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**PHARMACOVIGILANCE OF HERBAL MEDICINES- A NEED FOR
HOUR**

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INTRODUCTION

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, and prevention of adverse drug reactions in humans. Pharmacovigilance has been regarded as a type of continual monitoring of unwanted effects and other safety-related aspects of drugs, which are already placed in markets. In general, pharmacovigilance is the science of collecting, monitoring, assessing, and evaluating information from healthcare professionals and consumers on the undesired effects of medications including herbal and traditional drugs.⁽¹⁾The worldwide movement for the improvement of patient safety is gaining momentum, so the subject of drug safety becomes even more prominent in the present day scenario. These days, herbal medicines are being used by various communities throughout the world. Herbal formulations have reached widespread acceptability as therapeutic agents such as cough remedies, hepatoprotectives, and antidiabetics. Herbal medicines are traditionally considered harmless since these belong to natural sources. However, this is not true as there are several case reports of adverse reactions of herbal drugs mentioned in published literature.⁽²⁾

OBJECTIVES

- ❖ The main objectives of pharmacovigilance involve exhibiting the efficacy of drugs by monitoring their adverse effect profile for many years from the lab to the pharmacy; tracking any drastic effects of drugs improving public health and safety in relation to the use of medicines; encouraging the safe, rational and cost-effective use of drugs; promoting understanding, education and clinical training in pharmacovigilance; and effective communication to the generic public.
- ❖ In addition, providing information to consumers, practitioners and regulators on the effective use of drugs alongwith designing programs and procedures for collecting and

analyzing reports from patients and clinicians conclude to the objectives of pharmacovigilance studies.⁽³⁾

NEEDS

- ❖ It is widely accepted that clinical development of medicines is a complex process which also includes herbal drugs and their products. Once a drug is marketed, it leaves the secure and protected scientific environment of clinical trials and is free for consumption by the general public. At this point, most herbal medicines will only have been tested for short-term safety and efficacy on a limited number of carefully selected individuals⁽⁴⁾.
- ❖ Hence, need of pharmacovigilance in herbal drugs arises which include, securing the early detection of new adverse reactions or patients subgroups of exceptional sensitivity; and introducing certain measures in order to manage such risks.
- ❖ Moreover, it is essential that new and medically still evolving treatments are monitored for their effectiveness and safety under real-life conditions after being marketed.
- ❖ Furthermore, more information is generally needed about use in specific population groups like children, pregnant women and the elderly, about the efficacy and safety of chronic use in combination with other drugs⁽⁵⁾.

ADVERSE DRUG REACTION (ADR) OF HERBAL MEDICINES

- ❖ *Charaka* says, “that even a strong poison can become an excellent medicine if administered properly. On the other hand, even the most useful drug can act as a poison if handled carelessly.”
- ❖ Due to the lack of clinical trials for most herbal medicinal products, post-marketing pharmacovigilance becomes a critical source of safety information. However, the assessment of adverse reactions associated with herbal medicinal products offers unique challenges in the quantity and quality of available information
- ❖ It is undeniable that plants have an important role in the development of modern medicines. More than 60-70% of modern medicines in the world market are directly or indirectly derived from plant products.⁽⁶⁾
- ❖ Widely reported issues, such as ADRs associated with Ephedra and Aristolochia, have shown that herbal medicinal products can produce toxicity in human beings. The most common adverse effects reported are hepatic and renal problems. However, it is difficult to identify the causative agent associated with the ADRs encountered because traditional herbal preparations often contain multiple ingredients.⁽⁷⁾
- ❖ A list of some suspected and known herbal drug associated with adverse effects is given in Table No.1

PREVENTION OF ADVERSE DRUG REACTION IN AYURVEDIC MEDICINES

- ❖ Patients are not adequately aware that Ayurvedic medicines can cause adverse reactions and can take medicines for years on end with no monitoring as they believe that these medicines can do no harm. Hence, they do not even give a history of taking these

medicines.⁽⁸⁾

- ❖ Education in Ayurveda or modern medicine at both under-graduate and post-graduate levels does not cover pharmacovigilance of Ayurvedic medicines, thus never exposing the young physicians to this concept.
- ❖ The Ayurvedic pharmaceutical industry is not motivated to focus on pharmacovigilance of Ayurvedic medicines. Hence, there is no attempt at generating safety data - either before or after marketing of the formulation.⁽⁹⁾

RECOMMENDATION

Based on these observations, there are several ways to attempt to embrace pharmacovigilance systems into Ayurveda.

1. Encourage pharmacovigilance concepts into the curriculum of Ayurved at the under-graduate and post-graduate level
2. Encourage studies on drug safety
3. Make reporting of adverse reactions to regulators mandatory for Ayurvedic formulations
4. Make unbiased and easily accessible drug information available
5. Development and validation of scales to assess the causality of the reported reactions to Ayurvedic medicines
6. It will be necessary to train Ayurvedic experts in the science of pharmacovigilance and include them not only in reporting but also assessment of the adverse reactions.⁽¹⁰⁾

CONCLUSION

Medicinal herbs as a potential source of therapeutics aids have attained a significant role in health care system all over the world for human beings not only in the diseased condition but also as a potential material for maintaining proper health.^[9,10] A major factor impeding the development of the medicinal plant-based industries in developing countries has been the lack of information on the social and economic benefits that could be derived from the industrial utilization of medicinal plants.

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