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Homeopathy and pharmacovigilance: A framework for patient safety

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Abstract
The most recent medical art and science is homeopathy. Pharmacovigilance plays a significant role in homeopathy, similar to that in conventional medicine. Raising awareness and motivating homoeopathic experts to monitor drug safety, record adverse occurrences, and report them is essential. After an analysis of the collected and reported data, the Pharmacovigilance (PV) aspects of homoeopathy might provide confirmation of the efficacy of homeopathic medications.
Within the field of pharmacy, PV also referred to as drug safety is entirely scientific and process-oriented. It refers to monitoring the effectiveness and action of pharmaceuticals.

Keywords: AYUSH, Pharmacovigilance, homoeopathy, adverse drug reactions, aggravation

Introduction
The field that deals with Adverse Drug Reactions (ADRs), their identification, and reporting is called pharmacovigilance. The World Health Organization defines pharmacovigilance as a science that includes initiatives associated with the identification, evaluation, comprehension, and avoidance of adverse effects or any other issues relating to drugs. Despite the fact that India has been using AYUSH medicine systems for centuries, systematic records on their safety and the incidence of side effects are still lacking. Because AYUSH medications are made from natural sources, there is a strong belief among practitioners and the general public that they are free from side effects.
It can be difficult to assess the safety of traditional medicines due to a number of factors, including heavy metal content, industrial pollutants, pesticides, adulteration, environmental factors, concurrent use of allopathic medicines, over-the-counter sales, and poor pharmacopoeial standards compliance. As a result, establishing and comprehending the safety profile of AYUSH medications has become a crucial aspect of Indian pharmacovigilance.

AYUSH medicines regulation
The Drugs and Cosmetics Act of 1940 and the Drugs and Cosmetics Rules of 1945 contain sufficient provisions for the regulatory framework and for keeping updated on the efficacy, safety, and quality of medications that are part of AYUSH systems. In India, Schedule M-1 of the Act specifies good manufacturing standards for homeopathic medicines, whereas Schedule T of the Act specifies good manufacturing practices for Ayurvedic, Siddha, and Unani medicines. State governments appoint licensing authorities to supervise the application of the laws governing the production and distribution of AYUSH medications.

Pharmacovigilance System for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) medicines
The initiative's goal is to collect, compile, and evaluate information about potential Adverse Drug Reactions (ADRs) and monitor marketing for ASU&H medications in order to scientifically demonstrate the clinical safety of these medications.

The program's primary goals are to:
- Encourage consumers and ASU&H professionals to report suspected Adverse Drug Reactions (ADRs) and instances of misleading marketing for Ayurvedic, Siddha, Unani, and homeopathic medications;

- Create a system-wide database of ADRs linked to ASU&H medications; and
- Develop evidence-based recommendations for regulatory actions regarding the clinical safety and misleading advertising of ASU&H medications [2].

Structural Framework of NPP-ASU&H

There is a three tier structure comprising a National Pharmacovigilance Coordination Centre (NPvCC), Intermediary Pharmacovigilance Centres (IPvCs) and Peripheral Pharmacovigilance Centres (PPvCs). The NPvCC receives inputs in terms of suspected ADRs from the IPvCs, and the IPvCs provide support to the PPvCs [2].

Functions and responsibilities of pharmacovigilance centres under National Pharmacovigilance Program for Ayurveda, Siddha, Unani and Homoeopathy Drugs

National Pharmacovigilance Coordination Centre (NPvCC)	• Document and monitor suspected ADRs associated with ASU&H medicines. • Management of periodic safety update reports (PSURs) from manufacturing companies for their ASU&H medicines for all patent and proprietary products. • Organize awareness and capacity building workshops for stakeholders. • Undertake causality assessment for suspected ADRs associated with ASU&H medicines and recommend necessary regulatory action to the Ministry of AYUSH. • Provide information to end users through seminars, drug alerts and other means. • Report objectionable advertisements. • Other related activities
Intermediary Pharmacovigilance Centres (IPvCs)	• Document and monitor suspected ADRs associated with ASU&H medicines • Collect information regarding suspected ADRs associated with ASU&H medicines from the respective PPvCs • Report suspected ADRs associated with ASU&H medicines to NPvCC at regular intervals for causality assessment • Organize awareness building and capacity building workshops for stakeholders • Scrutinize project proposals received from the PPvCs and forward the same to the NPvCC along with recommendations • Report objectionable advertisements
Periphery Pharmacovigilance Centres (PPvCs)	• Document and monitor suspected ADRs associated with ASU&H medicines • Report suspected ADRs associated with ASU&H drugs to the concerned IPvC at regular intervals • Report objectionable advertisements

