Industrial Pharmacognosy

Unit V

International Regulatory Perspectives

Pills & Python Notes

From-zero teaching standard: every technical term is defined before use.

Syllabus coverage: Unit V (7 hours).

CHAPTER 9

Global Regulations, Harmonization, Pharmacovigilance & Monographs

9.1 Learning Objectives

1. Compare how WHO, US FDA, EMA, TGA (Australia) and Canada regulate herbal products.
2. Explain harmonization challenges and mutual recognition.
3. State the importance of safety, efficacy and pharmacovigilance.
4. Name the pharmacopoeias with herbal monographs and what a monograph contains.

DEFINITIONS

- **Regulation:** Government rules that decide what can be sold as a medicine and under what conditions.
- **Dietary Supplement (USA):** Under the DSHEA Act (1994), herbs in the USA are mostly sold as dietary supplements (foods), not as approved drugs — the maker is responsible for safety; FDA acts mainly after problems appear.
- **Traditional Herbal Medicinal Product (EU):** In Europe, herbal products can be registered via a simplified traditional-use route if used safely for 30 years (15 within EU) — no full clinical trials needed, but quality and safety data are mandatory.
- **TGA-ARG (Australia):** Therapeutic Goods Administration's Australian Regulatory Guidelines for Complementary Medicines — most herbal products are "listed" (low risk) with pre-market assessment of quality.
- **Natural Health Products (Canada):** Regulated by Health Canada's NHP Directorate — products need a licence with evidence of safety/efficacy and a Natural Product Number (NPN).
- **Pharmacovigilance:** Detecting, assessing and preventing side effects of medicines — including herbal ones.
- **Monograph:** An official book entry describing one drug: identity, purity tests, assay and limits.

9.3 Terminology

Term	Simple meaning
Harmonization	Different countries accepting similar rules
Mutual recognition	Country A accepting country B's approvals/tests
DSHEA	US Dietary Supplement Health and Education Act
EMA	European Medicines Agency
NPN	Natural Product Number (Canada's licence number)

9.4 Explanation — Global regulations compared (table)

Region	Framework	Herbal products treated as	Key point (simple)
WHO	Guidelines (GACP, quality control methods, traditional medicine strategy)	Guidance, not law	Sets the global reference many countries copy
USA (FDA)	DSHEA	Dietary supplements	Maker ensures safety; FDA acts on complaints; no pre-approval like drugs
EU (EMA)	Traditional Herbal Medicinal Products scheme	Medicines via simplified registration	30-year traditional use (15 in EU) can replace full trials; quality mandatory
Australia (TGA)	ARG for Complementary Medicines	Listed (low-risk) or Registered medicines	Most herbals are "listed" with quality assessment
Canada (NHP)	NHP Regulations	Licensed natural health products	Needs product licence + NPN + evidence

Key takeaway: the same ashwagandha capsule is a "dietary supplement" in the USA, a "traditional herbal medicine" in the EU, a "listed medicine" in Australia and an "NHP" in Canada — one product, four legal identities.

9.5 Harmonization challenges & mutual recognition

Technical concept: Because rules differ, a product approved in India may need fresh testing for Europe — costly and slow. Harmonization (ICH, WHO efforts) tries to align quality/safety/efficacy expectations; mutual recognition means accepting another regulator's GMP inspection or data.

Simple explanation: It is like driving licences — your Indian licence is not automatically valid everywhere; some countries "recognize" it, others ask for a new test. Challenges: different legal definitions of "herbal medicine", different traditional-use evidence rules, different contaminant limits, language and documentation gaps.

India context: AYUSH Premium Mark and WHO-GMP help Indian products enter foreign markets; industry associations push for mutual recognition of AYUSH standards.

9.6 Safety, efficacy & pharmacovigilance

- **Safety:** Herbs can cause allergy, liver injury (rare), and interactions (e.g., St. John's Wort + many drugs). "Natural ≠ always safe."
- **Efficacy:** Traditional use + modern clinical data together build the proof; regulators ask for evidence matching the claim.
- **Pharmacovigilance:** India runs a pharmacovigilance programme (PvPI) that also captures AYUSH/herbal adverse reactions; globally, WHO's Uppsala centre collects reports. Pharmacists must report suspected herbal ADRs.

9.7 Pharmacopoeial monographs (table)

Pharmacopoeia	What it covers (herbal)	Simple note
Indian Pharmacopoeia (IP)	Herbal drug monographs with identity, purity, assay	Legal standard in India
USP – Herbal Medicines & Dietary Supplements	Herbal monographs + dietary supplement chapters	US quality benchmark
Ayurvedic Pharmacopoeia of India (API)	Ayurvedic raw drugs and formulations	Ministry of AYUSH official
Unani Pharmacopoeia of India (UPI)	Unani raw drugs and formulations	Ministry of AYUSH official

What a monograph contains (simple): definition & source → characters (macro/microscopy) → identity tests (TLC/HPLC) → purity tests (ash, extractives, heavy metals, microbial limits, aflatoxins, pesticides) → assay of marker → storage.

9.8 Diagrams (describe for drawing)

- **Diagram 1 — "One capsule, four passports":** one ashwagandha bottle with four stamps: USA (supplement), EU (traditional medicine), Australia (listed), Canada (NPN).
- **Diagram 2 — Monograph anatomy:** labelled book page showing definition → identity → purity → assay sections.

