

Concept of Pharmacovigilance in ASU drugs - A Literature Review

Dr. Shital Anil Raskar

Associate Professor
Dept. of Rasashastra & Bhaishjya Kalpana
L.R.P. Ayurvedic Medical College, Hospital, P.G. Institute and Research Centre
Islampur, Tal: Walwa, Dist.: Sangli.

Abstract- Pharmacovigilance is the science dedicated to reduce the risk of drug-related harms to the consumers. Looking into the conditions prevailing in the present scenario, it is high time to deliberate regarding the concerns over traditional and classical Ayurvedic, Siddha, Unani products and practices.

Key Words: Pharmacovigilance, Ayurveda, ASU, Siddha, Unani.

I. INTRODUCTION:

Pharmacovigilance is defined as the detection, assessment and prevention of adverse drug reactions in humans. Ministry of AYUSH, Government of India, New Delhi has initiated the Pharmacovigilance Program for ASU & H drugs.

II. AIMS AND OBJECTIVES:

1. To understand the concept of Pharmacovigilance.
2. To review the literature of concept of Pharmacovigilance in ASU & H drugs.

III. MATERIALS AND METHODS:

Available textbooks, handbooks, e-books, search engines like Google, original research articles from various high impacting international peer reviewed journals etc. were the sources utilized for understanding the concepts under study.

IV. LITERATURE REVIEW:

1. Definition –

Pharmacovigilance is the process and science of monitoring the safety of medicines and taking action to reduce the risks and increase the benefits of medicines. It is a key public health function.

Major components of pharmacovigilance-

The major components of a pharmacovigilance system are data collection, which can be passive, active, or mandatory, and data analysis and reporting.

Pharmacovigilance process -

- Pharmacovigilance Process (Stage 1): Detection.
- Collection of Individual Case Safety Reports (ICSRs) ...
- Pharmacovigilance Process (Stage 2): Assessment. ...
- Pharmacovigilance Process (Stage 3): Understanding the drug safety profile.
- Pharmacovigilance Process (Stage 4): Prevention of adverse effects. [1,2]

2. Aim of Pharmacovigilance –

The main goal of pharmacovigilance is thus to promote the safe and effective use of health products, in particular by providing timely information about the safety of health products to patients, health-care professionals, and the public

3. National Program for ASU -

Pharmacovigilance is the science dedicated to reduce the risk of drug-related harms to patients. In India, National Pharmacovigilance Program under the control of Central Drug Standards Control Organization (CDSCO) has initiated during 2003. WHO emphasizes that, traditional medicines are to be included into pharmacovigilance system and has published guidelines on safety monitoring of herbal medicines in pharmacovigilance systems in 2004.

The nationwide programme under central sector scheme funded by Ministry of AYUSH, New Delhi for ASU & H drugs to establish and manage a data base of Adverse Drug Reactions (ADR) for developing system wise database of adverse drug reactions and evolving evidence based recommendations towards clinical safety of ASU & H Drugs. Besides this; the program also undertake surveillance of objectionable or misleading advertisements.

Since ages Ayurveda, Siddha and Unani systems are being practised in India. In this era of globalization, concerns are being raised with regards to their clinical safety. Ayurveda has categorized toxic plants separately and for their use special processing is essential. There is a wide spread misconception that all drugs of “natural” origin are “safe”. There is also a common belief that long term use

of a medicine based on tradition, assures both safety and efficacy. Further when ASU & H medicines are used in conjunction with other medicines, there is a possibility of drug interactions. There are also examples of ASU & H medicines being adulterated or contaminated with allopathic medicines, chemicals such as corticosteroids, non-steroidal anti-inflammatory agents etc. Further many ASU & H drugs are manufactured for global use and they have moved beyond the traditional and cultural framework for which they were originally intended. Currently, majority of adverse events related to the use of herbal / traditional products that are reported are attributed either due to poor product quality or to improper use.

ASU & H systems of medicines have their own principles and have their own pharmacopoeia, but at times even are practised in the country as OTC drugs without any authentic prescription.

