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Pharmacovigilance, Unani Medicine, Traditional Medicine Safety, Adverse Drug Reaction, AYUSH, Herbal Interactions.

AN OVERVIEW OF PHARMACOVIGILANCE IN UNANI MEDICINE: BRIDGING TRADITIONAL WISDOM AND MODERN SAFETY STANDARDS

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ABSTRACT

Introduction: The increasing global interest in traditional medicine systems, including Unani, underscores the critical need for robust pharmacovigilance to ensure patient safety and therapeutic efficacy. This review aims to explore the historical foundations, current framework, implementation strategies, and challenges of pharmacovigilance in the Unani system of medicine. **Materials & Methods:** A comprehensive narrative review was conducted, analysing historical texts, regulatory milestones, and contemporary pharmacovigilance initiatives in India related to Unani medicine. Data for this present article were gathered from the authoritative and pertinent books of Unani Medicine. Besides this, information that is pertinent for this present review were also acquired from journal publications containing scientific research through PubMed, Science Direct, Google Scholar and Google search engine. Some keywords like Unani Medicine, Pharmacovigilance, AYUSH, Adverse drug reaction etc. were used to gather the information. **Results:** Although Unani medicine incorporates principles aligned with modern pharmacovigilance, challenges such as low adverse drug reaction (ADR) reporting, quality control issues, and lack of standardization persist. India has made significant progress by establishing dedicated pharmacovigilance centres and integrating Unani medicine within national safety programs. **Conclusion:** Pharmacovigilance is indispensable for validating and safely integrating Unani medicine into evidence-based healthcare. Enhancing ADR reporting systems and increasing awareness among practitioners are vital for ensuring the quality, safety, and efficacy of Unani therapeutics.

INTRODUCTION

According to WHO, Pharmacovigilance a term derived from the Greek word Pharmakon (meaning medicine) and the Latin word Vigilare (meaning to be watchful),[1] represents the scientific discipline concerned with the detection, assessment, understanding, and prevention of adverse effects of drugs or any other possible drug related problem at therapeutic concentrations that is used or is intended to be used to modify or explore physiological system or pathological states for the benefit of recipient. Originally developed in the context of modern, allopathic medicine, pharmacovigilance has evolved to encompass traditional systems of medicine, including Unani (WHO, 2002).[2,3]

Unani system of Medicine (also known a Greco-Arab medicine) was developed carefully and systematically from 500 BC till date as an ancient system of medicine. Unani System of medicine not only offers effective treatments for diseases, but its holistic approaches encompass distinctive ideas of diet, lifestyle, and particularly therapies, aimed at balancing and enhancing all facets of physiology and psychology.[4] The Unani system of medicine employs a variety of medications for the treatment of an array of diseases and disorders, predominantly derived from plant sources, followed by those of animal and mineral origins.[5] Hippocrates (460-370 BC), a seminal figure in the Unani System, articulated the theory of the four humours—Sanguine (Dam), Phlegm (Balgum), yellow choler (Safra), and Melancholic (Sauda)—in his renowned work, "Materia Medica." The equilibrium and disruption of these humours are posited as the primary determinants of health and disease. The main medicinal plants employed in the Unani System of medicine for therapeutic purposes were beautifully illustrated in Dioscoridous' extensive illustrated book "De Materia Medica," written in 70 AD. In his work Encyclopaedia "Al-Qanoon," the ancient Greek physician Ibn-Sina (980–1037 AD) provided a thorough account of the pharmacological knowledge and therapeutic qualities of herbal remedies based on clinical observations.[5,6,7]

Objectives of Pharmacovigilance

Pharmacovigilance is crucial for improving the safety and effectiveness of medical treatments, including those within traditional systems like Unani. Its core objectives are:

