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Challenges in Ayurvedic Pharmacovigilance: A Review of Adverse Drug Reactions in Traditional Medicine.

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ABSTRACT

Efficacy and safety are the two major concerns about any drug. While efficacy of a drug can be detected with relative ease, the same cannot be said about the safety. Because, the adverse effects of drug may be un-common but very serious. Many patients may be affected and subjected to a potential risk before the relationship with the drug is established. This concern about the safety of a drug gave birth to a new branch in pharmacology and this branch is known as Pharmaco vigilance.

Ayurveda, the ancient system of medicine rooted in Indian tradition, is widely considered safe due to its natural origin and holistic principles. Ayurveda does have limitations though, much like any other medical approach. With increasing global usage and commercialization of Ayurvedic drugs, the incidence of Adverse Drug Reactions (ADRs)—although relatively rare—has been on the rise. This has led to a greater emphasis on pharmacovigilance, even within traditional systems of medicine.

Keywords: *Pharmacovigilance, Traditional Medicine, Drug Reaction, Ayurveda.*

INTRODUCTION

The science and practices involved in identifying, evaluating, comprehending, and preventing pharmacological side effects or other potential drug-related issues are known as pharmacovigilance.

In general, it is the science of collecting, documenting, investigating, analysing, and evaluating data from patients and healthcare professionals.

Pharmacon (Greek) - the Drug

Vigilance (Latin) - To keep awake / to be Alert / to keep watch.

ROLE OF PHARMACO VIGILANCE [1]

- To recognise, quantify, and record issues related to drugs.
- To contribute to reduce the risk of drug related problems on health care systems.
- To increase knowledge and understanding of factors and mechanism which are responsible for drug related injuries.

BENEFITS OF PHARMACO VIGILANCE

- To prevent ADRs & ADEs in hospitals.
- Provides information about ADRs in general population.
- Use of drug during a clinical trial is under controlled condition. So, post marketing surveillance of drug is more important.
- There is difference in diseases, prescribing practices, genetic comparison of population, diet & traditions of every population. Hence every country needs to have its own Pharmaco-vigilance Programme. Because data derived from within a country has relevance for that particular population and may be helpful for national regulatory decision making.

AIMS

- Identifying new information about hazardous effects of drugs.
- The assessment and articulation of the risks and advantages associated with pharmaceuticals.
- Early identification of undesirable medication side effects.
- Preventing harm to the patients.
- To take appropriate and regulatory actions.
- To ensure safer use of drugs.

Diagrammatic presentation of working pattern and reporting of Pharmaco vigilance and its functioning. [1]

CDSCO – National Pharmaco-vigilance Centre

(NE) (SW) – Zonal Pharmaco-vigilance Centre

(N) (E) (C) (S) (W) - Regional Pharmaco-vigilance Centre

- NPP – National Pharmaco vigilance Programme.
- CDSCO – Central Drug Standard Control Organization, launched on 23rd Nov 2004 & functioning since 1st Jan 2005 in India.

PHARMACO-VIGILANCE FOR ASU (AYURVEDA, SIDDHA & UNANI) DRUGS [2]

AIM

To establish & manage a database of ADRs for making uniformed regulatory decisions regarding marketing authorization of drugs in India for ensuring safety of drugs.

Actions by NPP (ASU)

- Preparation of protocol for NPP (ASU) drugs.
- Development of ADRs reporting form.
- Training Programme of the coordinators of RPCs, PPCs.
- ROTP on Pharmacovigilance for teachers of Ayurveda.
- Arranging different promotional activities.

FUNCTION OF NATIONAL PHARMACO-VIGILANCE COMMITTEE

- Reports of possible adverse drug reactions are continuously collected.
- Assessment of case reports.
- Quality control.
- Identification of reports.
- Transmission of reports to Upasala monitoring committee in suitable format.
- Generation of hypothesis and identification of signals.
- Communicating relevant safety information to regional sub centers.
- Further investigation of risk factors and pharmacological mechanism.
- Receipt and communication of appropriate information, literature, reports and data between agencies.
- Provision of feedback reports.
- Timely advice on drug safety issue to healthcare providers, professionals, and public (Consumers).
- Education and Training.
- Information sharing at Regional and Global levels.

