WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
Coden USA: WJPRAP Impact Factor 8.453
Volume 14, Issue 20, 288-292. Review Article ISSN 2277–7105

IMPORTANCE OF PHARMACOVIGILANCE FOR AYURVEDIC MEDICINES

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Article Received on 21 Sept. 2025,
Article Revised on 11 Oct. 2025,
Article Published on 01 Nov. 2025,

https://doi.org/10.5281/zenodo.17366309

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How to cite this Article: *Dr. Sapanjeet Kaur, Dr. Rajiv Mehta. (2025). Importance of Pharmacovigilance For Ayurvedic Medicines. World Journal of Pharmaceutical Research, 14(20), XXX–XXX.

ABSTRACT

Pharmacovigilance is defined as the activities relating to detection, evaluation, understanding and prevention of adverse drug reactions or other drug related problems. WHO established programme for International Drug monitoring in response to thalidomide disaster detection in 1961. In India, The National Pharmacovigilance Programme has organised a separate area for ASU drugs, lack of knowledge about the concept and importance of pharmacovigilance among Ayurvedic practitioners leads to the improper analysis and report of adverse effects. In case of Ayurvedic drugs there is misconception that they are devoid of any adverse reactions. But in reality, side effects are not completely absent but they are comparatively less. Moreover, with the increase in demand of herbal drugs, Ayurvedic drug manufacturing companies are compromising in the quality of the medicines. This can have a profound impact on the safety and efficacy of ASU drugs in the market. This paper aims to assess the need of pharmacovigilance in Ayurveda.

KEYWORDS: National Pharmacovigilance programme, ASU drugs, Adverse reaction.

INTRODUCTION

Several evidences show the adverse effects of poor quality medication on health care. But actual impact of this problem is impossible to calculate, since most cases go undetected. Most of the evidences are available from developed countries. In case of developing and under

developed countries the situation is more urgent because of the poor health system infrastructure and lack of essential study reports. Hence the importance of pharmacovigilance arises for addressing the product quality, adverse drug reaction (ADR). Adverse Drug Reaction significantly decreases quality of life, increases hospitalization and mortality.[1] New drugs are being approved for marketing without much long-term safety studies. In a new drug development process many stages are there involving chemical studies, animal studies and human studies for evaluating the safety and efficacy. But after the product is approved, it may have been tested in only thousands of patients. So, the information on effects generated in premarketing studies is incomplete relative to the full complement of likely users, making post-marketing surveillance an important tool for completing the safety and efficacy profile of a drug.[2] This is a part of phase 4 clinical study as per ICMR ethical guidelines.

Ayurveda a boon for India, is a crucial part of health organization. Since past thousands of years, clinical trials evidences based on safety and efficacy of Ayurvedic drugs has been prioritized, to create transparency and awareness among consumers.[3] Associated with this escalating use of Ayurvedic drugs are increasing apprehension about the safety of drugs. There is a chief delusion amongst community and also a great numbers of doctors that Ayurvedic medication are secure and do not produce any ADR's. The most important aim of pharmacovigilance, that is to enhance patient care and safety of the drug use, and as a result elevate rational drug use are recurring premise of Ayurvedic pharmacology (Dravyagunavigyan) and therapeutics (Chikitsa).[3]

Important role of Pharmacovigilance in Ayurveda

It is misconception that Ayurveda drugs are safe and do not have any adverse reaction. Ancient texts clearly mention that if a drug is used without the knowledge of its proper action, it would certainly act as a poison.[4] Moreover, if a drug is prepared according to its SOP and used clinically in the dose prescribed, then the adverse reactions can be minimized to a great extent. The decision making regarding prescription of a drug also relies upon the Yukti of the physician and his minute assessment of the Roga and Rogi Bala, the time of administration of drug (kala), its place (desha), Satwa, Satmya, Ahara Shakti, Vayam Shakti.[5] Besides the knowledge of proper identification of drug, its properties, therapeutic dosage and its combination with other drugs some of the subjective tools and crude principles of Pharmacovigilance used since ancient times to keep ADR's of Ayurveda medicines at bay. Consideration regarding age of the patient for dose administration and contraindications of

some formulations in certain conditions also speaks of ADR prevention in Ayurveda. However, scientific assessment of the ADR's and AE's (adverse events) on objective parameters is the need of the hour that would definitely help. Practice of pharmacovigilance will compel us to strive harder to make more safer and authentic medicines and make Ayurveda more rational and reliable. However, this can only be seriously followed after the quality control is ensured reliably for all the marketed formulations, either traditional or proprietary.

