

NEED TO INCORPORATE PHARMACOVIGILANCE OF HERBAL MEDICINE TO THE CURRICULUM

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World Health Organization defines "Pharmacovigilance" as the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.^[1] Pharmacovigilance programs can play an important role in early detection and prevention of adverse drug reactions (ADRs). Pharmacovigilance is also defined as 'the study of the safety of marketed drugs under the practical conditions of clinical usage in large communities'.^[2] It is better to extend safety monitoring and detect drug adverse events that have previously been unrecognized despite evaluation in clinical trials. Although these methods were developed for monitoring pharmaceutical medicines they are also used for additional evaluation of the safety of other medicinal products including herbals, blood products, vaccines and even medical devices.

Studies from both developed and developing countries document a poor knowledge and practice of pharmacovigilance among pharmacists.^[3,4] Developed countries have incorporated pharmacovigilance teaching in the pharmacy curriculum.^[5]

Pharmacovigilance is designed to monitor drugs continuously after their approval and commercialization, aiming at assessing and improving their safety profile. The main objective of pharmacovigilance is the increase of the spontaneous reporting of adverse drug reactions, i.e. reporting of suspecting adverse drug reactions by the medical staff to a national coordinating center. Pharmacovigilance contributes to the early identification of signals leading to the formation of hypotheses and further investigation through observational studies or large prospective studies. Taking into account all the aspects outlined above, the contribution of pharmacovigilance is vital for the improvement of the safety of drugs. All relevant authorities should take action towards reporting of adverse drug reactions associated with drug use and towards dissemination of this information to the scientific community.^[5]

Approval for a medicine is based on controlled and regulated clinical trials. Once an approved medicine is placed on the market, it leaves the controlled scientific environment of clinical trials. At this point, most medicines will only have been tested for short-term safety and efficacy on a limited number of carefully selected individuals. Therefore, it is important that the use of these medicines is monitored for their ongoing effectiveness and safety. Pharmacists have an important responsibility in monitoring the ongoing safety of medicine.

As the use of herbal medicines has increased, so too have the reports of suspected toxicity and adverse events. Such unwanted reactions can be due to (i) side effects (usually detectable by pharmacodynamics and often predictable); (ii) reactions occurring as a result of overdose, overduration, tolerance, dependence-addiction (detectable either by pharmacodynamics or pharmacovigilance), (iii) hypersensitivity, allergic and idiosyncratic reactions (detectable by pharmacovigilance), (iv) mid-term and long-term toxic effects including liver, renal, cardiac and neurotoxicity also genotoxicity and teratogenicity (detectable by *in vitro* and *in vivo* toxicological studies or by pharmacovigilance). As many herbal products on the market have not been thoroughly tested for their pharmacology and toxicology, pharmacovigilance has paramount importance in detecting unwanted reactions.

In addition, there is an ongoing problem with unexpected toxicity of herbal products due to quality issues, including use of poor quality herbal material, incorrect or misidentified herbs, incorrect processing methods, supply of adulterated or contaminated herbs or products.^[6] The safety of herbal medicines has become an issue for the regulatory authorities, as serious effects have been reported, including hepatotoxicity, renal failure and allergic reactions.^[7] The World Health Organisation, recognising the growing importance of the use of herbal medicines worldwide developed guidelines for the

monitoring of herbal safety within the existing pharmacovigilance framework.^[8]

There is a perception that herbal medicines are safe, even if taken at the same time as prescription drugs.^[9] Herbs may be used to treat the primary condition or to reduce the side effects of their conventional treatment. Under-reporting of suspected interactions between herbs and drugs is of increasing concern and arises from the same reasons as under-reporting of herbal ADRs.

Why is Pharmacovigilance of Herbal Drugs Important?

Some countries accept traditional, experience based evidence while others consider herbal remedies as dangerous or of questionable value. Medicinal herbs as potential source of therapeutics aids has attained a significant role in health care system all over the world for human beings not only in the diseased condition but also as potential material for maintaining proper health.^[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.^[11]

Pharmacovigilance is essential for developing reliable information on the safety of herbal medicines as used in Europe and the US. The existing systems were developed for synthetic medicines and require some modification to address the specific differences of medicinal herbs. Traditional medicine from many different cultures is used in Europe and the US which adds to the complexities and difficulties of even basic questions such as herb naming systems and chemical variability. Allied to this also is the perception that a 'natural' or herbal product must be safe simply because it is not synthetic which means that the safety element of monitoring for such medicines can be overlooked because of the tag associated with such products. Cooperation between orthodox physicians and traditional practitioners is needed to bring together the full case details. Independent scientific assistance on toxicological investigation, botanical verification can be invaluable for full evaluation of any case report. Systematic pharmacovigilance is essential to build up reliable information on the safety of herbal medicines for the development of appropriate guidelines for safe effective use.

With the advent of new curriculum of pharmacology and

availability of pre compounded, 'ready to use' dosage forms, clinical pharmacy has replaced the conventional dispensing pharmacology.^[12] However, curriculum needs to be modified to focus on "processes and approaches" rather than on contents only. Along with the advancement in the field of pharmacovigilance of herbal medicines, numerous challenges have emerged with the exponential rise in the incidence of adverse drug reactions resulting in to the increased rates of hospitalization, contributing to the growth of overall burden of disease which is somewhere failing to be managed efficiently, consequently giving space for the emergence of the concept of incorporation of pharmacovigilance of herbal medicines to the curriculum of medical and pharmaceutical students. The objectives were to introduce the pharmacovigilance program to the students, emphasize the importance of pharmacovigilance programs, and also familiarize them with a few operational aspects of pharmacovigilance programs.

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