

Unit 5: Herbal Products: India, USA and European Union

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5.1 The herbal regulatory problem: quality, safety and the evidence of use

A herbal product reverses the usual regulatory order. For a synthetic drug, identity is easy and efficacy is hard; for a herbal medicine, efficacy claims rest on generations of use while identity itself is the problem: the starting material is a plant, variable by species, part, season, soil and processing, its chemistry is a mixture of many constituents, the therapeutically relevant ones may be incompletely known, and the finished product's consistency must be built by controlling botany, extraction and markers rather than by assaying a single molecule. The three systems of this unit answer the same three questions differently: how is **quality** assured for a material that cannot be fully specified; how is **safety** judged for products with long human exposure but little formal toxicology; and what **legal route** lets traditional use count as evidence, and for which claims. Read each system below as a distinct weighting of those three answers.

5.2 India: the ASU framework, Schedule T, and the phytopharmaceutical route

India regulates its traditional medicines inside the same statute as modern drugs, in a dedicated chapter: **Chapter IVA of the Drugs and Cosmetics Act 1940** governs Ayurvedic, Siddha and Unani (ASU) drugs, with manufacture licensed by the state licensing authority for ASU drugs and the administrative oversight of the **Ministry of AYUSH**. The quality arm of the system is **Schedule T** of the Drugs and Cosmetics Rules, the good manufacturing practice schedule for ASU medicines, prescribing premises, equipment, record keeping and quality control requirements suited to classical manufacture; pharmacopoeial standards for identity, purity and strength are provided by the Ayurvedic Pharmacopoeia of India and the corresponding Siddha and Unani pharmacopoeias and formularies. The classification does the gatekeeping. **Classical medicines** prepared strictly according to the formulae of the authoritative texts listed in the First Schedule travel the lightest route; **proprietary (patent or proprietary) ASU medicines**, novel combinations and dosage forms, face additional scrutiny of their ingredients and claims; and a list of poisonous substances in **Schedule E(1)** conditions the use of the toxic classical ingredients. Safety evidence in the classical tradition rests on the documented history of use within the texts, with the licensing authority able to demand safety and effectiveness evidence for proprietary products. Beside this traditional framework, India created a scientific bridge: the **phytopharmaceutical** route, introduced through the Drugs and Cosmetics Rules for a purified and standardised fraction of a plant supported by a modern data package of quality, preclinical and clinical evidence, and carried forward in the NDCT framework, which brings a plant derived product through the new drug machinery on evidence standards closer to those of Unit 1 than to those of the classical texts. The two routes together are India's answer: tradition is honoured as evidence within its own system, and a herbal product that seeks modern drug claims can earn them by modern proof.

5.3 USA: dietary supplements under DSHEA and the botanical drug pathway

The United States places most herbal products in an entirely different legal house: under the **Dietary Supplement Health and Education Act 1994 (DSHEA)**, botanicals sold as **dietary supplements** are regulated as a category of food, not as drugs. There is **no premarket approval** and no efficacy demonstration: the manufacturer is responsible for ensuring safety, FDA acts principally after marketing against adulterated or misbranded products, new dietary ingredients require a premarket safety notification, manufacture follows the supplement cGMP of 21 CFR Part 111, and labelling may carry **structure and**

function claims, statements about the product's effect on the structure or function of the body, provided they are truthful, carry the prescribed disclaimer that the claim has not been evaluated by FDA, and are notified to the agency; disease treatment claims remain drug claims and are not permitted on a supplement. The same plant material can, however, choose the drug house: FDA's **Botanical Drug Development guidance** lays out how a complex botanical mixture can be developed under an IND and approved by NDA, with the agency accepting the mixture's inherent variability in exchange for rigorous botanical raw material control, chemical fingerprinting and clinically demonstrated effect; the small number of approved botanical drugs, a green tea extract ointment and a crofelemer product among them, show the route is real but demanding. The contrast is the teaching point of the section: in the USA the same herb is a supplement with structure function claims on a light regime, or a drug on proof, and the manufacturer's choice of claims decides which law it lives under.