- ✓ Improve Patient Safety and Therapeutic Outcomes: The primary aim of pharmacovigilance is to protect patients from preventable harm by identifying, analysing, and preventing adverse drug reactions (ADRs). This leads to safer treatment regimens and improved health outcomes.[2]
- ✓ Support Public Health by Identifying and Mitigating Risks: By systematically collecting and evaluating data on drug-related problems, pharmacovigilance helps health authorities and regulatory bodies detect patterns of harm early. This supports timely interventions such as issuing safety warnings, modifying usage guidelines, or withdrawing harmful products from the market.[8]
- ✓ Facilitate Rational Drug Use Based on Benefit-Risk Assessment: Pharmacovigilance ensures that the benefits of a medicine outweigh its risks. Ongoing monitoring provides evidence for making informed decisions about drug approval, labelling, and recommended usage, promoting rational and evidence-based therapy.[9]
- ✓ Promote Healthcare Provider Education and Public Communication: Educating healthcare professionals about drug safety and encouraging transparent communication with the public foster's awareness and responsible use of medications. This also builds trust in both traditional and modern healthcare systems. These objectives collectively help integrate Unani and other traditional medicines into mainstream healthcare while ensuring safety and accountability.[10]

Need for Pharmacovigilance in Traditional Systems

With the increasing global interest in complementary and alternative medicine, Unani treatments are gaining attraction as safe and holistic therapeutic options. However, the perception of traditional medicine as inherently safe can lead to underreporting and insufficient monitoring of potential adverse effects. The increasing reliance on traditional medicine, including Unani, underscores the urgent need for a structured pharmacovigilance system.[11] Many individuals

self-prescribe or use Unani medicines without proper supervision, raising the risk of adverse effects and inappropriate dosing.[12] The growing prevalence of substandard or counterfeit formulations further endangers patient safety, as these may contain harmful or undisclosed ingredients.[13] Additionally, the concurrent use of Unani and allopathic medicines without medical guidance can lead to dangerous herb-drug interactions.[14]

Traditional formulations often lack comprehensive clinical trials, and even when tested, the trials may not reflect real-world usage. Clinical trials, while essential for evaluating a drug's initial safety and efficacy, have notable limitations in detecting adverse effects.[15] They typically involve a relatively small number of participants under controlled conditions, which does not reflect the complexities of real-world use involving millions of diverse individuals. Vulnerable groups such as pregnant women, children, and the elderly are often excluded, despite being common users. Additionally, trials usually avoid co-morbidities and polypharmacy, unlike real clinical settings where such factors are prevalent. Fixed dosages in trials also contrast with the variable dosing and environmental influences encountered in routine practice. These limitations highlight the need for robust post-marketing surveillance and reinforce the critical role of pharmacovigilance in Unani and traditional medicine for safeguarding public health.[9,16,17]

Historical Cases Related to Pharmacovigilance

The concept of pharmacovigilance, though formalized in the modern era, finds its roots in several historical events that underscore the critical need for monitoring drug safety. One early case involves Sir James Simpson, who introduced chloroform as a more effective anaesthetic than ether. However, in 1848, a young girl named Hannah Greener died after receiving chloroform anaesthesia for a minor surgical procedure. The exact cause of death remained undetermined, with theories ranging from overdose to unforeseen complications. Growing concerns prompted "The Lancet" to establish a commission that urged doctors across the British Empire to report anaesthesia-related deaths. These reports culminated in a publication in 1893, marking an early step toward organized drug safety monitoring. [1, 18, 19, 20, 21] In 1937, a drug intended to treat streptococcal infections caused over 100 deaths in the United States due to the usage of diethylene glycol, a hazardous solvent. At that time, safety testing was not mandatory. The tragedy led to the 1938 Food, Drug, and Cosmetic Act, expanding the FDA's authority and enforcing safety studies before drug approval. [1, 18, 22] Perhaps the most notorious case is the thalidomide disaster (1957–1961). Prescribed for morning sickness, thalidomide caused thousands of birth defects. The link, identified by Dr. William McBride and Dr. Widukind Lenz, led to its global withdrawal and revolutionized pharmacovigilance through systematic adverse drug reaction (ADR) reporting. [1, 20, 23, 24, 25, 26] Even historical Unani medicine isn't exempt. Ibn Sina (Avicenna 980-1037 AD), a celebrated physician, died following a series of medication errors, including overuse of enemas, incorrect herbal dosing, and opium overdose. His case highlights the dangers of self-medication and the absence of oversight in traditional systems.[11,27,28]

These incidents collectively illustrate the evolution and necessity of pharmacovigilance across both modern and traditional medicine, emphasizing that drug safety must always be evidence-based and rigorously monitored.

