



HOMOEOPATHY AND PHARMACOVIGILANCE: BRIDGING SAFETY AND EFFICACY

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ABSTRACT

Background

Pharmacovigilance, the science of monitoring the safety and efficacy of drugs, is essential for all therapeutic systems, including Homeopathy. Despite the growing acceptance of Homeopathic treatments, there is a significant gap in the understanding and implementation of pharmacovigilance practices among practitioners. This research aims to address the challenges faced in reporting and analyzing adverse drug events (ADEs) in Homeopathy.

Methods

The study involved comprehensive literature review of Organon of Medicine, Homeopathic texts, journals, and contemporary research articles, all scientific books, websites and relevant literary works to assess the state of pharmacovigilance in Homeopathy.

Objectives

The primary objectives of this study were to identify barriers to effective pharmacovigilance in Homeopathy, enhance the understanding of adverse event reporting, and propose strategies for improving data collection and analysis.

Results

Findings revealed significant gaps in awareness and education regarding pharmacovigilance among Homeopathic practitioners. Underreporting of ADEs was prevalent, primarily due to the individualized nature of Homeopathic treatment and challenges in establishing causal links between remedies and adverse events. The Modified Naranjo Criteria was found to require adaptation for better applicability in Homeopathy.

Conclusion

Effective pharmacovigilance is crucial for ensuring patient safety in Homeopathy. By addressing the identified challenges and fostering a culture of reporting and education, the Homeopathic community can enhance the understanding of treatment safety.

Keywords: Homoeopathy, Pharmacovigilance, Adverse Drug Events, Adverse drug reaction, Misleading advertisements.

INTRODUCTION

Pharmacovigilance is derived from the Greek word "*Pharmakon*" meaning "*drug*" & Latin word "*Vigili*" meaning "*To keep watch*". Pharmacovigilance is defined as "*the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems*".^[1] It literally means to keep watch on the action of medicinal substances.^[2]

In India, Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homoeopathy (AYUSH) are vastly used & widely practiced systems of medicine. They are considered as safest medical systems. With gradual increase and demand of ASU&H systems esp. Homoeopathy globally, pharmacovigilance of these systems has not only become essential but compulsion. The system of

Pharmacovigilance gives any therapy a sense of completeness.^[1] Pharmacovigilance practice is the need of hour for all systems of medicine including Indian Systems of Medicine, as it ensures patients safety, more scientific and up to date.^[3]

REFERENCES OF ADVERSE DRUG REACTIONS BY OUR MASTER IN ORGANON OF MEDICINE^[4].

Even our master Dr. Samuel Hahnemann warned us regarding adverse drug reaction if medicine is prescribed in too large doses or is un-Homoeopathic to a disease state in 5th and 6th Edition of Organon of Medicine.

In 5th Edition under §276 Hahnemann mentions:

- For this reason, a medicine, even though it may be homoeopathically suited to the case of disease, does harm in every dose that is too large, the more harm the larger the dose, and by the magnitude of the dose it does more harm the greater its homoeopathicity and the higher the potency selected....
- It does much more injury than any equally large dose of a medicine that is unhomoeopathic, and in no respect adapted (allopathic) to the morbid state.
- The very analogous medicinal disease produced by the vital force stirred up by the excessively large dose of medicine, in the parts of the organism that are most suffering and most irritated by the original disease - which medicinal disease, had it been of appropriate intensity, would have gently effected a cure - rises to an injurious height; the patient, to be sure, no longer suffers from the original disease, for that has been homoeopathically eradicated, but he suffers all the more from the excessive medicinal disease and from useless exhaustion of his strength.

What happens when wrongly selected Homoeopathic medicine is administered? (§249 6th edition)

When any medicine not selected Homoeopathically when administered produces new symptoms which are not appertaining to the original disease which are harmful than the original ailment and need to be antidoted, and it is always to be remembered that only small doses, with the power of Dynamization and considering Individualization strictly in the process of prescribing any medicine will help in prevention of Adverse effects due to medicine. **§249 6th edition:** "Every medicine prescribed for a case of disease which, in the course of its action, produces new and troublesome symptoms not appertaining to the disease to be cured, is not capable of effecting real improvement, and cannot be considered as homoeopathically selected; it must, therefore, either, if the aggravation be considerable, be first partially neutralized as soon as possible by an antidote before giving the next remedy chosen more accurately according to similarity of action; or if the troublesome symptoms be not very violent, the next remedy must be given immediately, in order to take the place of the improperly selected one."

