



v. Knowledge of pharmaco-vigilance in Āyurveda

v. Knowledge of pharmaco-vigilance in Āyurveda and conventional system of medicine

Pharmacovigilance (PV)—“the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem” (WHO)—is crucial for **patient safety** in both **conventional** and **traditional** (Āyurvedic) healthcare systems. This overview combines **historical contexts**, **present frameworks**, **challenges**, **case examples**, and **future directions** to illustrate how **pharmacovigilance** ensures the safe, effective, and evidence-based use of medicines.

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Definition and Core Objectives of Pharmacovigilance

- **Definition:** Per WHO, pharmacovigilance oversees the **safety** of medicines post-marketing, rapidly identifying and mitigating drug-related risks.
- **Objectives:**
 1. **Ensure patient safety** by monitoring adverse drug reactions (ADRs).
 2. **Promote evidence-based prescribing** and optimize therapeutic outcomes.
 3. **Communicate** findings to healthcare professionals and the public, facilitating informed risk-benefit decisions.

Historical Background

Thalidomide Tragedy (1960s)

1. **Incident**
 - Thalidomide, launched as a sedative/anti-nausea drug for pregnant women, caused severe congenital malformations (*phocomelia*) in >20,000 infants worldwide.
2. **Global Impact**
 - **USA (1962):** Amended the Federal Food, Drug, and Cosmetic Act to mandate comprehensive safety and efficacy data pre-approval.
 - **UK (1964):** Launched the **Yellow Card Scheme** for ADR reporting.
 - **WHO (1968):** Established the **Programme for International Drug Monitoring**, anchoring a global PV network.

Broader Pharmacovigilance Systems

- **ICH (International Council for Harmonisation):** Issues guidelines for PV in conventional medicine.
- **WHO Guidelines (2004):** Called for the inclusion of **traditional medicines** in national PV systems, acknowledging their widespread usage and potential risks if unmonitored.

Pharmacovigilance in India

Conventional Medicine (Allopathic)

1. **Establishment**
 - **2003: Pharmacovigilance Programme of India (PvPI)** under the Central Drugs Standard Control Organization (CDSCO).
 - Collaborates with WHO-Uppsala Monitoring Centre (UMC) for global signal detection.
2. **Key Features**
 - **ADR Reporting:** Vigiflow software centralizes data.
 - **Regulatory Oversight:** Monitors post-marketing drug safety, issues alerts on potential hazards.

Ayurveda, Siddha, and Unani (ASU) Medicine

1. Traditional Perception of Safety

- ASU drugs historically deemed “safe” due to natural origin. Yet, sporadic ADRs (heavy metal contamination, incorrect usage) raised concern for formal PV.

2. Milestones

- 2007:** IPGT & RA, Jamnagar workshop: “Pharmacovigilance for Ayurvedic Drugs.”
- 2008:** Launch of the **National Pharmacovigilance Programme for ASU Drugs (NPP-ASU)**, sponsored by WHO.
- Objective:** Collect, analyze, and disseminate ADR data for safe use of classical and proprietary Ayurvedic formulations.

3. NPP-ASU Implementation

- Reporting Form:** Specially designed for suspected ADRs with herbal details, classical references if any.
- Encourages multi-level engagement: practitioners (reporting), manufacturers (quality compliance), regulators (signal detection).

Scope of Pharmacovigilance in Āyurveda

Challenges

1. Complex Formulations

- Many ASU drugs are multi-ingredient (polyherbal or herbo-mineral), complicating pinpointing the culprit ingredient in ADRs.

2. Lack of Awareness

- Underreporting from practitioners or patients due to cultural assumptions of no side effects.

3. Standardization Issues

- Inconsistent raw materials or varied manufacturing protocols hamper uniform safety profiles.

Key Areas of Focus

1. Heavy Metal Toxicity

- Bhasma or Rasa preparations containing mercury, lead, or arsenic must comply with permissible limits (e.g., lead ≤ 10 ppm, arsenic ≤ 3 ppm as per national guidelines).

2. Herb-Drug Interactions

- E.g., *Ashwagandha* potentially interacts with sedatives; *Guduchi* might potentiate certain immunosuppressants.

3. Adulteration Detection

- Checking for steroid contamination or substitution with cheaper herbs, essential for consumer safety.

Implementation Strategies for Pharmacovigilance in Āyurveda

NPP-ASU Framework

1. Data Collection

- ADR forms from AYUSH hospitals, clinics, pharmacies.
- Real-time reporting of minor or major suspected reactions.

2. Analysis

- Trend detection, signal generation (if multiple reports converge on a specific drug).
- Safety alerts or recall advisories if severe risk emerges.

3. Communication

- Disseminate safety information to practitioners, public, and government agencies.
- Revisions in labeling or dosage if needed.

Role of Stakeholders

1. Practitioners



- Document ADRs meticulously, counsel patients on rational use and potential side effects.
2. **Manufacturers**
 - Comply with GMP (Schedule T) and QC protocols (heavy metals, microbial load).
 3. **Regulators**
 - Enforce PV guidelines, update safety bulletins, refine schedule E(I) or API standards if a pattern emerges.

Case Studies

Heavy Metal Toxicity in Bhasma

- **Issue:** Reports of lead/mercury poisoning from improperly calcined bhasma (e.g., *Nāga bhasma*).
- **Resolution:** Stricter **Schedule T** enforcement, ensuring multi-stage śodhana and final product testing for permissible heavy metal limits (≤ 10 ppm lead, etc.).

Herb-Drug Interactions

- **Example:** *Ashwagandha* (*Withania somnifera*) co-administered with sedatives → possible additive sedation.
- **Solution:** Label disclaimers, counseling on concurrent usage with psychotropics or anxiolytics.

Future Directions

1. **Integration with Modern Systems**
 - Linking **NPP-ASU** and **PvPI** for a **comprehensive** national PV database.
 - Encourages consistent training in BAMS curricula on ADR reporting and coding.
2. **Technological Advancements**
 - AI-based signal detection for large volumes of AYUSH data.
 - Blockchain to ensure authenticity of supply chains, addressing adulteration.
3. **Global Collaboration**
 - Share data with WHO's T&CM pharmacovigilance network for mutual knowledge exchange.
 - Align labeling/warnings to match EU or USFDA norms, facilitating export acceptance.

Conclusion

Pharmacovigilance is pivotal in **protecting patients** from adverse reactions, whether from allopathic or **Āyurvedic** medicines. Historically spurred by the **thalidomide** tragedy, PV has expanded to **traditional systems**—including **Āyurveda, Siddha, and Unani (ASU)**—due to rising global usage of herbal remedies. In India, while the **Pharmacovigilance Programme of India** addresses allopathic drugs, a parallel **National Pharmacovigilance Programme for ASU (NPP-ASU)** ensures that **classical** and **proprietary** Ayurvedic medicines also undergo systematic ADR monitoring.

By highlighting challenges such as **heavy metal toxicity, herb-drug interactions, and adulteration**, PV in **Āyurveda** fosters **safe prescribing** and heightened consumer confidence. Ongoing initiatives—**technical training, research** on synergy vs. toxicity, **regulatory** synergy with global bodies—signal a future where AYUSH medicines are both **traditionally authentic** and **scientifically validated**, ensuring that integrative healthcare truly benefits patients worldwide.