

Embarking on the journey of pharmacovigilance of homoeopathic drugs

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Abstract

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*A river that cannot flow,
Losing its speed,
Definitely will be obstructed
By sea weed.*

-Rabindranath Tagore

The current of a river keeps it free from all kinds of impurities by carrying away all the waste. The plants growing on the banks of the river obstruct the rippling stream, and the speed and glory of the river. The river loses its dynamism, rhythm and flow and becomes lifeless. Regular surveillance is thus necessary to keep the flow going on.

Pharmacovigilance is a crucial part of the health-care system that keeps a watch over the instances of harmful or adverse pharmacological action of medicines to ensure safe therapeutic effects. According to the World Health Organization, pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse events or any other possible drug-related problems. Pharmacovigilance refers to a continuous post-marketing monitoring system to systematically document the safety profile of a medicine.^[1]

Acceptance of Ayush systems of medicine is increasing day by day all across the globe.^[2,3] However, strict vigilance of the quality, efficiency and safety of the herbal and traditional medicines is to be ensured.

Further, the disparities in the regulatory status of herbal products among different countries has serious implications on the international access to, and distribution of such products. Health-care providers, including traditional medicine practitioners, regulators, manufacturers and the general public, share a responsibility for the informed and safe use of medicinal products.^[4] The tools for pharmacovigilance of conventional drugs, when applied to monitor the safety of herbal medicines, present unique challenges, possibly due to the ways in which herbal medicines are named, perceived, sourced and utilised.^[5] The concerns of pharmacovigilance have thus been widened to include herbal, traditional and complementary medicines.^[6] The World Health Organization has produced guidelines for the assessment of the safety, efficacy and quality of herbal medicines. New systematic approaches for monitoring the safety of plant-derived medicinal products have been developed. A number of national pharmacovigilance centres are now monitoring the safety of traditional medicines.^[4]

It is necessary for the interest of public health to oversee the impact and safety profile of ASU&H drugs which are consumed by the people. The purpose of the Pharmacovigilance initiative

for Ayurveda, Siddha, Unani, and Homoeopathic (ASU&H) drugs is to collect, collate and analyse data to establish evidence for the clinical safety of the ASU&H drugs in a scientific manner for documenting clinical evidence of the safety of these drugs and undertake surveillance of advertisements of these ASU&H drugs.^[7] The ASU&H drugs are regulated in India in accordance with the exclusive provisions of the Drugs and Cosmetics Act, 1940, and Rules.^[8] The quality issues of these drugs are raised from various sources. Dissemination and advertisement of improper drug information is also a matter of concern that needs to be addressed with systematic surveillance and regulatory action. ADRs observed by a practitioners are documented and reported to the concerned pharmacovigilance centres (PPvCs / IPvCs) using suspected adverse reactions reporting form for ASU&H Drugs.^[9]

The terminologies of Adverse drug reactions (ADRs) and adverse drug events (ADEs) are relatively new to most of the homoeopathic practitioners. ADRs are insufficiently reported and documented in homoeopathy, as compared to the conventional system of medicine. Since ultra diluted homoeopathic medicines are deemed to be safe, a few ADRs that are reported could be a result of taking medicines without proper guidance or supervision of a qualified homoeopathic physician. It is therefore pertinent to spread awareness among the masses for seeking homoeopathic treatment from qualified and registered homoeopathic practitioners only, instead of self-proclaimed healers who may intentionally or unintentionally, dispense unknown of harmful medicinal substances, in the name of homoeopathy. Also, improper knowledge could cause harmful practices and poor quality of care.^[10]

A common myth is that homoeopathic medicine first aggravates the suffering before subsequent amelioration and cure. The concept of homoeopathic aggravation is thus misinterpreted. Such notions need to be addressed by the stakeholders of homoeopathy. There is a necessity to create awareness and encourage homoeopathic professionals to focus on issues such as drug safety surveillance, documentation and ADEs.^[11]

Advancement in basic research in homoeopathy is enabling stronger and more reliable pharmacovigilance tools. Researchers have shown the presence of nanostructures in homoeopathic medicines using transmission electron microscopy, electron diffraction and chemical analysis by inductively coupled plasma atomic emission spectroscopy, Raman spectroscopy, ultraviolet visible spectroscopy, nuclear magnetic resonance, quantum electrodynamics and different other ultramodern instruments and essays. Gene expression analysis, proteomic and metabolic studies are

also producing reports of the involvement of homeopathic medicines in different physiological pathways, thus paving way for the possibility of pharmacovigilance of potentised drugs using these techniques. The overview of such evidence in favour of Homeopathy at clinical, biological, molecular and even nano-molecular levels has been compiled in the Council's publication, Scientific Framework of Homeopathy, jointly prepared by the Liga Medicorum Homeopathica Internationalis; Central Council for Research in Homeopathy, and the European Committee for Homeopathy.^[12]

A good pharmacovigilance practice identifies the risks and the risk factors in the shortest possible time so that harm can be timely avoided or minimised. This information allows for the intelligent and evidence-based use of medicines and has the potential for preventing many adverse reactions. The information collected also provides the tools for the effective management of problems. The integration of pharmacovigilance may be crucial to the success of public health programmes that use medicines, to optimise the use of scarce health resources and prevent potential tragedies.^[6] It is hoped that the continuous efforts of homeopathic physicians and pharmacists, drug-improving experts and basic researchers will enhance the awareness and implementation of pharmacovigilance, thus resulting in the overall prosperity of homeopathy.

In this issue, a survey exploring the homeopathic physicians' knowledge, awareness, attitude and practice (KAAP) towards the Pv programme in homeopathy is presented, which I hope will be read with interest in this regard.^[13]

Further, an *in vitro* study is presented, which evaluates the antioxidant and cytotoxicity activity of potentised preparation of *Cordyceps sinensis* in carcinoma cell-lines.^[14] Further, a randomised, double-blind and placebo-controlled trial on patients with chronic rhinosinusitis is published which shows a positive trend to support the effect of individualised homeopathic remedies.^[15] Furthermore, case reports of homeopathic treatment of generalised anxiety disorder and diabetic gangrene are presented.^[16,17]

I convey my best wishes to all the readers for the World Homeopathy Day to be celebrated on 10th April, 2023.

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