Historical Development of Pharmacovigilance

The history of pharmacovigilance spans over a century, shaped by various tragic incidents and significant regulatory advancements. The journey began in 1848 with the death of a girl named Hannah due to chloroform, marking one of the earliest recognized drug safety issues. [1, 18, 19, 20, 21] In 1937, a tragedy in the USA involving the solvent diethylene glycol led to over 100 deaths. This incident prompted the establishment of the Federal Food, Drug, and Cosmetic Act in 1938, significantly renovating the public health system.[1,18,22] In 1955, the gastrointestinal toxicity of acetylsalicylic acid (ASA or aspirin) was scientifically proven.[29] The thalidomide disaster in the early 1960s, which caused severe birth defects, led to McBride's letter in 1961 drawing attention to its dangers. This event played a pivotal role in shaping global drug safety practices. [1, 20, 23, 24, 25, 26] By 1964, the Yellow Card Scheme for adverse drug reaction (ADR) reporting was structured in the UK. The following year, the European legislation began evolving with the development of EC Directive 65/65.[1] In 1968, the World Health Organization (WHO) established the Programme for International Drug Monitoring, institutionalizing global pharmacovigilance efforts. [1, 30] The European Medicines Agency (EMA) was founded in 1995, followed by the funding of the EudraVigilance system in 2001 to enhance drug monitoring across Europe. Significant strides continued with the introduction of new European pharmacovigilance legislation under Directive 2010/84/EU in 2012. Finally, in 2017, the new EudraVigilance format was introduced, marking a modernized approach to pharmacovigilance in the European Union.[1]

The science of pharmacovigilance has evolved through a series of landmark events that exposed the risks of drug use and emphasized the need for systematic safety monitoring. Table:1 provides an extended timeline of key developments that shaped modern pharmacovigilance. These milestones collectively illustrate the gradual evolution from unregulated drug use to a global, data-driven, and technologically advanced pharmacovigilance infrastructure that continues to evolve with medical innovation and public health needs

Table: 1 Timeline of Development of Modern Pharmacovigilance

Year	Event	Description
1848	Chloroform Anaesthesia Death	Death of Hannah Greener led to the first organized reporting of drug-related fatalities. [1, 18, 19, 20, 21]
1906	U.S. Pure Food and Drug Act	Introduced to prevent mislabelling and adulteration of medicines. [1, 19, 20]
1937	Sulphanilamide Tragedy	Over 100 deaths led to the 1938 U.S. law mandating drug safety testing. [1, 18, 22]
1961	Thalidomide Disaster	Caused birth defects; triggered global drug safety reforms. [1, 20, 23, 24, 25, 26]
1962	Kefauver-Harris Amendment (U.S.)	Required proof of drug safety and efficacy before approval.[1]
1963	UK Committee on Safety of Drugs	Formed to review drug safety before market release.[1]
1964	Yellow Card Scheme (UK)	System to collect spontaneous ADR reports.[1]
1968	WHO Drug Monitoring Programme	Enabled global sharing of adverse drug reaction (ADR) data. [1, 30]
1972	CIOMS Established	Promoted international harmonization of drug safety standards. [20, 21, 31]
1992	ISoP Formation	Expanded pharmacovigilance collaboration internationally.[1]
1995	EMA Established	Coordinated medicine regulation and safety across the EU.[1]
2001	EudraVigilance Launched	Central EU database for managing ADR reports.[1]
2010	PRAC Formed	EMA committee to assess medicine safety in the EU.[1]