Awareness, training of AYUSH physicians in pharmacovigilance aspects, proper screening methods, and ADR reporting culture all play a pivotal role in the successful functioning of the programme that ultimately helps the systems to join the mainstream.

Implementation and monitoring of NPP-ASU&H

The implementation of the NPP-ASU&H is under the supervision of a monitoring committee that comprises experts from the Ministry of AYUSH, the Indian Pharmacopoeia Commission (IPC), the Central Drugs Standard Control Organisation (CDSCO) and the Pharmacopoeial Commission for Indian Medicine and Homoeopathy (PCIM&H). These committees are mainly concerned with reviewing and analysing the ADRs reported at different levels and suggesting proper remedial measures.

In order to monitor the implementation of the programme and measure its efficacy, the NPvCC established several key indicators, such as

- Process
- Outcome and
- Impact of the programme.

The Pharmacovigilance Programme of India (PvPI) at Indian Pharmacopoeia Commission receives spontaneous ADR data associated with the use of drugs or other medical products (such as medical devices, blood products, vaccines) in the form of individual case safety reports (ICSRs) from its recognized ADR monitoring centre, doctors, pharmacists, the pharmaceutical industry and others [2].

Adverse Drug Reaction (ADR)

An adverse drug reaction is an undesirable and unexpected reaction that happens at dosages normally used in people for prevention, treatment of an illness, or alteration of physiological function.

Aggravations in homoeopathy

The worsening of symptoms or a worsening of the condition following medication administration is known as aggravation.

Adverse drug reaction in homoeopathy

Large dosages of prescription medications are the primary cause of ADR. Hahnemann was aware of this in his early years of practice. Prior to 1801, Hahnemann took large amounts of medication, which resulted in unwanted aggravation and adverse pharmacological reactions. As a result, he began regularly diluting the medication with strokes to administer the smallest doses possible, a process he called "potentization."

In a cross-sectional study, Norwegian homeopathic patients were asked to record any reactions fourteen days after receiving a homeopathic medication. A total of 26 individuals claimed that their symptoms had gotten worse. A third were categorized as unfavourable incidents. The Common Language Criteria for Adverse Events were used to evaluate half of these as minor and the other half as moderate. It was determined that two-thirds were homeopathic aggravations.

To learn about the negative consequences of homeopathy, a comprehensive analysis of published case reports and case series was conducted. This systematic review's goal was to critically assess the evidence supporting homeopathy's Adverse Effects (AEs). Thirty of the 38 primary reports dealt with direct negative reactions to homeopathic remedies [3].

Difference between aggravation and ADR

An adverse drug reaction is a dangerous and unintentional reaction that happens at dosages typically used in humans

for disease prevention, diagnosis, or treatment, or for altering physiological function, and that wasn't expected or recognized before. However, homoeopathic medicine is either aware of or expects disturbance.

Pharmacovigilance in homoeopathy

To promote pharmacovigilance practices in Ayurveda, Siddha, Unani, and Homoeopathy, the Department of Ayush has launched a new central program. It is the area that deals with Adverse Drug Reactions (ADRs), including how to identify and report them. The widespread misconception regarding herbal medications is that they are entirely safe and can be taken by the patient on their own, without the guidance of a physician. This idea has caused many people to self-administer medications on a large scale, which frequently results in unfavourable side effects or disappointing outcomes.

Current challenges in reporting and documentation of adverse drug reactions in homoeopathy

Currently ADR is poorly reported and documented in homoeopathy. It may be either because of carelessness on part of physician or non-development of ADR at all.