AIMS OF PHARMACOVIGILANCE

- To identify new information about hazards associated with products.
- To prevent harm to patients.
- To minimize risk & maximize benefits.
- Detect problems related to the use of medicines and communicate the findings in a timely manner.^[1]
- Encourage the safe, rational and more effective (including cost-effective) use of medicines.^[1]

PHARMACOVIGILANCE CENTRES:^[5]

The nationwide programme under central sector scheme funded by Ministry of AYUSH, New Delhi for ASU & H drugs to establish and manage a data base of Adverse Drug Reactions (ADR) for developing system wise database of adverse drug reactions and evolving evidence based recommendations towards clinical safety of ASU & H Drugs. Besides this; the program also undertake surveillance of objectionable or misleading advertisements.

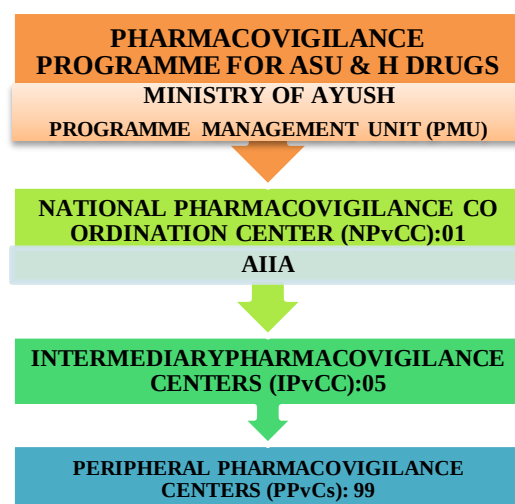


Figure 1: Pharmacovigilance Programme for ASU & H drugs

National Pharmacovigilance Coordination Centre (NPvCC):01

It is a tertiary pharmacovigilance centre, acting as National Centre in the administrative structure of the program. Ministry of AYUSH, New Delhi has designated All India Institute of Ayurveda (AIIA), New Delhi as National Pharmacovigilance Coordination Centre (NPvCC).

Intermediary Pharmacovigilance Centres (IPvCs) for ASU & H Drugs:05

Secondary pharmacovigilance centres, acting as second level centres in the administrative structure of the program. **Five National Institutes** (National Institute of Ayurveda, Jaipur; Institute of Teaching and Research in Ayurveda, Jamnagar; National Institute of Siddha, Chennai; National Institute of Unani Medicine, Bengaluru; and National Institute of Homoeopathy, Kolkata) are designated as Intermediary Pharmacovigilance Centres.

Peripheral Pharmacovigilance Centres (PPvCs) for ASU & H Drugs

Primary pharmacovigilance centres. They are relatively smaller ASU & H colleges or institutions including. These are the first contact ADR data collection units. They would be identified and coordinated by IPvCs in consultation with NPvCC. These are 99 in number out of which Homoeopathic PPvCs are 15.

