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### Pharmacovigilance in Phytopharmaceuticals

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Pharmacovigilance is a branch of pharmacology defined as the science and activities relating to the assess, detect, understand, and to prevent the adverse effects or any other possible drug-related problems in the society. It is not only confined to chemical drugs but extended to herbal, traditional and complementary medicines, biologicals, vaccines, blood products and medical devices [1].

Implementation of safety monitoring systems and processes are emerging for herbal medicines [2,3]. Ginseng is one of the safe herbal products that is widely used. There have been a few adverse drug reactions reported for Ginseng. Although, it is considered as one of the safe herbal product, it is not applicable to every herbal product. Medicinal herbs, as the potential source of therapeutic aids, have attained a significant role in health care system all over the world for human beings and not only in the diseased condition but also as a potential material for maintaining proper health. Therefore, Pharmacovigilance is essential for the herbal drug before being considered as a safe for human health [4,5]. For example, our previous reports reveal that cinnamaldehyde, a widely used food additive induces pro-oxidant state and thereby exerting toxic effects at the WHO suggested ADI level [6-9]. Cinnamaldehyde has been also used as an antidiabetic and also anticancer agent.

World Health Organization (WHO) has formulated certain specific guidelines for the assessment and monitoring the safety, efficacy and quality of herbal medicines as a prerequisite for global harmonization and safe use. The Medicines and Healthcare Products Regulatory Agencies, UK had launched 'yellow card' scheme for monitoring the safety of herbal medicines. The Canadian Health Care department, has analyzed various unapproved ayurvedic medicinal products that contain high levels of minerals such as lead, mercury, and arsenic in various Indian formulations [Maha Sudarshan Churna (Zandu Pharmaceuticals, India), Shilajit capsules (Dabur, India), Karela capsules (Himalaya Drug, India), Safi liquid (Hamdard, India & Pakistan)]. Some herbal products were found to contain 0.1 to 0.3 mg of betamethasone which produced corticosteroid-like side effects.

The frequency of undesirable effects of phyto-pharmaceuticals is remarkably low, even if the present lack of data about side-effects

is considered. However, reports have been received by drug safety monitoring agencies of prolonged prothrombin time, increased coagulation time, subcutaneous hematomas, and intracranial hemorrhage that are associated with the use of Ginkgo biloba. WHO sponsored pharmacovigilance program in 2008 at Gujarat Ayurveda University to evaluate all ayurvedic products. The WHO, under DFC program, had sponsored four capacity building training programs in India for the coordinators of regional and peripheral centers of pharmacovigilance of Ayurvedic system of medicine in 2010 and 2011 [10]. Standard Pharmacological Program guidelines have to be followed along with the local drug regulations/ international norms for all phyto-pharmaceuticals.

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