ADR (ADVERSE DRUG REACTION) & ADE (ADVERSE DRUG EVENT) [3]

ADR is a response to medicine which is noxious and unintended, which occurs at doses normally used in man.

ADE is any undesirable medical condition that may occur when taking medication but does not always have any connection to the course of therapy.

Reason of ADR of Ayurvedic Medicine

देशकालप्रमाणानां सात्म्यासात्म्यस्य चैव हि। सम्यग्योगोऽन्यथा होषां पथ्यमप्यन्यथा भवेत् ।। २९३।।च चि 30[4]

यत् किञ्चिद्दोषमास्त्राव्य न निर्हरति कायतः। आहारजातं तत् सर्वमहितायोपपद्यते ॥ ८५।च सू)[5]

All drugs and diet which dislodge the various dosas but do not expel them out of the body are to be regarded as unwholesome.

Result of ADR according to Ayurveda

Drug drug interaction or drug diet interaction –

1. Blockage of the action site
2. Excessive mala production
3. Production is something new
4. Breaking of the drug each other

Difficulties of ADR reporting in Ayurveda

- Lack of knowledge about the medicine
- Lack of knowledge about the preparation
- Lack of knowledge about the ingrediance
- Physician thought to establish as a no side effect
- Physician thought about loss of their popularity
- No standardization and quality control
- Common belief is no side effect

Steps Forward

1. Training and capacity building for Ayurvedic professionals in pharmacovigilance.

2. Inclusion of pharmacovigilance modules in undergraduate and postgraduate AYUSH curricula.

3. Development of standardized monographs and pharmacopeial standards.

4. Encouraging research and clinical trials to identify and mitigate ADRs.

5. Public awareness campaigns to educate consumers about safe use of Ayurveda.

Tools for Reporting ADRs

To facilitate ADR reporting, the Ministry of AYUSH has developed:

Ayush Sanjivani Portal: An online platform for reporting ADRs and accessing information on ASU&H drugs.

SiddAR Mobile App: A smartphone app designed to make ADR reporting simple for consumers and practitioners.

Recent ADR Data in Ayurveda Adverse Drug Reactions (ADRs)

1. AYUSH Ministry Reports (Jan–Oct 2023)[2]

355 suspected ADRs related to Ayurvedic medicines were reported under the Pharmacovigilance Program of AYUSH.

None were classified as serious—they were mild, self-limiting, and required no hospitalization or resulted in any death.

2. COVID-19-related ADRs (Earlier Data for Context)Between April 2020 and April 2022, 142 adverse events were reported with Ayurvedic medicines used during COVID treatment; 17 were confirmed ADRs

Misleading Advertisements & Regulatory Actions

1. Supreme Court Action on Patanjali

In Feb 2024, India's Supreme Court temporarily barred Patanjali Ayurved from publishing misleading ads that claimed "permanent cures" for diseases like asthma and diabetes.

In April 2024, Uttarakhand State Authority suspended licenses of 14 Patanjali products.[6]

2. First Regulatory Warning in Kerala[7]

In Jan 2025, Kerala's Deputy Drug Controller (Ayurveda) issued its first-ever warning to Pankajakasthuri Herbals for publishing an ad without approval.

The violation was under Rule 170, which requires pre-approval of ads for Ayurvedic products.

: 3. Spike in Misleading Ads[8]

As of Nov 2024, over 9,032 complaints were filed regarding misleading advertisements of AYUSH products, showing a rising trend.

Regulatory Reforms & Monitoring

In Jan 2025, a Parliamentary panel recommended stronger post-marketing surveillance and ADR reporting mechanisms for Ayurvedic drugs, especially those with high levels of heavy metals.

CONCLUSION

While Ayurveda offers valuable therapeutic options, it's crucial to recognize that ADRs can occur, especially with improper use or contamination. Strengthening pharmacovigilance systems, enhancing quality control, and increasing awareness among practitioners and consumers are essential steps to ensure the safe use of Ayurvedic medicines.

If you need assistance with accessing ADR reporting tools or require more detailed information on specific Ayurvedic formulations, feel free to ask.

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