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PHARMACOVIGILANCE FOR AYURVEDA, SIDDHA, AND UNANI DRUGS: ENSURING SAFETY AND EFFICACY

Dr. Simaran Shahmadar*[1], Dr. Devendra Singh Chahar[2], Dr. Rameshwar Lal[3] and Dr. Sankalp Sharma[4]

[1]PG Scholar, Department of Kayachikitsa, PGIA, DSRRAU, Jodhpur, India.
[2]Associate Professor & HoD, Department of Maulik siddhant, PGIA, DSRRAU, Jodhpur.
[3]Assistant Professor, Department of Maulik Siddhant, PGIA, DSRRAU, Jodhpur.
[4]Assistant Professor Department of Maulik Siddhant PGIA DSRRAU Jodhpur.

***Corresponding Author: Dr. Simaran Shahmadar**

PG Scholar, Department of Kayachikitsa, PGIA, DSRRAU, Jodhpur, India.

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ABSTRACT

The Ayush system of medicine is an age-old medical system in our country. In times of pandemics like COVID-19, it has proven beneficial in preventing, treating, and managing post covid complications. However, there are some side effects associated with taking ASU drugs. Pharmacovigilance (PV) is an essential field for ensuring patient safety in all aspects of medications that are consumed or injected. India's PV industry is still in its early stages, with much to learn about assuring safe execution of operations and projects. The biggest issue in India is the underreporting of adverse drug reactions (ADRs). There is a growing number Adverse drug reactions (ADRs) can lead to hospitalization and make it difficult to determine the specific reason, especially when many medicines are used concurrently. In this overview, we will look at the many sorts of evaluation scales.

KEYWORDS: *Ayush* system, ASU drugs, pharmacovigilance, Adverse drug reactions, ADR assessment.

INRTODUCTION

Ayurveda, Siddha, and Unani are traditional systems of medicine that have been practiced for centuries in India and other parts of the world. These systems use natural herbs, minerals, and animal products to treat various medical conditions and promote health and well-being. While these traditional medicines are considered safe and effective by many, there is a growing need for pharmacovigilance to monitor the safety of Ayurveda, Siddha, and Unani (ASU) drugs and ensure their efficacy in clinical practice. It detects and assesses adverse drug reactions, provides advice for safe use of ASU medications, and manages ADRs.

NEED & SCOPE

Worldwide mevement for the improvement of patient safety is gaining momentum, hence the subject of drug safety becomes even more prominent in the present day scenario.

In context of ASU, with increased use of drugs of these systems, the scope for adultera- tion, preparation of counterfeit drugs and development of formulations which don't have concep- tual basis in ASU system has increased. Further cultivation of medicinal plants with laboratory generated species is being attempted on the basis of chemical composition and is likely to be used in increased manner for commercial purpose. These changes may have profound impact on safety and efficacy of ASU drugs in the market. Hence a machanism is required to put in place to address them. This became the basis of pharmacovigilance setup for ASU drugs in India.

ASU system of medicines have their own principles, have their own pharmacopoeia, but are practised in the country as OTC drugs and without an authentic prescription Arecent WHO survey showed that around 90 countries, less than half of WHO member state, currently regulate herbal medicines.[1]

Inclusion of traditional medicine in pharmacovigilance system is becoming important given the growing use of ASI products and medicines globally.

CHALLENGES IN PHARMACOVIGILANCE FOR ASU DRUGS

Pharmacovigilance for ASU drugs faces unique challenges due to the complex nature of traditional medicine formulations, the lack of standardized manufacturing processes, and the limited scientific evidence on their safety and efficacy. ASU drugs often contain multiple ingredients, making it difficult to assess their individual effects and potential interactions.

Additionally, variations in the quality and potency of herbal ingredients can impact the safety and effectiveness of ASU drugs. Another challenge in pharmacovigilance for ASU drugs is the underreporting of adverse drug reactions (ADRs) and other drug-related problems. Healthcare providers may be less familiar with traditional medicine systems and may not recognize or report ADRs associated with ASU drugs. Patients may also be hesitant to disclose their use of traditional medicines, leading to underestimation of the risks associated with these products.

KEY STRATEGIES FOR PHARMACOVIGILANCE OF ASU DRUGS

To enhance pharmacovigilance for ASU drugs, several key strategies can be implemented

1. Establishing Pharmacovigilance Centers: Dedicated pharmacovigilance centers can be set up to monitor the safety of ASU drugs, collect ADR reports, and analyze data on adverse events associated with traditional medicines.
2. Training Healthcare Providers: Healthcare providers should receive training on recognizing and reporting ADRs related to ASU drugs. Educational programs can raise awareness about the importance of pharmacovigilance in traditional medicine practice.
3. Standardizing Manufacturing Processes: Standardizing the manufacturing processes of ASU drugs can help ensure the quality, potency, and safety of traditional medicine formulations. Good manufacturing practices should be followed to minimize variations in product quality.
4. Conducting Post-Marketing Surveillance Studies: Post-marketing surveillance studies can provide valuable data on the safety and efficacy of ASU drugs in real-world clinical practice. These studies can help identify rare or unexpected ADRs and inform regulatory decisions.