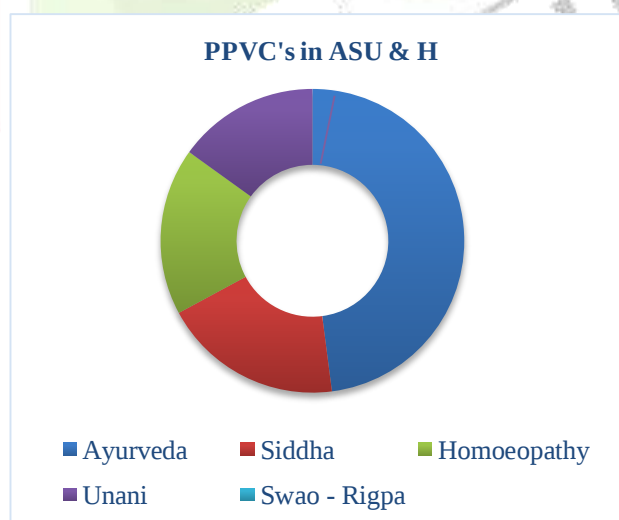


Figure 2: Peripheral Pharmacovigilance Centres in ASU & H

DDPR CRI (H), Noida is designated as one of the Peripheral Pharmacovigilance Centres to record and develop the culture of ADR reporting, documentation and analysis of homoeopathic medicines for regulatory action. To achieve this goal a pharmacovigilance department has been setup in July, 2018 at this institute. ^[6]

CRIH: Noida, UP; NHRIM: Kottayam, KL; RRIH: Gudivada, AP; RRIH: Guwahati, AS; RRIH: Kolkata, WB; RRIH: Mumbai, MH; GHMC: Bhopal, MP; MBHMC: Howrah, WB; SKHMC: Kanyakumari, TN; FMHMC: Mangalore; AHMC: Bhubaneswar, OD; RRIH: Imphal, MN; RRIH: Agartala, TR



Figure 3: Peripheral Pharmacovigilance Centres in Homoeopathy

ROLE OF PHARMACOVIGILANCE CENTERS

- Safety Monitoring of Drugs
- Proper dissemination of Drug Information
- Create awareness among Public against Self medication
- Adverse Drug Events (ADR)
- Tracking Manufacturer/Supplier/Marketing Company
- Reducing channel of action by directly forwarding the complaints to the State Regulators
- Monthly reporting.

KEY ASPECTS OF PHARMACOVIGILANCE

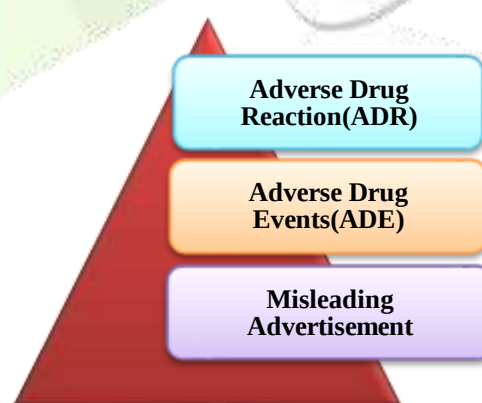


Figure 4: Key Aspects of Pharmacovigilance

The system of pharmacovigilance was beautifully justified by Vladimir Lepakhin, former as “**Dying from a disease is sometimes unavoidable; dying from a medicine is unacceptable**”. It is estimated that ADRs are the sixth leading cause of death worldwide^[1].

ADVERSE DRUG REACTION (ADR)

ADR is defined by the World Health Organization (WHO) as a response to a drug that is noxious, unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of a physiological function^[7]. There is a causal link between a drug and an adverse drug reaction.

Adverse Drug Reaction (adverse effects) are any unwanted effects of a drug. There are several different types:

- Dose-related.
- Allergic.
- Idiosyncratic.

The Naranjo Criteria algorithm is one that has been utilized to classify the probability that an adverse event is related to drug therapy based on a list of weighted questions. But this criteria need some modification to fit the evaluation criteria of Action of Homeopathic medicines.

IMPACT OF ADR'S ON HEALTH AND ECONOMY

Global Significance:

- ADRs are the sixth leading cause of death worldwide, with serious drug reactions occurring in nearly 7% of hospitalized patients.

India's Reporting Challenge:

- India's ADR reporting rate is below 1%, significantly lower than the global average of 5%, indicating a need for enhanced pharmacovigilance (PV).^[8]

CAUSALITY ASSESSMENT OF SUSPECTED ADR

Several algorithms and probability scales have been created to determine causality. Among the notable ones are the Jones algorithm, the Begaud algorithm, and a quantitative approach algorithm (Srinivasan 2011). However, three algorithms are more frequently used due to their simplicity and efficiency: the World Health Organization. Uppsala Monitoring Centre causality assessment scale, the Naranjo ADR Probability Scale, and the Liverpool ADR causality assessment tool.^[8]

