

Pharmacovigilance of Herbal Drugs: Rethinking Safety, Evidence, and Regulation

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Abstract: *Herbal medicines have gained unprecedented global popularity over the past two decades, with approximately 80% of the world population relying on herbal preparations for primary healthcare. The global market for herbal remedies has expanded from approximately USD 83 billion in 2008 to over USD 100 billion currently. Consequently, pharmacovigilance of herbal medicines has become increasingly critical to ensure patient safety and therapeutic efficacy. This comprehensive review examines the current status of pharmacovigilance systems for herbal medicines, the specific challenges encountered in monitoring their safety, and future perspectives for strengthening these systems. The review synthesizes evidence from multiple sources regarding adverse drug reactions (ADRs) associated with herbal products, discusses the distinctive characteristics of herbal medicines that complicate pharmacovigilance activities, and presents recommendations for improving safety monitoring frameworks globally. Key findings indicate that while significant progress has been made in establishing pharmacovigilance programs in traditional medicine systems, particularly in India, substantial gaps remain in standardization, quality control, and systematic adverse event reporting mechanisms. This review provides a comprehensive framework for understanding the complexities of herbal medicine pharmacovigilance and offers actionable recommendations for regulatory authorities, healthcare professionals, and researchers.*

Keywords: Pharmacovigilance, Herbal medicines, Adverse drug reactions, Safety monitoring, Quality control, Traditional medicine, Regulatory framework

