

Pharmacovigilance and Homoeopathy: A Review

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ABSTRACT

Background and objective: Pharmacovigilance in conventional system of medicine is operational for more than sixty years. Homoeopathy, being the second largest way of treatment, is widely practiced all over the world. Hence pharmacovigilance in Homoeopathy is indispensable especially in wake of malpractices like use of drugs violating its principles, increasing incidences of misleading and objectionable advertisements etc. Through this review we shall explore the status of pharmacovigilance in Homoeopathy.

Methods: An intense literature search was made on the web pages, databases, journals, bibliographic resources regarding practice of pharmacovigilance in Homoeopathy. Available Publications till May 2020 along with literatures of Homoeopathy were analysed.

Results: Data of adverse drug reaction (ADR) arising out of homoeopathic drugs are negligible in the literatures. In India Homoeopathy is patronised by the Government under AYUSH systems. Recently, Ministry of AYUSH, Govt. of India, has taken an initiative of Pharmacovigilance of Ayurveda, Sidha, Unani & Homoeopathy (ASU&H) drugs for reporting and taking measures against ADR of ASU&H drugs and objectionable advertisements in print and electronic media. Some European countries have also started pharmacovigilance of herbal and traditional medicine. Homoeopathy remained careful regarding adverse drug reaction since beginning which is evident from its literatures having full of criticisms to adverse drug events/reactions (ADE/ADR) with examples. Christian Friedrich Samuel Hahnemann (1755-1842), The Father of homoeopathy, devoted his whole life in providing a least harmful, gentle and simple system of therapeutic.

Conclusion: Although the data of ADRs in Homoeopathy is negligible but in view of increasing incidence of malpractices and misleading advertisements in Homoeopathy, system of pharmacovigilance with full participation of whole homoeopathic fraternity is the need of the hour for enhancing its validity and market value.

Key words: Pharmacovigilance; Homoeopathy; Adverse drug reaction; Drug proving; Aggravation; Materia Medica; Misleading and objectionable advertisement

INTRODUCTION

The word Pharmacovigilance (Pv) is a mixture of Greek word "Pharmakon" which means "medicinal substances" and the Latin word "Vigili" which means "to keep watch". It literally means to keep watch on the action of medicinal substances. Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. Currently it also covers the allied substances like blood & blood products, medical devices &

vaccines [1]. Adverse drug reaction (ADR) means the unintended and noxious reactions of administered drug and related items. The origin of medicine routes back to those of human being but the science of Pharmacovigilance is new which has emerged as an important branch in recent times. The system of pharmacovigilance was beautifully justified by Vladimir Lepakhin, former Director of USSR and Russian Drug Authority as "Dying from a disease is sometimes unavoidable; dying from a medicine is unacceptable." It is estimated that ADRs represent the fourth leading cause of

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death in the United States and Canada behind heart disease, cancer, and stroke. Further, it is estimated that ADRs are the sixth leading cause of death worldwide [2]. Despite much advances we have not been able to produce the full proof drugs. The system of Pharmacovigilance gives any therapy a sense of completeness. Health care of only few countries has the feature of medical pluralism like India. Ayurveda, Sidha, Unani and Homoeopathy (ASU&H) are vastly used and practiced in India. With gradual increase and demand of ASU&H systems esp. homoeopathy globally, pharmacovigilance of these systems has not only become essential but compulsion. In comparison to conventional system reporting and documenting of ADR in ASU&H is negligible. In contrary, print and electronic media are full of advertisements of ASU&H products. That is why there was an urgent need of system like pharmacovigilance as “Police of ASU &H drugs” for keeping constant vigil on such irrational practice and taking necessary care. After going through this discourse readers will be able to know the works done in Pharmacovigilance of ASU&H drugs in India and why it is essential for Homoeopathy etc? Since the start of this scheme in India questions are being raised from different quarters that there is no use of pharmacovigilance in Homoeopathy as there is no substantial evidence of major adverse drug reaction given to the minuteness of the dose. The motive of this article is to explore the relations between pharmacovigilance and homoeopathy and its relevance from historical, homoeopathic principles and reporting of adverse reactions and misleading advertisements points of view.