2012	New EU PV Legislation	Enhanced ADR reporting and transparency in the EU.[1]
2020	COVID-19 Vaccine Surveillance	Rapid global systems set up to monitor vaccine safety.[1]

Pharmacovigilance in India

It is essential for countries to support their own pharmacovigilance (PV) programs because adverse drug reactions (ADRs) can be influenced by unique cultural, dietary, and genetic factors specific to each population. Citizens may follow traditional practices and consume diets that affect how their bodies respond to medications. Additionally, traditional or herbal remedies—often widely used in many countries—can lead to ADRs that are not typically observed in other regions. Certain ADRs may also occur predominantly or exclusively in specific ethnic groups due to genetic differences in drug metabolism. Furthermore, alternative brands of medicines, whether imported or manufactured locally, may vary in composition or production quality, potentially altering their safety profiles. By maintaining independent PV systems, countries can ensure that drug safety monitoring is tailored to their unique population needs, ultimately enhancing patient safety and treatment effectiveness.[35,45,46,66]

India's pharmacovigilance framework has evolved steadily, addressing the safety of both modern and traditional medicines. These milestones reflect India's commitment to building a comprehensive, inclusive pharmacovigilance system across all streams of medicine. These key milestones are shown in Table:2

Table 2: Pharmacovigilance in Indian Context

Year	Event	Description
1986–87	India Joins WHO Programme	India becomes part of WHO's International Drug Monitoring Programme. [20, 32, 33]
1997	ADR Monitoring Initiated	CDSCO begins formal ADR monitoring in selected centres. [34, 35]
2005	National Pharmacovigilance Programme (NPP)	Launched with WHO & World Bank support; Schedule Y amended to mandate ADR reporting in clinical trials. [34, 35, 36, 37]
2008	End of NPP	NPP concluded due to limited impact and structural issues. [35, 38]
2010	Launch of PvPI	Pharmacovigilance Programme of India established; IPC made the National Coordination Centre. [32, 35]
2014	Expansion of PvPI Scope	PvPI starts monitoring ADRs for medical devices and vaccines. [39, 40, 41]
2017–2018	AYUSH Pharmacovigilance	Initiation of safety monitoring for traditional medicine systems.[42]
2020	Global Integration	PvPI connects with UMC for international ADR data sharing.[43]
Ongoing	Digital Strengthening	Enhanced ADR reporting via mobile apps and online platforms.[44]

Concept of Pharmacovigilance in Unani Medicine

Unani medicine, deeply rooted in the tradition of Greco-Arabic health care, has long emphasized the importance of patient safety and careful observation, principles central to modern pharmacovigilance. This system of medicine flourished under the guidance of renowned scholars who significantly contributed to its development.[4] Hippocrates (460–370 BC) is considered the "Father of Medicine" and laid the foundation of Unani medicine through ethical medical practice and systematic patient observation. His emphasis on clinical experience and natural healing set the tone for later advancements. [5, 47] Galen (129–200 AD) expanded upon Hippocratic teachings by introducing principles of drug action, dosage, and adverse effects. His contributions to pharmacology, including drug compounding and classification, provided a structured approach to medicinal therapy and laid the groundwork for recognizing and managing adverse drug reactions. [6, 48] Avicenna (Ibn Sina, 980–1037 AD) further advanced Unani medicine through his seminal work "Al-Qanun fi al-Tibb" (The Canon of Medicine). This encyclopaedic text outlined the pharmacological properties, therapeutic applications, and potential side effects of drugs in detail, demonstrating an early commitment to drug safety and efficacy that parallels modern pharmacovigilance practices. Together, these scholars laid a strong foundation for the safe and ethical practice of Unani medicine, incorporating principles that align closely with today's pharmacovigilance objectives.[7,49,50]