FRAME WORK FOR PHARMACOVIGILANCE FOR ASU DRUGS

The national pharmacovigilance resource centre for ASU drugs is assigned to coordinate a country wide pharmacovigilance programme under the aegis of Department of AYUSH, MOHFW, Govt. of India.

The programme is coordinated at institute for post graduate teaching & Research in Ayurveda (IPGT & RA) Jamnagar, Gujarat, India. The national pharmacovigilance programme for ASU drugs operate under the guidance of the National Pharmacovigilance Technical Advisory Comittee (NPTAC) to recommend procedures and guidelines for regulatory interventions.

The programme would comprise of the following steps.

(1) Step 1- Identifying the various centres across the country for recording ADR related data

(a) Setting up of 8 Regional pharmacovigiliance centres (RPC) under the programme Fach RPC shall provide sufficient space with requisite infarstructure

(b) Identifying 30 peripheral pharmacovigilance centres TPP across the counters prefer ably one in every state.

(2) Step 2- An induction training programme shall be arranged for healthcare profession also participating in the NPP for ASU drugs Intensive interactions/training sessions will be organized for all participants to.

(a) Clearly define their individual and team roles and responsibilities.

(b) Set operational benchmarks.

(c) Evolve SOP's for generating and forwarding ADR data capture namely.

i. Appropriate communication skills to elicit ADR related information.
ii. For recording ADR information through hands on training.
iii. For meticulous collation and completeness of data.
iv. For fostering notification culture.

These training programmes and interaction meetings shall be held every 6 months after the initial traning besides contineous communication through emails, carrying relevant information re- lated to ADR monitoring methods shall be maintained among the participating centres As per the provision of this programme any healthcare professional may report the sus pected adverse drug event, but not from the layman or other person than the health care profes sional.

The reporting should be submitted in the prescribed format to the pharmacovigilance centre. Confidentiality is assured through this programme.[2]

PHARMACOVIGILANCE CENTRES

A three tier structure is in vogue comprising of.

National Pharmacovigilance Co-ordination Centre (NPvCC)

Intermediary Pharmacovigilance Centres (IPvCs)

Peripheral Pharmacovigilance Centres (PPvCs)

All India Institute of Ayurveda, New Delhi is the National Pharmacovigilance Co-ordination Centre (NPvCC) for implementation of the pharmacovigilance program for ASU & H Drugs. The NPvCC will receive inputs in terms of suspected ADRs from the Intermediary Pharmacovigilance Centres (IPvCs), which will initially include.

National Institute of Ayurveda, Jaipur.

Institute for Post-Graduate Teaching & Research in Ayurveda, Jamnagar.

National Institute of Unani Medicine, Bengaluru.

National Institute of Siddha, Chennai.

National Institute of Homoeopathy, Kolkata.[3]

WHO CAN REPORT ADR

All healthcare professionals (clinicians, dentists, pharmacists, nurses) and patient/consumers can report ADRs to NCC or AMCs. The pharmaceutical companies can also send individual case safety reports for their product to NCC.[4]

DISCUSSION

The present state of pharmacovigilance in Ayurveda reflects a crucial need for heightened awareness, integration of reporting mechanisms, and systematic monitoring of adverse reactions associated with traditional medicines. The challenges, such as the lack of communication between different medical systems, insufficient education on pharmacovigilance, and the belief in the inherent safety of Ayurvedic medicines, underscore the urgency for comprehensive reforms. The incorporation of pharmacovigilance concepts into Ayurvedic education, encouraging research on drug safety, and making reporting mandatory are vital steps. The dissemination of unbiased drug information, coupled with the development of standardized scales for causality assessment, will contribute to a more robust and transparent pharmacovigilance framework. Human resource development, involving the training of Ayurvedic experts, and fostering collaboration between pharmacovigilance professionals and Ayurvedic practitioners, are pivotal for the success of these endeavours. As we navigate the future of pharmacovigilance in Ayurveda, the collective efforts of stakeholders can pave the way for a safer and more accountable healthcare landscape, ensuring the well-being of patients and fostering confidence in the use of Ayurvedic medicines.[5]

CONCLUSION

Pharmacovigilance is essential for ensuring the safety and efficacy of Ayurveda, Siddha, and Unani drugs. By implementing robust pharmacovigilance systems, monitoring mechanisms, and risk management strategies, healthcare providers can promote the safe use of traditional medicines and protect patient health. Collaboration between healthcare professionals, regulatory agencies, and traditional medicine practitioners is key to advancing pharmacovigilance for ASU drugs and improving patient outcomes.

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