METHODS

A literature search was conducted using various publications, print journals, compendia, bibliographic databases like pubmed, google scholar, google search engines to collect all relevant articles, anecdotal records, reports, homoeopathic archived texts, literatures, web pages etc published upto May 2020 focussing on the scope of pharmacovigilance in AYUSH systems esp Homoeopathy. Based on the available information, the present scenario and recommendations regarding scope, utility and relevance of Pharmacovigilance in Homoeopathy was deduced.

RESULTS

History of Pharmacovigilance

A series of adverse drug events in the past compelled to establish a system of vigilance over the phenomena of drugs after its clearance for mass use. As per the records, the history of ADR dates back to Jan 29, 1848 when a young girl (Hannah Greener) from the north of England died after receiving chloroform anaesthetic before removal of an infected toe nail [3]. The Thalidomide tragedy in 1961, was the eye opener for the medical fraternity and its regulators. Following which Dr. McBride, an Australian doctor, wrote a letter to the editor of the Lancet Journal, in which he suggested a connection between congenital malformation of babies and thalidomide in which around twenty thousand babies were affected with phacomalia [4]. Gradually the whole world started working for developing a system of pharmacovigilance. In 1978 Uppasala Monitoring Centre (UMC) started in Sweden as the WHO collaborating centre for international drug monitoring. It operates the technical and scientific aspects of the WHO's worldwide pharmacovigilance network [5]. Currently 136 countries are the full members of the WHO Programme for International Drug Monitoring.

Pharmacovigilance in India

In India awareness about the ADR was first started in October 1983 by organising a seminar under the auspices of India Pharmacovigilance society at Maulana Azad Medical College, New Delhi. In 1989 ICMR sponsored the first project on adverse drug reactions in India in the department of pharmacology Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh. The first conference on ADR was organised in January 1997 by the Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai. Society of Pharmacovigilance India (SoPI) was constituted and registered in 1999 as a dedicated platform for future discussions. National Pharmacovigilance Programme (NPP) was launched in 2010 under the command of Central Drug Standard Control Organization (CDSCO), Ministry of Health & Family Welfare, Government of India, New Delhi. In 2011 The National Coordinating Centre was shifted from the All India Institute of Medical Sciences (AIIMS), New Delhi to the Indian Pharmacopoeia Commission (IPC), Ghaziabad, (U.P) form where it is working since then [6].

Following the conventional medicine, need of pharmacovigilance was also felt in herbal or traditional medicines. Consequently National Pharmacovigilance Program was established in various countries to collect, process, understand and report adverse events of the medicines including the herbal medicines [7]. The European medicine agency (EMA) provided its rule for pharmacovigilance of herbal medicines and provided its reviews of various herbal medicines as per the available data [8].

First work related to the Adverse drug reaction in AYUSH sector occurred in 2005 when Ibn Sina Academy of Medieval Medicine & Science (Aligarh), established a special cell namely “Centre for safety & Rational Use of Indian Systems of Medicine” in collaboration with WHO. After that Institute of Post Graduate Teaching & Research in Ayurveda (IPGT & RA), Jamnagar, conducted two days National workshop on 3rd and 4th December 2007. In 2008 Department of AYUSH, Ministry of Health and FW, Govt. of India, New Delhi, organized the first National Consultative Meet of National Pharmacovigilance Programme for ASU drugs. In March 2018 Ministry of AYUSH signed MoU with NCC-IPC subsequently National Pharmacovigilance Program for Ayurveda, Sidhha, Unani & Homoeopathy was launched as Central sector schemes. It initiated its working with All India Institute of Ayurveda (AIIA), New Delhi, as the National Pharmacovigilance Centre, 5 intermediary and about 42 functional peripheral centres.

Need of Pharmacovigilance In AYUSH

The core concerns of contemporary pharmacovigilance is the safety of modern medicines, traditional (herbal) medicines, vaccines, in some places, devices, substandard and falsified (SF) medical products [9].

In addition to the above, reasons for Pharmacovigilance of ASU&H drugs are -

1. **Misconceptions about ASU&H drugs** - There are misconceptions regarding ASU&H systems that these drugs are absolutely safe, can be taken for long time, they have only placebo effect, can be used in conjunction with other drugs etc [10]. Such misconceptions are detrimental to the patients and the system. Pharmacovigilance can play a great role in resolving this notion.