National Pharmacovigilance Programme for ASU Drugs

The National Pharmacovigilance Programme for ASU drugs was envisaged in December 2007, when a workshop, sponsored by WHO was organised at IPGT and RA, Jamnagar, India on possibility of implementing Pharmacovigilance programme for ASU drugs.[6] The protocol and ADR reporting forms were prepared and discussed by the Department of AYUSH, Govt. of India at a meeting held in August 2008. It was on 29 September 2008 that the draft was finalised and released by Department of AYUSH. Since then, IPGT and RA, Jamnagar, India has been working as National Pharmacovigilance Resource Centre for ASU drugs in India.

Events to be reported under National Pharmacovigilance Programme for ASU Drugs[7]

The programme particularly solicits reporting of all adverse reactions suspected to have been caused by ASU drugs either alone or in conjunction with other drugs, all suspected drug interactions, reactions to any other drugs suspected of significantly affecting a patient's management, including reactions suspected for events like death, life threatening, hospitalization, disability, congenital anomaly, required intervention to prevent permanent impairment or damage.

Report sources[8]

Consumer organizations, clinical trials, Health care professional, Literature, consumer, Media, UMC pharmaceutical companies report.

Report by specific person[9]

Any health care professional may report suspected adverse drug events. The cases reported by lay members of the public, or non-health care professionals are not accepted under the programme. However, they can report through the physician under whom they have undergone treatment.

Criteria of Reporting

The reporting of any ADR suspected to Ayurvedic formulations includes patient detail (age, sex, weight), suspected drug detail (drug name, dose, route, frequency etc.), suspected ADRs detail (reaction started date, Date of recovery), reporter detail (name , address, date of report).

Processing of submitted report

The peripheral Pharmacovigilance centres forward the confidential forms to their regional Pharmacovigilance centres where casualty analysis is carried out. The information is then forwarded to the National Pharmacovigilance Resource Centre, where it is consolidated, statistically analysed, and forwarded to the Department of AYUSH.

CONCLUSION

Educating physicians and encourage them to analyse and report any adverse effects that occur in a patient. Quality drugs are one of the main pillars of effective treatment. The morality of manufacturing standard drugs can go a long way in minimizing the adverse effects and generating confidence in therapeutic efficacy. Further, this shall in long term lead to characterization of Ayurvedic drugs as OTC (over the counter), prescription or scheduled drugs for better safety and acceptance of Ayurvedic medicines. Thus requirement of appropriate post-clinical surveillance program for Ayurvedic drugs based on its quality, safety, and efficacy, for public health and disease management, which is now accessible in National Pharmacovigilance Programme for ASU drugs.

REFERENCES

1. Studies on drug safely should be encouraged with strict implementation of regulations related to collection, manufacturing, preservation, dispensing and ethical guidelines.
2. Reporting of adverse reactions to regulators should be made mandatory.
3. Susheel kumar, Importance of Pharmacovigilance in Ayurveda, JPTMR, 2021; 9: 02.
4. Kashinath Shastri and Gorakhnath Chaturvedi, Charaka Samhita of Agnivesha elaborated Vidyotini Hindi commentary, Sutra sthana 1st chapter Dirghamjeevitiya adhyaya, Chaukhambha Bharati Sansthan, Varanasi, reprint edition, 2005; 48.
5. Kashinath Shastri and Gorakhnath Chaturvedi, Charaka Samhita of Agnivesha elaborated Vidyotini Hindi commentary, Vimana sthana 8th chapter Rogbhishagjitiya adhyaya, Chaukhambha Bharati Sansthan, Varanasi, reprint edition, 2005; 767.
6. Protocol for National Pharmacovigilance programme for ASU drugs, http://www.ayushsuraksha.com/NATIONAL%20, 2014.

7. Rastogi, S., Why and how? Addressing to the two most pertinent questions about pharmacovigilance in Ayurveda. Int. J. Ayurveda Res., 2011.
8. Wal, P., Wal, A., Gupta, S., Sharma, G., Rai, A. K., Pharmacovigilance of herbal products in India. J. Young Pharm., 2011; 3: 256–258.
9. Apte, A., Reporting of adverse events for marketed drugs: Need for strengthening safety database. Perspect. Clin. Res., 2016; 7: 111.