5.4 European Union: traditional use registration and the HMPC

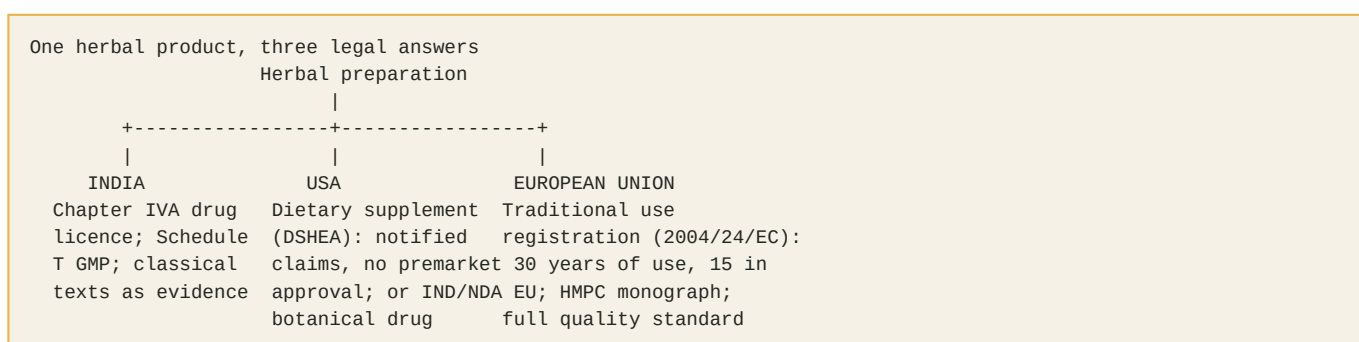
The EU built the route India and the USA gesture toward, a registration designed for tradition itself.

Directive 2004/24/EC, amending the Community code, created the **traditional use registration** for herbal medicinal products: a simplified registration, without clinical efficacy trials, available where the product has been in **medicinal use for at least 30 years, including at least 15 years within the European Union**, has a specified strength and route, is intended for use without medical supervision for conditions suitable to that setting, and is shown safe in the conditions of use, with efficacy accepted as **plausible on the basis of long standing use and experience**. Quality is not simplified: the applicant must meet the full pharmaceutical quality standard, with the herbal substance and preparation defined, tested and controlled to the European Pharmacopoeia and the relevant guidelines. The scientific machinery is the **Committee on Herbal Medicinal Products (HMPC)** at EMA, which prepares **Community herbal monographs**, the agreed assessments of herbal substances setting out their well established or traditional uses, safety and conditions, and the **Community list** of herbal substances whose entries a registration may rely on; a product that follows a monograph's traditional use inherits its assessment, which is what makes the simplified route administrable at scale. Beside it stands the ordinary route: a herbal product with data of its own, or a recognised **well established use** supported by bibliographic evidence, may take a full or bibliographic marketing authorisation and carry therapeutic claims the traditional registration, limited to its traditional indication and a statement that the use is based exclusively on long standing use, cannot.

5.5 The three systems compared

Set side by side, the three systems divide the same plant three ways. India integrates herbals into its drug statute under a traditional chapter with its own pharmacopoeias and GMP schedule, letting classical textual authority carry the evidence within that system, and adds a phytopharmaceutical bridge to the modern new drug route. The USA defaults herbals to the food side of its law as dietary supplements, with no premarket efficacy judgment at all and claims confined to structure and function, reserving the drug route, guidance supported, for sponsors willing to prove a botanical drug. The EU keeps herbals inside medicines law but builds a registration in which documented tradition substitutes for trials, quality remains full standard, and the HMPC's monographs convert individual traditions into common assessments. For the regulatory professional the practical consequences travel with the product: the identical herbal preparation may be a licensed classical medicine in India, a supplement in the USA and a traditionally registered medicine in the EU, with three different labels, three different claim sets and three different evidence files, and a global herbal dossier is therefore written jurisdiction by jurisdiction, quality core shared, legal story retold each time.

Point	India	USA	European Union
Legal home	Drugs and Cosmetics Act, Chapter IVA (ASU drugs); AYUSH oversight	DSHEA dietary supplements (food category); or drug route by choice of claims	Directive 2001/83/EC as amended by Directive 2004/24/EC
Main route	Licence to manufacture ASU drugs; classical and proprietary categories	No premarket approval for supplements; NDA for a botanical drug	Traditional use registration; full or bibliographic authorisation beside it
Evidence of efficacy	Classical textual authority; evidence demandable for proprietary products	None premarket for supplements; full proof for a botanical drug	Long standing use (30 years, 15 in the EU) makes efficacy plausible
Quality standard	Schedule T GMP; ASU pharmacopoeias and formularies	Supplement cGMP, 21 CFR Part 111	Full pharmaceutical quality; European Pharmacopoeia standards
Claims	ASU indications as licensed	Structure and function claims with disclaimer; no disease claims	Traditional use indication, labelled as based on long standing use
Scientific machinery	AYUSH, pharmacopoeia commissions	FDA botanical drug guidance	HMPC, Community herbal monographs, Community list