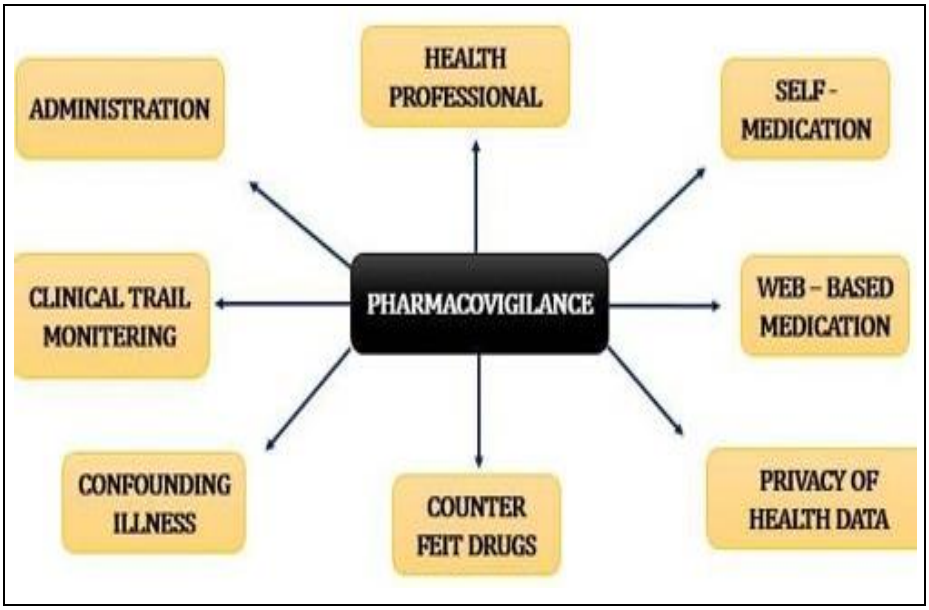

Fig 1: Challenges

The culture of homeopaths reporting ADRs needs to be improved. Because pharmacovigilance in homeopathy will not only protect consumers but also greatly benefit the system by establishing a database that would support the safety of homeopathic medications, which may improve homeopathy's credibility among scientists and raise its market value.

The difficulties in reporting ADRs can be addressed with the following solutions

- The primary funding source for the administration of the Pharmacovigilance program at all levels is the government. The government ought to launch a program that offers incentives or prizes in addition to appropriate gratitude and acknowledgment to homeopathic doctors who report Adverse Drug Reactions (ADRs) with the required paperwork. Physicians will be inspired and encouraged to report and document ADRs at the clinical level by this program.
- When properly verified, ADRs can enhance our medical knowledge because they may provide new indications for that specific homoeopathic treatment. These kinds of benefits can be elucidated by holding frequent Continuing Medical Education (CME) sessions for health professionals that focus on pharmacovigilance and urge them to report and document adverse drug reactions.
- Educating the public about the negative health impacts of self-medication and online medication by holding health camps, broadcasting ads on television, and encouraging people to see a doctor right away if an adverse drug reaction occurs.
- As a major alternative for confounding sickness, single remedy constitutional treatment should be used. This will enable doctors to simply identify and document the Adverse Drug Reactions (ADRs) of a specific single prescription without any confusion, which is not possible when several drugs are provided.
- Controlling the production and supply of drugs would be made easier with stricter state licensure oversight of drug suppliers.

Conclusion

Healthcare systems primarily rely on the detection and reporting of Adverse Drug Reactions (ADRs) to identify new drug reactions, track the frequency of ADR reports, analyze potential risk factors for patients, and inform medical professionals in an effort to stop future ADRs. All medical practitioners have an equal responsibility to monitor medication safety, and the gathering, reporting, and interpretation of Adverse Drug Reactions (ADRs) must always be the main focus. Given the growing popularity of homeopathy, it is imperative that all obstacles be overcome in order to enhance the reporting culture of homeopaths. As a result, the system will have greater scientific validation and be safer to use [3].

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