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Beyond Efficacy: Risks, Drug Interactions, And Regulatory Challenges In Herbal Antidiabetic Therapies

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ABSTRACT :

Herbal medicines are widely used in the management of diabetes mellitus due to their accessibility and traditional credibility. However, many patients and healthcare professionals overlook potential risks, drug interactions, and regulatory inconsistencies. This review explores adverse effects, pharmacokinetic and pharmacodynamic interactions, and the gaps in regulatory oversight of herbal antidiabetic therapies. Emphasis is placed on the need for improved clinical awareness, standardization, and international harmonization of safety protocols.

Keywords: Herbal antidiabetics, drug-herb interactions, adverse effects, pharmacovigilance, regulatory gaps, diabetes The increasing prevalence of diabetes mellitus has led to a surge in complementary and alternative medicine use, particularly herbal remedies. While many herbs demonstrate antihyperglycemic effects, assumptions about their safety can be misleading. This review addresses overlooked aspects such as side effects, herb-drug interactions, and the regulatory vacuum surrounding these products.

Commonly Used Herbal Antidiabetics

Herbs such as fenugreek (*Trigonella foenum-graecum*), bitter melon (*Momordica charantia*), cinnamon (*Cinnamomum verum*), gymnema (*Gymnema sylvestre*), and ginseng (*Panax ginseng*) are widely consumed for glycemic control. Despite their popularity, their consumption often occurs without clinical supervision or safety monitoring.

Documented Adverse Effects

While perceived as safe, many herbal agents are associated with side effects such as hepatotoxicity (e.g., neem), hypoglycemia (bitter melon), gastrointestinal discomfort, and allergic reactions. Overdosing or chronic use without clinical monitoring heightens these risks.

4. Drug-Herb Interactions

<i>Herb</i>	<i>Interaction</i>	<i>Affected Drugs</i>	<i>Effect</i>
Fenugreek	Potentiates hypoglycemia	Insulin, metformin	Increased hypoglycemia
Ginseng	CYP450 modulation	Warfarin, statins	Alters metabolism
Bitter melon	Mimics insulin	Sulfonylureas	Hypoglycemia risk
Cinnamon	Possible hepatic enzyme modulation	Hepatotoxic drugs	Potential liver toxicity

5. Lack of Standardization and Quality Control

The lack of standardization in herbal formulations leads to inconsistent therapeutic outcomes. Contamination with heavy metals, microbial load, and adulteration with pharmaceuticals have been reported. Products often lack proper labeling and dosage guidelines.

6. Regulatory Landscape

- India: Governed by AYUSH; lacks robust adverse event reporting.
- USA: FDA classifies herbs as dietary supplements; efficacy testing not mandatory.

- EU: THMPD allows traditional use registration, but uniform validation is lacking.
- There is no globally harmonized framework enforcing consistent quality and safety assessments.

7. Pharmacovigilance for Herbal Medicines

Herb-related adverse reactions are underreported. India's PvPI and WHO's VigiBase do not adequately capture herb-specific ADRs. Expansion and customization of these systems are needed for reliable monitoring and reporting.

8. Recommendations

1. Mandate documentation of herbal use in clinical records
2. Educate pharmacists and clinicians about herb-drug interactions
3. Promote standardized extraction and labeling protocols
4. Expand pharmacovigilance coverage for herbal products
5. Encourage collaborative regulation between modern and traditional medicine systems

9. Conclusion

Herbal antidiabetics offer therapeutic potential but also pose real risks. The lack of regulation, potential for drug interactions, and underreporting of adverse events raise major concerns. Strengthened oversight and education are essential for safe integration of herbal therapies in modern diabetes care.

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