regulated with proper licensing and quality standards.

WHO Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems

What is Pharmacovigilance?

- Pharmacovigilance means monitoring the safety of medicines after they are released in the market — especially tracking adverse drug reactions (ADRs) or side effects.



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