- 2. Adulterations and contaminations of ASU&H drugs-** ASU&H drugs have been found to be adulterated with heavy metals etc [11].
- 3. Malpractices-** Common malpractices are low product quality, improper and indiscriminate use as 'over the counter' drugs etc.
- 4. Globalization of AYUSH systems-** AYUSH systems are widely and thoroughly practiced in India since centuries irrespective of their use in other countries. Further many ASU&H drugs are manufactured for global use and they have moved beyond the traditional and cultural framework for which they were originally intended. Considering the growing use of ASU&H products globally; inclusion of traditional medicines in Pharmacovigilance system becomes important [12].
- 5. Lack of safety profile of drug is a great hurdle in globalization of AYUSH:** People round the globe are becoming conscious and more concerned about the safety of drugs they consume. Pharmacovigilance of ASU&H drugs can help in creating a safety profile of each drug both generic and patent leading to their easy acceptability globally.
- 6. Increased incidence of Objectionable Advertisements-** In recent times incidence of misleading and objectionable advertisements of ASU&H products in print and electronic media is a common phenomenon. As per Ministry of AYUSH, Govt. of India 66 cases of improper advertising of AYUSH and allied products in 2015, 204 cases in 2016, 547 cases in 2017 and 358 in 2018 have been reported from the Grievances Against Misleading Advertisements (GAMA) portal maintained by the Department of Consumer Affairs and complaints also received in this regard from different sources [13], So there is a considerable number of misleading advertisements which can be curtailed through this initiative.

Framework of The Pharmacovigilance Of Asu&H Drugs Programme In India [14]:

Under the umbrella of Ministry of AYUSH, Govt. of India there are currently 63 Pharmacovigilance centres including Ayurveda-28, Siddha-14, Homoeopathy-11 and, Unani- 10. It has three tiers.

National Pharmacovigilance Coordination Centre (NPvCC) - All India Institute of Ayurveda (AIIA), New Delhi.

Intermediary Pharmacovigilance Centres (IPvCs)- 05: All the national institutes (AYUSH) has been designated as IPvCs. For homoeopathy National Institute of Homoeopathy, Kolkata, West Bengal is the IPvC.

Peripheral Pharmacovigilance Centres (PPvCs): As we are discussing Pharmacovigilance in homoeopathy so here only Homoeopathic institutions designated as PPvC all over India are given below.

1. Central Research Institute for Homoeopathy, under CCRH, Noida, UP
2. National Homoeopathy Research institute in Mental Health, under CCRH Kottayam, Kerala.
3. Regional Research Institute for Homoeopathy, under

CCRH, Gudivada.

4. Regional Research Institute for Homoeopathy, under CCRH, Guwahati.
5. Regional Research Institute for Homoeopathy, under CCRH, Kolkata.
6. Regional Research Institute for Homoeopathy, under CCRH, Mumbai.
7. Government Homoeopathic Medical College and Hospital, Bhopal.
8. Mahesh Bhattacharya Homoeopathic Medical College & Hospital, Howrah, West Bengal.
9. Sarada Krishna Homoeopathic Medical College, Kulasekharam, Kanyakumari, Tamil Nadu.
10. Father Muller Homoeopathic Medical College & Hospital University Road, Deralakatte, Mangaluru-575018
11. Dr. Abhin Chandra Homoeopathic Medical College & Hospital, Unit-III, Kharvel Nagar, Bhubaneswar, 750001.

Reporting of Data

Reporting of ADE/ADR and objectionable advertisement can be done in the following way.

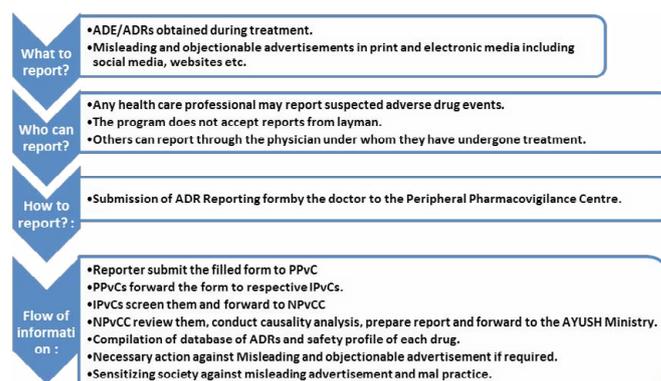


Figure 1 Capturing and flow of data.