Unani medicine is deeply rooted in the principles laid down by Hippocrates, who emphasized beginning treatment with restrictions and dietary management before the use of drugs. This approach reflects an early awareness of the potential harm that medicinal substances might cause, highlighting that Unani physicians should aim to maximize benefits while minimizing harm. The holistic approach of Unani medicine prioritizes a hierarchical strategy of treatment: starting with Ilaj Bil Tadbeer (Regimental therapy), followed by Ilaj Bil Ghiza (Dietotherapy), then Ilaj Bil Dawa (Pharmacotherapy), and finally Ilaj Bil Yad (Surgery).[11,28]

Pharmacotherapy in Unani medicine revolves around the concept of temperament (Mizaj), which influences both the individual and the drugs prescribed. Drugs are classified into four degrees owing to their effectiveness, strength, and temperament, thereby managing their potential adverse effects: from the first degree with negligible effects to the fourth degree which are extremely strong, toxic, and potentially fatal. Before prescribing, the temperament of the patient, disease, and even the season are carefully considered, with drugs of opposing temperaments used to balance and neutralize harmful effects—for example, hot drugs treat cold disorders and vice versa.[28,47]

An essential part of pharmacovigilance in Unani medicine is Tadbeer-e-Adviyah, or drug processing, which detoxifies toxic substances and reduces side effects. Proper purification and detoxification (Mudabbar) of drugs are vital to prevent adverse reactions. Strong toxic drugs of higher degrees require more elaborate detoxification to be safely used in therapy. Additionally, Unani texts detail the concept of Muzir (Harmful effects) and their Musleh (Correctives), which involve combining drugs or modifying formulations to minimize undesirable effects and balance temperament. Furthermore, when drugs are unavailable, costly, or excessively toxic despite detoxification, alternative medicines known as Abdal-e-Advia (Therapeutic interchange) are used. This systematic approach to drug safety and personalized treatment illustrates the intrinsic pharmacovigilance embedded within the Unani system, aiming to ensure therapeutic efficacy while safeguarding patient health.[11,51]

Traditional pharmacovigilance practices in the Unani system of medicine were deeply embedded in the clinical routines of practitioners, long before the concept was formally defined. Early Unani physicians employed methods such as recording unknown side effects in personal notebooks called Bayaz. These served as individualized pharmacovigilance records, documenting unusual reactions and therapeutic outcomes, thereby preserving valuable clinical knowledge. Another key traditional method included sharing personal clinical experiences with students, which can be viewed as an early

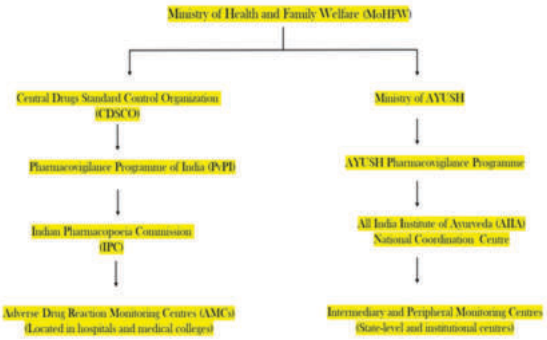
form of prescription auditing and monitoring. This ensured that adverse drug reactions (ADRs) and therapeutic observations were passed down and critically assessed within the scholarly and medical community.[11,47]

One of the earliest documented efforts specifically focused on ADRs in Unani medicine is credited to Hakim Alvi Khan, a distinguished member of the Alvi family and one of the most celebrated physicians of his time. His pioneering work included a detailed compilation of adverse effects, particularly among children, published in a journal titled Risale Dawaul Atfal (Journal of Pediatric Medicine). [11, 52] Furthermore, he published a series of case reports on ADRs in different age groups under the title Matab Hakim Alvi Khan, which is considered a landmark contribution to Unani pharmacovigilance literature. These efforts reflect a structured and insightful approach to drug safety, rooted in traditional clinical wisdom.[11,53]