The Naranjo Criteria is a standardized tool designed to assess the causality of adverse drug reactions (ADRs). While originally created for conventional pharmaceuticals, it is also relevant to homeopathy for evaluating the link between homeopathic remedies and potential ADRs through a series of weighted questions. However, some of these questions were not well-suited for homeopathy, making it challenging to assess ADRs in this context. As a result, modifications were made, leading to the development of the **Modified Naranjo Criteria for Homeopathy**. This version, also known as the **Causal Attribution Inventory**, was first adapted by Rutten and later refined by the Clinical Data Working Group of the Homeopathic Pharmacopoeia Convention of the United States (HPCUS), is proposed to assess the likelihood of causal attribution of the clinical outcome to the medicine(s) prescribed in homeopathic cases and case reports. The Modified Naranjo Criteria has proven to be a valuable tool in determining the causal relationship between homeopathic treatment and clinical outcomes. Its reliability and validity have been established for most domains, with the exception of those concerning the "direction of cure" (domains 6A and 6B).^[10]

Table 1 : Modified Naranjo Criteria

DOMAINS	YES	NO	NOT SURE OR N/A
1. Was there an improvement in the main symptom or condition for which the homeopathic medicine was prescribed?	+2	-1	0
2. Did the clinical improvement occur within a plausible timeframe relative to the drug intake?	+1	-2	0
3. Was there an initial aggravation of symptoms?	+1	0	0
4. Did the effect encompass more than the main symptom or condition (i.e., were other symptoms ultimately improved or changed)?	+1	0	0
5. Did overall well-being improve? (suggest using validated scale)	+1	0	0
6A Direction of cure: did some symptoms improve in the opposite order of the development of symptoms of the disease?	+1	0	0
6B Direction of cure: did at least two of the following aspects apply to the order of improvement of symptoms: –from organs of more importance to those of less importance? –from deeper to more superficial aspects of the individual? –from the top downwards?	+1	0	0
7. Did “old symptoms” (defined as non-seasonal and non-cyclical symptoms that were previously thought to have resolved) reappear temporarily during the course of improvement?	+1	0	0
8. Are there alternate causes (other than the medicine) that—with a high probability—could have caused the improvement? (Consider known course of disease, other forms of treatment, and other clinically relevant interventions)	-3	+1	0
9. Was the health improvement confirmed by any objective evidence? (e.g., laboratory test, clinical observation, etc.)	+2	0	0
10. Did repeat dosing, if conducted, create similar clinical improvement	+1	0	0

Note: Maximum score: 13, minimum score: 6.

NEED FOR PHARMACOVIGILANCE IN HOMOEOPATHY

The increasing global acceptance and use of homoeopathic treatments necessitate a robust pharmacovigilance framework. Reports suggest that many patients use homoeopathy alongside conventional medicine, which can lead to potential interactions and complications. Understanding the safety profile of homoeopathic medicines can help practitioners provide informed care and mitigate risks associated with polypharmacy. ^[11]

MISLEADING/OBJECTIONABLE ADVERTISEMENT IN HOMOEOPATHY ^[12]

On and off we use to see advertisements in print and electronic media having false claim on different types of diseases and homoeopathy. Such advertisements exploit the people's belief on homeopathy. Through this programme we can put a tap over misleading or objectionable advertisements and action can be taken as per provisions of the law. For enforcing Pharmacovigilance of ASU&H drugs multiple laws are available in India.

REGULATORY AUTHORITIES

1. **Food Safety and Standards Authority (FSSAI)**
Ensures food safety and standards, including penalties for misleading food product advertisements.
2. **Central Drugs Standard Control Organization (CDSCO)**
Regulates drug approval and monitoring in India.
3. **Insurance Regulatory and Development Authority (IRDA)**
Oversees the insurance industry, ensuring consumer protection and fair practices.
4. **Telecom Regulatory Authority of India (TRAI)**
Regulates telecom services and promotes competition.
5. **Securities and Exchange Board of India (SEBI)**
Governs the securities market to protect investors and ensure fair trading.
6. **Reserve Bank of India (RBI)**
Regulates the banking sector and monetary policy.
7. **Medical Council of India**
Sets standards for medical education and practices.