Considering the growing use of ASU & H products and medicines globally; inclusion of traditional medicines in Pharmacovigilance systems became equally important. Pharmacovigilance is defined as the detection, assessment and prevention of adverse drug reactions in humans.

Ministry of AYUSH, Government of India, New Delhi has initiated the Pharmacovigilance Program for ASU & H drugs. Worldwide movement for the improvement of patient safety gains momentum, the subject of drug safety becomes even more prominent. Pharmacovigilance is the science dedicated to reduce the risk of drug-related harms to the consumers. Looking into the conditions prevailing in the present scenario, it is high time to deliberate regarding the concerns over traditional and classical Ayurvedic, Siddha, Unani and Homoeopathy products and practices. Thus the program is initiated to collect, collate and analyze data to establish evidence for clinical safety of ASU & H drugs in a scientific manner for documenting clinical evidence of safety and to undertake surveillance of misleading advertisements of ASU & H drugs and improper advertisements of ASU & H drugs for regulatory actions.

The program shall be coordinated by NPvCC under the supervision of Ministry of AYUSH, New Delhi that would monitor the program and also recommend regulatory interventions based on the generated Adverse Drug Reaction (ADR) data and objectionable advertisements. [1]

4. Ayurvedic Concept of Pharmacovigilance

Concepts and Regulations of Pharmacovigilance in Ayurveda: Given the current scenario of the usage of the traditional and alternative medicine at a global scale, it becomes imperative to ensure the safety of the patients consuming these medications. This makes the science of pharmacovigilance, a significant domain in the field of medicine and public health as well. Nevertheless, the adverse drug reaction of traditional Ayurvedic medicine may range from trivial effects to serious fatal outcomes leading to the death of a patient. Furthermore, the application of the principles of pharmacovigilance in the realm of Ayurveda is a challenging job owing to several of the inherent characteristic features associated with such a science. Albeit recent researches are based on in-vivo and/or in-vitro trials of many herbal preparations, however, the science of Ayurveda is the science of ages and is transmitted from generation to generation. During the recent past considering the significance of pharmacovigilance in Ayurveda and other indigenous systems of medicine, a national pharmacovigilance unit of ASU (Ayurveda, Unani and Siddha) systems of medicine has been initiated at Gujrat Ayurveda University in the year 2008. [2]

5. Need of Pharmacovigilance for Ayurvedic Medicine

In India, Ayurveda, Siddha and Unani (ASU) systems of medicine are considered to be the oldest system of medicines. They prescribe drugs of herbal, mineral, metallic and animal origin for the treatment of many diseases. Being time tested systems of medicine and majority of the drugs used by them are of herbal origin these systems are considered to be safe. The use of ASU medicines continues to expand rapidly across the world. The interest and demand for ASU system of medicine is day-by-day increasing both within India and abroad. Since people are more attractive towards ASU system and their awareness about ASU also increased dramatically, they are more concern about the safety of ASU system of practice. For the purpose of rationalization, there is a need for monitoring safety and efficacy of drugs of these medical systems and this is a matter of highest concern in current scenario. Though the traditional medical practices are deemed to be safest, few adverse effects were reported which are basically due to the non-judicial use, or use without the prescription, guidance or without supervision of a qualified medical practitioner etc. Hence the modern world demands a database for safe use of traditional medicine. [3]

V. DISCUSSION AND CONCLUSION:

Pharmacovigilance practice is the need of hour for all systems of medicine including Indian Systems of Medicine, as it helps to prove this system safe, more scientific and up to date in modern terms. It is an absolute requirement to ensure public safety and to promote the healthy development of ASU systems of Medicine.

REFERENCES:

- [1] <https://www.ayushsuraksha.com/pharmacovigilance/>
- [2] Pharmacovigilance in Ayurveda – Concept and Regulation. Current Pharmacogenomics and Personalized Medicine. Author – Janmejaya Samal. Volume 16, Issue 1, 2018.
- [3] Journal of Pharmacovigilance, Need of Pharmacovigilance in AYUSH Drugs, Rajanandh and Chamundeeswari, J Pharmacovigil 2017, 5:1