Development of National Pharmacovigilance Program of ASU&H Drugs

India has played a pioneering role in promoting pharmacovigilance for Ayurveda, Siddha, and Unani (ASU) medicines. In 2004, the WHO published guidelines on the safety monitoring of herbal medicines, setting the stage for national-level initiatives. In 2005, the Ibn Sina Academy of Medieval Medicine and Sciences in Aligarh established the Centre for Safety and Rational Use of Indian Systems of Medicine (CSRUISM) to collect and analyse adverse drug reactions using globally accepted tools such as the WHO causality assessment scale and the Naranjo algorithm. [2, 54] In 2006, the first National Symposium on Herbal Pharmacovigilance was held at the Jawaharlal Nehru Medical College (JNMC), Aligarh, which led to the recommendation of a dedicated national pharmacovigilance program for ASU medicines. Subsequently, on 29 September 2008, the Ministry of AYUSH launched the National Pharmacovigilance Program for ASU drugs. The Institute for Post Graduate Teaching and Research in Ayurveda (IPGT & RA), Jamnagar, was designated as the National Pharmacovigilance Resource Centre (NPRC-ASU), under the leadership of Prof. M.S. Baghel and coordination by Dr. Rabinarayan Acharya. In March 2018, the program was restructured to include Homeopathy, thus becoming the pharmacovigilance program for ASU&H drugs.[42,55]

The organizational structure of pharmacovigilance in India is bifurcated under two main ministries: the Ministry of Health and Family Welfare (MoHFW) and the Ministry of AYUSH. Under the MoHFW, the Central Drugs Standard Control Organization (CDSCO) plays a central role in regulating drug safety. CDSCO oversees the Pharmacovigilance Programme of India (PvPI), which is implemented by the Indian Pharmacopoeia Commission (IPC). The IPC is responsible for coordinating the national network of Adverse Drug Reaction Monitoring Centres (AMCs), which are primarily located in hospitals and medical colleges across the country. These centres are tasked with collecting and analyzing data on adverse drug reactions (ADRs) associated with conventional (allopathic) medicines. [35,56,57] Parallelly, under the Ministry of AYUSH, the AYUSH Pharmacovigilance Programme functions to monitor the safety of traditional medicine systems like Ayurveda, Siddha, Unani, and Homeopathy. The nodal body for this program is the All-India Institute of Ayurveda (AIIA), which serves as the National Coordination Centre. Reporting and monitoring are supported by Intermediary and Peripheral Monitoring Centres, established at the state and institutional levels, ensuring the effective implementation of pharmacovigilance practices across the AYUSH systems. This dual-framework ensures that both conventional and traditional medicines in India are subjected to vigilant post-marketing surveillance, ultimately safeguarding public health.[57,58]



Under the National Pharmacovigilance Programme for Ayurveda, Siddha, Unani & Homeopathy (NPP-ASU&H), healthcare providers and stakeholders are encouraged to report all suspected adverse reactions related to ASU drugs. This includes any drug interactions that may affect patient safety. Reports should especially cover adverse events suspected to cause serious outcomes such as death, hospitalization (either initial or prolonged), life-threatening situations where there is a real risk of dying, disability that is significant, persistent, or permanent, and congenital anomalies potentially linked to drug exposure. Timely and accurate reporting of these events is crucial for monitoring drug safety and protecting public health within traditional medicine systems. [50,59]

Only healthcare professionals are authorized to report adverse drug reactions under the National Pharmacovigilance Programme for ASU drugs. Reports from the lay public or non-health practitioners are not accepted directly; however, they can submit information through the treating doctor.[50] Reporting should be done using the prescribed format and submitted to a local Pharmacovigilance Centre. Additionally, an online reporting system has been launched, and adverse drug reactions (ADRs) can be reported via the website www.ayushsuraksha.com. Peripheral Pharmacovigilance Centres collect the reports and forward the confidential forms to their respective Regional Pharmacovigilance Centres for causality assessment. The analyzed data is subsequently transferred to the National Pharmacovigilance Resource Center for statistical analysis and consolidation before addressed to the Department of AYUSH.[58, 59] Based on pharmacovigilance data, several regulatory actions may be implemented, including restrictions on drug use, adjustments in recommended dosages, introduction of safety warnings on product labels, reclassification of medicines (e.g., from over-the-counter to prescription-only), or even product recall if the risks outweigh the benefits. These measures ensure continued patient safety and rational use of traditional medicines.[60]