The above data shows there is huge and robust infrastructure of Pharmacovigilance of ASU&H Drugs in India patronised by the government. AYUSH medicines are widely used in Indian subcontinents with or without prescription. Since its initiation this programme has done commendable job in reporting and preventing the ADE/ADRs and objectionable advertisements. Due to lack of awareness about existence of such programme malpractices by the manufacturers, advertisers or true occurrence of ADE/ADR are overlooked. So there is a need of wide spread publicity and awareness about this programme among common mass, manufacturers, practitioners esp private practitioners etc for increasing the reporting culture in this sector.

PHARMACOVIGILANCE AND HOMOEOPATHY

Homoeopathy is more than two centuries old system of therapeutic, in which such a medicine is applied in a given disease condition which has the capacity to produce a similar disease condition in healthy human being. Since its inception number of practitioners and users has gradually increased and currently it is used by over 200 million people on a regular basis in the world [15]. It is gradually

finding its place in state healthcare systems of various countries. According to the A.C Nelson reports, 62% of the population using homeopathic products do not wish to try conventional pharma products and 82% of the users are not inclined to switch to conventional forms of medicine. It has occupied a good chunk of market share as its business is increasing day by day. The global homeopathic products market is valued at 3110 million US\$ in 2018 is expected to reach 5110 million US\$ by the end of 2025, growing at a CAGR of 6.4% during 2019-2025. Moreover, the e-commerce industry has joined hands with the market leaders in the homeopathic pharma industry to ensure prompt availability of products. Homeomart, which is a leading online sales platform for homeopathic products, pools together more than 50 manufacturers to provide essentials not only in India but also abroad. A recent study of IMRB conducted across the major cities of India reveals that 59% of the population has shifted from allopathy treatments to homeopathic medicine. Europe is the second largest player in the homeopathic market, with 29% of the population trusting the ritualistic medical system [16]. In view of the above circumstances the proper implementation of pharmacovigilance in Homoeopathy is warranted as it will increase and ensure the safety of the drugs which is very essential for its sustained all round growth. Following terminologies and theories of Homoeopathy are closely related to ADE/ADR which needs to be understood for expelling confusion and proper better observation of pharmacovigilance by the Homoeopaths.

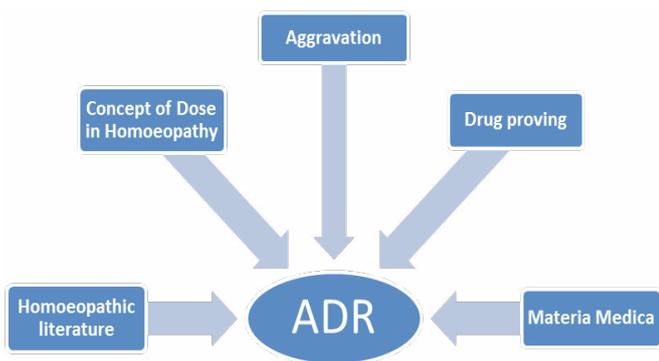


Figure 2 Homoeopathic terminologies and ADR.

ADE/ADR and Homoeopathic literature.

The basic philosophy or concept of pharmacovigilance of “making drug safe” is one of the factors that led to the discovery of homoeopathy by the German physician, Christian Friedrich Samuel Hahnemann in 1796. In fact the toxicity or harm caused to the patient by the contemporary methods of treatment bent Hahnemann to leave medical practice and start translating books for his livelihood. In homoeopathy references of ADRs or similar phenomena are present in its literature years before the world community apprehended its threat in 1848. In later part of 18th century he warned the world community against the collateral damages by the applied drug during treatment. In the book viz. “Samuel Hahnemann His Life And Work” written by Dr. Richard Haehl, we find numerous instances of ADRs. The overdosing of veratrum caused patient nearly died of artificial nerve colic in 1797 [17]. Hahnemann has denounced the administration of multifarious, compounds and haphazard administration of several substances at one time with unascertained efficacy as “very absurd which only lead to a blind and confused practice”. He added that without the investigation (and unless their pure pathogenetic action on the healthy individual has previously been ascertained)

all treatment of disease must continue to be not only a foolish, but even a criminal action, a dangerous attack upon human life [18]. So since very beginning homeopathy has tried to address the issue of safety of drug (Pharmacovigilance).