ADVERTISING REGULATIONS

- **Cigarettes and Other Tobacco Products Act, 2003**
Prohibits advertising and regulates trade in tobacco products.
- **Cable Television Network (Regulation) Act, 1995**
Governs advertisements on private satellite TV channels.
- **Press Council of India**
Adjudicates misleading print media advertisements that violate journalistic standards.

Misleading advertisements can be reported by filling in Misleading Advertisement Reporting Form.

Misleading Advertisement Reporting Form^[5]

Centre: _____

Month/Year: _____

Attach image/photo of Misleading Advertisement with the form submission _____

Name of the Product: _____

or Name of the Drug _____

Name of Advertiser: _____

Please mention Advertising authority or Manufacturer or Marketing agency

Advertiser Contact Details: _____

Medium of Advertisement: _____

[print / electronic / internet / audio-visual) / Language]

Place: _____

Contents of the advertisement: _____

Reference details: _____

Source of Advt. Page number, Name of the publication, Address of Print media or Name TV Channel

Date of Advt. (Publication/ Telecasted on): _____

The advertisement violated or contravened which section of DMR Act – 1954:

Date: _____

Place: _____

Name of the Coordinator: _____

Send filled form to the below mentioned address

Postal Address: _____

The Coordinator, Intermediary Pharmacovigilance Centre for Ayurveda (IPvC)

Institute of Teaching and Research in Ayurveda (ITRA),

Opposite B Division Police Station, Gurudwara Road, Jamnagar, Gujarat – 361008

Email: ipvcjamnagar@gmail.com / Pharmacovigilance@itra.edu.in

EXCLUSIVE REGULATORY PROVISIONS FOR ASU & H DRUGS**DRUGS AND COSMETICS (D&C) ACT, 1940**

- **Sections 3(a) & (h):** Define ASU drugs and set foundational criteria.
- **Chapter IVA (Sections 331 to 330):** Specifically addresses regulations related to ASU drugs.
- **First Schedule:** Lists ASU drugs and their classifications.
- **Second Schedule (4A):** Establishes quality standards for homeopathic drugs.

DRUGS AND COSMETICS (D&C) RULES, 1945

- **Rules 151 to 170:** Cover regulations and requirements for ASU drugs.
- **Schedules E (I), T, TA:** Pertaining to specific ASU drug categories.
- **Rules 30AA, 67, 85 (A to I), 106-A:** Address regulations for homeopathic drugs.
- **Schedule K:** Lists exempted drugs from certain provisions.
- **Schedule M-1:** Outlines additional requirements for homeopathic drugs.

- OTHERS



Figure 5: The Drugs & Magic Remedies Act

- The Drugs and Magic Remedies (Objectionable Advertisements) Act. [Figure 5]
- The Food Safety and Standards Act, 2006.

REPORTING PROCESS ^[5]

- **What to Report:** Encourage reporting of all suspected drug-related adverse events, including interactions with other drugs or food, using the designated reporting form.
- **Eligible Reporters**
Who Can Report: Any healthcare professional can report suspected adverse drug events to the appropriate Peripheral or Intermediary Pharmacovigilance Centres.
- **Submission Guidelines**
Where to Report: Reports should be submitted to the nearest or relevant PPvCs or IPvCs using the prescribed format.
- **Report Handling**
Confidentiality and Analysis: Reports will be kept confidential, analyzed by Peripheral Pharmacovigilance Centres, and forwarded to the National Pharmacovigilance Centre for further action and reporting to the Ministry of AYUSH.