Herbal products: three jurisdictions, three answers

INDIA	USA	EUROPEAN UNION
Chapter IVA drug licence	Dietary supplement (DSHEA)	Traditional use registration
Schedule T GMP applies	No premarket approval	30 years of use, 15 in the EU
Classical texts as evidence	Structure and function claims	HMPC monographs guide it
Phytopharmaceutical bridge	Or an IND and NDA drug route	Full quality standard kept

One plant, three labels: the quality core is shared, the legal story is retold each time

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Figure: The three routes of section 5.5: India's traditional chapter inside the drug statute, America's supplement default with a drug route by choice, and Europe's registration built on documented tradition (Unit 5, section 5.5).

Frequently Asked Questions

Q: What is a similar biologic in the Indian framework? A similar biologic is a biological product shown to be similar in quality, safety and efficacy to an already authorised reference biologic, demonstrated through a stepwise comparability programme under the CDSCO and DBT Guidelines on Similar Biologics, revised 2016. It is not a generic: the molecules are highly similar, never identical.

Q: What does stepwise development mean for a biosimilar? It means the evidence is built in layers, and each layer's size depends on the layer before. Extensive analytical and functional characterisation

comes first; the preclinical and clinical work that follows is scaled to the uncertainty the characterisation leaves, so a very close candidate may earn a reduced clinical package, and a doubtful one cannot.

Q: How does a biosimilar differ from a generic drug? A generic contains the same molecule as its reference and is approved on pharmaceutical equivalence and bioequivalence. A biosimilar contains a highly similar protein made by a different living process, and is approved on the totality of evidence from a comparability programme, including immunogenicity assessment; in the US it is substitutable at the pharmacy only if separately designated interchangeable.

Q: What is the plasma master file in the EU? The PMF is a standalone dossier of the data on collection, testing and pooling of human plasma, certified by EMA and cited by every marketing authorisation whose product uses that plasma, so the plasma data are reviewed once and relied on many times. It is maintained by annual recertification carrying the updated epidemiological data.

Q: Why do vaccines undergo official batch release when other medicines do not? Because no end product test can fully characterise a vaccine batch, the process consistency evidence must be re examined batch by batch. An official laboratory therefore releases each batch, or a defined sample of batches, before sale: the Central Drugs Laboratory in India, CBER lot release in the USA, and the OMCL network under OCABR in the EU.

Q: What is ISBT 128? ISBT 128 is the global standard, maintained by the International Society of Blood Transfusion and administered by ICCBBA, for identifying and labelling medical products of human origin. Its donation identification number is unique worldwide, and its barcoded data structures carry the product code, blood group and expiry of a blood component in a form any compliant system can read.

Q: How does the EU traditional use registration for herbal products work? Under Directive 2004/24/EC, a herbal medicinal product with at least 30 years of medicinal use, including 15 years in the EU, may be registered without efficacy trials, efficacy being accepted as plausible from long standing use. Quality must meet the full pharmaceutical standard, and the HMPC's Community herbal monographs supply the common scientific assessment the route relies on.

Q: What is Schedule T in the Indian herbal framework? Schedule T of the Drugs and Cosmetics Rules is the good manufacturing practice schedule for Ayurvedic, Siddha and Unani medicines, prescribing the premises, equipment, records and quality control expected of ASU manufacture, alongside the standards of the ASU pharmacopoeias and formularies.

Q: What role does immunogenicity play in biosimilar regulation? It is the risk that analytical similarity can least guarantee away: a highly similar protein may still provoke a different immune response. Every framework in this subject therefore requires validated anti drug antibody and neutralising antibody assessment across the clinical programme, traceability by brand and batch after marketing, and immunogenicity surveillance in pharmacovigilance.

Q: What are TSE and BSE controls for biological products? Because prions cannot be reliably removed or tested out of a biological starting material, control is by risk minimisation at the source: materials are classified by species, tissue infectivity and the geographical BSE risk of their origin, the process's ability to reduce prion load is assessed, and compliance for specified materials is evidenced by an EDQM TSE Certificate of Suitability.

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