Currently ADE/ADR is poorly reported or documented in homoeopathy. It may be either because of negligence on part of doctor or non occurrence of ADR at all. A systematic review conducted on adverse effects of homeopathic medicines concluded that anecdotal reports of adverse effects in homoeopathic publications were not well documented and mainly reported aggravation of current symptoms. Case reports in conventional medical journals pointed more to adverse effects of mislabeled 'homeopathic products' than to true homeopathic medicines [19].

Concept of Dose in Homoeopathy and ADR

ADR is mainly caused by the immoderate doses of prescribed medicine. This was apprehended by Hahnemann in his early practice life. Before 1801 he used to prescribe large doses of medicines but due to unwelcome aggravation and secondary effects he switched on to small to smallest possible dose by repeated dilution of the medicine with strokes and labeled this process as “Potentization”. In 1799 he propounded the concept of “infinitesimal doses” [20]. In high potency (infinitesimal doses) the actual material of the drug is untraceable and that preparation exhibits the dynamic action in order to cure the patient. That is why the chance of ADR in high potency is minimum but long continued administration of low potency medicines with immoderate doses which is prevalent now a day’s may cause ADR like phenomena.

Aggravation & ADR:

Aggravation is the intensification or worsening of the symptoms/condition of the patient after application of the medicine. In homoeopathy three types of aggravation has been discussed [21].

Sl. No.	Aggravation	Description
1.	Homoeopathic aggravation	Slight intensification of symptoms of the patient similar to drug or medicinal symptoms but patient feels better generally.
2.	Medicinal aggravation	New symptoms of administered medicine appear in the patient and feels worse.
3.	Disease aggravation	Symptoms of nosological disease goes on increasing and patient feels worse.

Aggravation apparently looks similar to ADR but it is quite different. ADR is the unintended and noxious reaction of the drug which is not known earlier during different phases of medicinal/drug trial. But Aggravation of homeopathic medicine is either expected or known. If at all beyond purview of aggravation it will be new symptoms of the drugs on that particular person that can be included in our Materia Medica after verification for future use.

Drug proving and ADR

Drug proving is a unique process of drug development in homoeopathy. Adverse drug reaction and Drug proving are closely related. In fact ADR or noxious effect of drug is the basis of drug development. Once the pathogenetic effect of the substance is known sub-molecular or ultra molecular doses of these substances are used in homeopathic drug proving on healthy human being to produce symptoms and so generate new indications for clinical use of the homoeopathic medicine [22]. In homoeopathy the disease

producing power is the disease curing power in potentised form. In Organon of Medicine, the magnum opus in Homoeopathy, Hahnemann has referred ADR by different similar terminologies like pernicious effect, noxious and poisonous character of substance etc and appreciated these past recorded ADRs as the first rudiments of the true, pure Materia medica [23].

Materia Medica and ADR

Materia Medica of homoeopathy is the record or dictionary of signs and symptoms which a particular medicine can cure in the patient when applied on the basis of symptom similarity. It contains proved symptoms, clinical symptoms etc. Proved symptoms as we have seen above has evolved from its pathogenetic power or so called ADR. In homoeopathic Materia medica various relationships between medicines has been mentioned like complementary, compatible, inimical, contradictory, should not be used after etc [24]. These relationships are practically important during prescribing. Does the violation of these relationships while prescribing cause any drug interaction that can be tested by recording of events for a long time for which reporting and documentation under pharmacovigilance will prove helpful.