CHALLENGES IN HOMOEOPATHIC PHARMACOVIGILANCE ^[13,14,15,16]

1. **Lack of Awareness and Education:** Many practitioners are unaware of pharmacovigilance reporting systems, and there is a significant gap in education regarding recognizing and reporting adverse drug reactions (ADRs).
2. **Underreporting of Adverse Events:** Both practitioners and patients may fail to recognize or report mild adverse reactions, leading to an underestimation of potential risks.
3. **Individualized Treatment Approach:** The emphasis on individualized medicine complicates the establishment of a causal relationship between homoeopathic remedies and adverse events, making it challenging to apply standard assessment tools like the Naranjo Criteria.
4. **Variability of Remedies:** The lack of standardization in the preparation and potency of homoeopathic remedies complicates the identification and evaluation of adverse effects.
5. **Different Concepts of Cure:** The definition of cure in homoeopathy differs from that in other medical systems, further complicating the assessment of treatment outcomes.
6. **Limited Research and Scientific Evidence:** There is a scarcity of robust clinical research in homoeopathy, which hinders the accumulation of evidence on the safety and efficacy of treatments.
7. **Complexity of Patient Cases:** Many patients may present with multiple health issues or comorbidities, making it difficult to attribute adverse events solely to homoeopathic remedies.
8. **Resistance to Reporting:** Some practitioners may be hesitant to report adverse events due to fear of legal repercussions or skepticism about the value of such reports.
9. **Lack of Collaboration:** There may be insufficient collaboration between homoeopathic practitioners and conventional healthcare systems, leading to fragmented reporting and data sharing.
10. **Regulatory Challenges:** Variations in regulatory frameworks governing homoeopathy across different regions can lead to inconsistencies in pharmacovigilance practices.

These challenges underscore the need for enhanced awareness, standardized training, and improved reporting mechanisms to strengthen pharmacovigilance in homoeopathy.

HOW PHARMACOVIGILANCE WILL HELP HOMOEOPATHY?^[2]

Pharmacovigilance in homeopathy not only safe guard the consumers but can benefit the system immensely in following way.

- Creating a Safety Database for ASU&H Medicines
- Enhancing Homeopathy's Credibility within the Scientific Community
- Expanding Materia Medica with ADR Insights
- Identifying Relationships Between Homeopathic Remedies
- Boosting the Market Value of Homeopathy
- Providing Evidence for Homeopathy's Perceived Lack of Side Effects
- Safeguarding Homeopathy's Reputation by Preventing Deceptive Advertising
- Fostering Regulatory Support and Integration of Homeopathy into Healthcare Systems
- Enhancing Safety Through the Analysis of ADR Data

EMERGING TRENDS

To improve pharmacovigilance in homeopathy, several strategies can be implemented:

▪ **Establishing Robust Reporting Systems**

Developing dedicated platforms for reporting ADRs specific to homeopathic treatments can encourage practitioners and patients to share their experiences. Creating user-friendly digital tools may enhance participation and data collection ^[17].

▪ **Collaboration with Conventional Pharmacovigilance Systems**

Integrating homeopathic pharmacovigilance with existing pharmacovigilance frameworks in conventional medicine can facilitate a comprehensive approach to patient safety. Collaborative efforts can help identify interactions and enhance the overall understanding of both therapeutic and adverse effects ^[18].

▪ **Research and Development**

Investing in research to investigate the safety and efficacy of homeopathic remedies is essential. Rigorous clinical trials and observational studies can provide the evidence needed to inform practitioners and patients about the safety profiles of specific remedies ^[19].

CONCLUSION:

The vast majority of the global population, particularly in developing countries, relying on traditional medicines, the accountability of practitioners, especially homeopaths, in ensuring the safety and efficacy of their prescriptions is crucial. As Paracelsus the great Swiss physician and philosopher states *'What is there that is not poison? All things are poison, and nothing is without poison. Solely the dose determines that a thing is not a poison'*. Homeopaths in this aspect have a great advantage as they are trained about the significance of minimum dose and therefore it is the prime responsibility of Homeopaths to carefully and Homoeopathically prescribe the medicines to prevent ADRs The main motto of this subject is to improve awareness to clear the misconception that all that is natural doesn't make it safer, though its adverse effects are minimal compared to other systems, still it becomes a matter of concern in promising a qualitative cure. Effective pharmacovigilance is crucial for ensuring patient safety in homeopathy and enhance patient outcome. By addressing the identified challenges and fostering a culture of reporting and education, the homeopathic community can enhance the understanding of treatment safety

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