DISCUSSION

There is a general perception that Unani drugs are inherently safe. While this belief stems from the traditional and natural origins of Unani medicine, it's important to understand the fact behind this perception. Unani drugs are indeed considered safe, but this safety is not absolute or automatic—rather, it is the result of careful formulation and usage practices developed by Unani scholars over centuries.[11] The classical Unani system emphasizes minimizing side effects or adverse drug reactions (ADRs) through specific approaches in the preparation and administration of medicines. This includes the use of Muzhir (substances that may cause adverse effects), Musleh (correctives or substances added to neutralize potential side effects), and Tadbeer-e-Advia (methods of drug modification or detoxification). This illustrates that Unani scholars were acutely aware of potential ADRs, even if the concept was not categorized under the modern term pharmacovigilance. Their knowledge and preventive strategies were embedded

in classical literature and clinical practice, demonstrating a sophisticated understanding of drug safety long before the emergence of formal pharmacovigilance systems.[28,47]

Pharmacovigilance in Unani medicine faces several significant challenges. One major issue is the widespread ignorance among physicians regarding adverse drug reactions (ADRs), leading to very low reporting rates. Many practitioners hold the false belief that Unani drugs are inherently safe and do not have expiry dates, which undermines vigilance efforts. [7, 61] Additionally, the common practice of bulk dispensing, especially of potent drugs like kushta, often results in overdosing and increased risk of ADRs. The lack of quality control in drug production leads to inconsistent standards, while the informal pharmacy sector contributes to the sale of spurious, misbranded, and substandard drugs. Evaluating adverse reactions is further complicated due to the multi-ingredient nature of most Unani formulations.[50,62]The problem is exacerbated by the practice of pseudo-allopathy, where modern medicines are mixed with traditional treatments without proper monitoring. Moreover, many marketed Unani drugs lack authentic ingredients as per classical texts, often due to misidentification, false identification, or unavailability of the original medicinal plants, posing further risks to patient safety. These challenges collectively hinder the effective implementation of pharmacovigilance within the Unani system.[63,64]Hence, extending pharmacovigilance practices to Unani medicine is essential for ensuring patient safety and building scientific credibility. Systematic monitoring of Unani drugs, including documentation of side effects, interactions, and contraindications, can enhance public trust and support regulatory standards. As Unani medicine integrates further into mainstream healthcare systems, a robust pharmacovigilance framework tailored to its unique principles and formulations is critical for safeguarding public health and promoting evidence-based traditional medicine.[8,9,65]

CONCLUSION

Pharmacovigilance plays a vital role in ensuring the quality, safety, and efficiency of Unani medicine. With the increasing global use of traditional medicines, it is essential to systematically monitor, document, and analyze adverse drug reactions and interactions. This vigilance not only protects patient health but also strengthens the credibility and wider acceptance of Unani practices within modern healthcare systems. The implementation of robust pharmacovigilance frameworks bridges traditional knowledge with scientific validation, encouraging the responsible use of Unani drugs while supporting regulatory standards. Ultimately, effective pharmacovigilance fosters public trust and paves the way for integrating Unani medicine into evidence-based medical frameworks, contributing to holistic and comprehensive healthcare delivery.

Abbreviations

ADR: Adverse Drug Reaction
WHO: World Health Organisation
PV: Pharmacovigilance
ASU: Ayurveda, Siddha & Unani
CDSCO: Central Drugs Standard Control Organization
PvPI: Pharmacovigilance Programme of India
IPC: Indian Pharmacopoeia Commission
AYUSH: Ayurveda, Unani, Siddha & Homeopathy

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Conflicts of Interest

The authors declare that they have no conflict of interests.

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