Mode of Homoeopathic prescription and ADE/ADR

Samuel Hahnemann in §273, Organon of Medicine, has strictly said “in no case under treatment is it necessary and *therefore not permissible* to administer to a patient more than *one single, simple medicinal* substance at one time.” In contrary to that, prescriptions like poly-pharmacy, mixture of medicines, patent medicines, multiple bio-chemic tablets etc. for long duration has become a fashion. The adverse effects of such prescriptions have not been studied properly. Regarding poly pharmacy (administration of more than one drug simultaneously or alternately) there is a mixed reaction. In one of the studies it has been shown that poly pharmacy has no adverse effect in the patients [25]. It does not mean that ADE/ADR will not occur at all rather prevalence of wrong prescription including over dosing, administration of multiple drugs for long duration, adulteration and contamination etc always put threat for ADE/ADR in homeopathy. Homoeopathic medicine consists of two parts medicine proper (material) and vehicle. Different types of vehicles are used as per requirement like sugar of milk (Saccharum lactis, Lactose), globules or pillules, pellets, tablets or tabloids, cones, aqua distillate, alcohol glycerine, olive oil, almond oil etc [26]. More over there is a practice of self preparation and dispensing of medicine by the doctors in their clinic or chambers. So there is a maximum chance of contamination of these vehicles while preparing or dispensing which can be a potential cause of ADE/ADR. In 2017 U.S. Food and Drug Administration (FDA) alerted consumers that some homeopathic teething tablets had excessive amounts of the toxic substance belladonna [27].

Misleading/Objectionable Advertisement in Homoeopathy

Surveillance on Misleading/Objectionable Advertisement of homeopathic drugs through pharmacovigilance is a welcome step. 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. Few important ones are given below [28]

1. The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules 1955
2. Drugs and Cosmetics act. 1940 and Rules 1945.
3. The Food Safety and Standards Act, 2006.
4. The press council act 1978.
5. Cable Television Network Rules, 1994.
6. Code of Commercial Advertising on Doordarshan and All India Radio.
7. Electronics media monitoring centre (EMMC).
8. Norms of Journalist Conduct issued by the Press Council of India.
9. Code of Conduct of the News Broadcasters Association.
10. Emblems and Names (Prevention of Improper Use) Act, 1950.
11. Consumer Protection Act, 1986.
12. Etc.

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules 1955

“Advertisement”:

- Any notice, circular, label, wrapper or other document
- Any announcement made orally or by any means of producing or transmitting light, sound or smoke.

(Sec.-3)- Prohibition of advertisement of certain drugs for treatment of certain diseases and disorders:

1. the procurement of miscarriage in women or prevention of conception in women; or
2. the maintenance or improvement of the capacity of human beings for sexual pleasure;
3. the correction of menstrual disorders in women; or

(Sec.-4)- Prohibition of misleading advertisements relating to drugs:

1. directly or indirectly gives a false impression about the true character of the drug; or
2. makes a false claim for the drug; or
3. is false or misleading in any material particular.

Legal Provisions for ASU & H drugs:

1. Drugs and Cosmetics act. 1940
 - Section 3(a) & (h) chapter IVA from section 33B to 33O and first schedule pertain to ASU drugs.
 - Second schedule (4A) provides for quality standards of homoeopathic drugs.
2. Drugs and Cosmetics rules. 1945
 - Rules 151 to 170, schedules E(I), T, TA pertain to ASU drugs.
 - Rules 30AA, 67, 85(A to I), 106-A, schedule K, schedule M-I pertain to homoeopathy drugs.

How Pharmacovigilance Will Help Homoeopathy?

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

- To establish a Database support of safety of ASU&H drugs.
- Increasing credibility of homoeopathy among the scientific community etc.
- ADR after proper verification can enrich our Materia medica as ADR may give new indication for that homoeopathic medicine.
- Establishment of relationship of drugs like Inimical, Incompatible, Should not be used before and after, Complementary, Compatible etc. which may help in updating homoeopathic Materia Medica.
- Finally lead to the increase of market value of homoeopathy.
- Providing documentary evidence to the notion that homeopathy has no side effect- Homoeopathy is perceived of having no side effect. Dearth of ADR following long standing Pharmacovigilance of homoeopathic drugs may support this perception as shown in few studies.
- Safe guarding the image of Homoeopathy by preventing the misleading advertisements.
- Etc.

CONCLUSION

Keeping in view of the exponential expansion and use of Homoeopathy, there should be a system to keep constant vigil on it i.e why pharmacovigilance in Homoeopathy is as essential as for any other system of therapeutic. It will make this system more scientifically validated and safe for consumption. In recent times malpractices and misleading advertisements in respect of homoeopathic drugs and practice has increased which is a great cause of concern. The reporting culture of Homoeopaths must be improved. The initiative of Pharmacovigilance of ASU&H drugs by Ministry of AYUSH, Govt. of India will play a big role in prohibiting the malpractices, making a safety profile of each drug and scientifically acceptable system of therapeutics in India like other traditional systems of medicine in the world.

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