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CHALLENGES AND ISSUES IN PHARMACOVIGILANCE OF HERBAL MEDICINES IN INDIA

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The process of pharmacovigilance (PV) of herbals in India has come a long way since initiation. PV practices are helping in establishing and maintaining rational age of drugs within the ambit of Pharmacotherapy. ADR's (adverse drug reaction) from herbal medicines are least reported, many herbal preparations without following any drug safety requirements are marketed without its pharmacovigilance. Due to the lack of clinical trials of most herbal preparations, post marketing vigilance becomes a critical source of safety and information. Widely reported issues as ADR's associated with Ephedra and Aristolochia have shown herbal medicines can show high levels of toxicity in humans. The most common adverse drug effects reported are hepatic and renal problems. The WHO has database of over 16000 suspected herbal case reports. Central Drug Standards Control Organization and AYUSH are the major government organizations working to monitor ADR related to herbal ingredients. The number of reports related to herbals/traditional/alternative medicines is abysmally low. The current challenges in pharmacovigilance of herbal medicines includes ADR terminology not covered in Ayurvedic curriculum, drug safety problems, signal detection, lack of quality assurance/quality control, lack of information about active principles and with regard to the mechanism of action of herbal active principles. Some countries accept traditional, experience-based evidence while others consider herbal remedies as dangerous or of questionable value. Monitoring the safety of herbal medicinal products in the market or in the pipeline, will go a long way in restoring the confidence of their safety.

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