

Pharmacovigilance of drugs of natural origin

WHO Guidelines for Safety Monitoring of Natural Medicines

Introduction

- The World Health Organization (WHO) has developed guidelines for monitoring the safety of herbal medicines and traditional medicines.
- These guidelines help countries establish systems for detecting and reporting adverse reactions associated with natural medicines.

Objectives of WHO Guidelines

1. Improve Patient Safety

- WHO guidelines aim to reduce health risks associated with natural medicines.
- Early detection of adverse reactions improves patient protection.

2. Promote Rational Use of Herbal Medicines

- Proper monitoring ensures safe and effective use of herbal products.
- It helps healthcare professionals make informed decisions.

3. Strengthen Pharmacovigilance Systems

- WHO encourages countries to establish national pharmacovigilance programs.
- These programs collect and analyze safety information.

4. Detect Unknown Adverse Reactions

- Monitoring helps identify new adverse effects that were not previously recognized.
- Early detection prevents widespread harm.

Key Components of WHO Guidelines

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A. Collection of Safety Information

- Information regarding adverse reactions should be collected from healthcare professionals and patients.
- Reports should include complete details of the medicine and reaction.

B. Assessment of Adverse Events

- Reported adverse reactions should be scientifically evaluated.
- Assessment helps determine whether the reaction is related to the herbal medicine.

C. Documentation and Reporting

- All adverse events should be properly documented.
- Safety data should be reported to national pharmacovigilance centers.

D. Signal Detection

- Analysis of reports helps identify patterns of adverse reactions.
- These patterns may indicate previously unknown safety concerns.

E. Risk Communication

- Safety information should be communicated to healthcare professionals and the public.
- Timely communication reduces potential risks.

WHO Recommendations for Herbal Medicines

A. Proper Identification of Herbal Materials

- Herbal medicines should be accurately identified before use.
- Misidentification may cause serious health risks.

B. Quality Assurance

- Herbal products should meet established quality standards.
- Contamination and adulteration should be prevented.

C. Standardization

- Herbal medicines should be standardized to ensure consistent quality and efficacy.

D. Monitoring of Interactions

- Possible interactions with foods and conventional medicines should be monitored carefully.

AYUSH Guidelines for Safety Monitoring of Natural Medicines

Introduction

- AYUSH stands for Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homoeopathy.
- The Ministry of AYUSH, Government of India, has established a pharmacovigilance program for monitoring the safety of traditional medicines.

Objectives of AYUSH Pharmacovigilance Program

1. Monitoring Safety of AYUSH Medicines

- The program collects information on adverse reactions associated with AYUSH products.
- Continuous monitoring improves drug safety.

2. Detection of Adverse Drug Reactions (ADRs)

- The system identifies and evaluates adverse reactions occurring after the use of AYUSH medicines.
- Early identification helps prevent further complications.

3. Creation of Safety Database

- Information collected from various sources is maintained in a central database.
- The database supports future research and regulatory decisions.

4. Promotion of Safe Use

- AYUSH guidelines encourage proper use of traditional medicines.
- Safe use increases public confidence in traditional healthcare systems.

Components/ Structure of AYUSH Pharmacovigilance System

A. National Coordinating Centre

- The National Coordinating Centre supervises pharmacovigilance activities across the country.
- It collects and analyzes adverse reaction reports.

B. Intermediary Pharmacovigilance Centres

- These centers coordinate pharmacovigilance activities at regional levels.
- They provide support and training.

C. Peripheral Pharmacovigilance Centres

- These centers receive adverse reaction reports from healthcare providers and patients.
- Reports are forwarded for further evaluation.

D. Reporting and Analysis

- Adverse reactions are documented and analyzed systematically.

- Findings help improve medicine safety.

Functions of AYUSH Pharmacovigilance Program

A. Collection of ADR Reports

- Information regarding adverse reactions is collected systematically.

B. Assessment of Safety Data

- Reported cases are analyzed to determine causality and severity.

C. Development of Safety Alerts

- Safety warnings are issued when necessary.

D. Promotion of Safe Use

- Educational programs encourage safe and rational use of AYUSH medicines.

Spontaneous Reporting Schemes For Biodrug Adverse Reactions

Introduction

- A spontaneous reporting scheme is a system in which healthcare professionals, manufacturers, and patients voluntarily report suspected adverse reactions associated with medicines.
- It is one of the most important methods used in pharmacovigilance.

Definition

- Spontaneous reporting is the voluntary submission of information about suspected adverse drug reactions to a pharmacovigilance center.

Objectives of Spontaneous Reporting

1. Early Detection of Safety Problems

- New adverse effects can be identified quickly.

2. Monitoring of Marketed Products

- Safety of medicines continues to be monitored after marketing.

3. Risk Assessment

- Collected data helps evaluate risks associated with medicines.

4. Improvement of Drug Safety

- Appropriate regulatory actions can be taken when needed.



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