INFOGRAPHIC CONCEPT

Herbal Goes Global — Know the Rules USA: supplement (DSHEA) | EU: traditional-use registration | Australia: listed medicine (TGA) | Canada: licensed NHP (NPN) | WHO: global guidance **Harmonization dream:** one quality dossier, accepted everywhere. **Pharmacist's duty:** report herbal side effects — pharmacovigilance saves lives. **Monograph = the law book of quality** (IP, USP, API, UPI).

EXAMPLES

1. An Indian company registers its turmeric capsule in the EU under the traditional-use route citing long Ayurvedic use.
2. A Canadian NPN on the label tells the buyer the product is licensed by Health Canada.
3. A pharmacist reports a suspected liver reaction to a multi-herb slimming product to the pharmacovigilance centre.

ANALOGIES

- **Different regulations = different school boards:** same student (product), but CBSE/ICSE/State board have different syllabi — you prepare per board.
- **Pharmacovigilance = CCTV for medicines:** watches for problems after launch.

PHARMACY RELEVANCE

Regulatory-affairs pharmacists prepare dossiers per region; community pharmacists counsel on realistic claims and report ADRs; industry pharmacists ensure labels meet each market's rules.

INDIA CONTEXT

Ministry of AYUSH + IPC + export promotion councils help Indian herbal industry go global; PvPI includes AYUSH drugs in ADR reporting.

KEY POINTS

- USA: DSHEA dietary supplements; EU: traditional-use registration; Australia: TGA listed; Canada: NHP licence + NPN; WHO: guidance.
- Harmonization challenges: different definitions, evidence rules, limits; mutual recognition helps.
- Safety/efficacy/pharmacovigilance are non-negotiable everywhere.
- Monographs: IP, USP herbal & dietary supplements, API, UPI — contain identity, purity, assay.

COMMON CONFUSIONS

- **Dietary supplement vs drug (USA):** supplements need no FDA pre-approval; drugs do.
- **Listed vs registered (Australia):** listed = low risk, lighter assessment; registered = higher claims, full evaluation.
- **API (Ayurvedic Pharmacopoeia) vs API (Active Pharmaceutical Ingredient):** same abbreviation, totally different meaning — read context!

COMMON MISTAKES

- Saying "WHO approves herbal drugs" — WHO gives guidelines; countries approve.
- Claiming EU needs no evidence — it needs traditional-use evidence + full quality data.
- Forgetting pharmacovigilance applies to herbals too.

MNEMONIC

- Regions: **"W U E T C"** — **W**HO, **U**SA, **E**U, **T**GA, **C**anada ("**W**orld **U**ses **E**very **T**raditional **C**ure").
- Monographs: **"I U A U"** — **I**P, **U**SP, **A**PI, **U**PI.

EXAM SUMMARY

Global herbal regulation differs: WHO gives guidance; US FDA regulates herbals as dietary supplements under DSHEA; EMA allows traditional-use registration; Australia's TGA lists complementary medicines; Canada licences Natural Health Products with NPN. Harmonization and mutual recognition face challenges of differing definitions and evidence rules. Safety, efficacy and pharmacovigilance are essential everywhere. Official monographs appear in the IP, USP (Herbal Medicines & Dietary Supplements), Ayurvedic Pharmacopoeia of India and Unani Pharmacopoeia of India.

ONE-MINUTE REVISION

- W U E T C: WHO, USA, EU, TGA, Canada.
- USA = supplement; EU = traditional-use; Australia = listed; Canada = NPN.
- Harmonization = same rules everywhere (still a work in progress).
- Report herbal ADRs — pharmacovigilance.
- I U A U: IP, USP, API, UPI monographs.

9.20 Exam questions

Short answer:

1. How are herbal products regulated in the USA under DSHEA?
2. What is the EU traditional-use registration route?
3. Define pharmacovigilance and its relevance to herbals.
4. What does a herbal monograph contain?

Long answer:

5. Give an overview of global regulations for herbal products (WHO, US FDA, EMA, TGA, Canada NHP).
6. Discuss harmonization challenges and mutual recognition of traditional medicine.

MCQs:

7. Under DSHEA, herbal products in the USA are: (a) Approved drugs (b) Dietary supplements (c) Banned (d) Medical devices — **Answer: (b)**
8. Canada's herbal licence number is called: (a) NPN (b) DIN (c) API (d) GMP — **Answer: (a)**
9. TGA belongs to: (a) USA (b) Australia (c) Canada (d) UK — **Answer: (b)**
10. API (Ayurvedic) is published by: (a) IPC (b) Ministry of AYUSH (c) WHO (d) USFDA — **Answer: (b)**

Viva:

11. Why can't one dossier be used in all countries directly?
12. Give one example each of safety and efficacy concern for herbals.

Application-based:

13. Your company wants to sell an ashwagandha capsule in the USA and the EU. List the regulatory pathway for each in two lines.

UNIT V — REFERENCES

1. Ayurvedic Pharmacopoeia Committee. Ayurvedic Pharmacopoeia of India. Government of India, Ministry of AYUSH.
2. Unani Pharmacopoeia Committee. Unani Pharmacopoeia of India. Government of India, Ministry of AYUSH.
3. European Medicines Agency. Herbal Monographs and Regulatory Guidelines.
4. Indian Pharmacopoeia Commission. Indian Pharmacopoeia. Government of India.
5. United States Pharmacopeial Convention. United States Pharmacopeia.
6. Natural Health Products Directorate. Regulatory Framework for Natural Health Products.
7. International Council for Harmonisation. ICH Guidelines on Quality, Safety, Efficacy and Multidisciplinary Topics.
8. World Health Organization. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants.
9. Drugs and Cosmetics Act and Rules (India). Government of India.
10. Indian Drug Manufacturers' Association. Indian Herbal Pharmacopoeia.