Popularity, Safety and Quality of Homoeopathic Medicines

The increasing health concerns of population are leading to increased burden to the healthcare system of the countries. Essential health services are not available to many. According to a new report from the World Bank and the WHO, at least half of the world's population cannot obtain essential health services.[1] Thus, the WHO is putting substantial focus on health for all and universal health coverage (UHC) as essential pillars for sustainable development goals. Homoeopathy being popular among traditional, complementary and alternative medicine in the European, Southeast Asian and even African regions if integrated meaningfully in the national healthcare system can help in achieving the UHC.[2] In India, it is not only popular but also successfully contributing in the national healthcare services. India's National Health Policy 2017 outlined the role of Ayurveda, Yoga, Unani, Siddha and Homoeopathy in pluralistic healthcare legacy of country.

Many people integrate, use and value Homoeopathy as a complementary treatment option and are very satisfied with its efficacy and tolerability.[3] A recent market survey by Ipsos and Omeoimprese (November 2018) confirms that Homoeopathy has a strong support in France and Italy.[4] Three out of four French people hold a good image of Homoeopathy. Similarly, the homoeopathic market in India is increasing exponentially with annual growth rate cited as 30% in the ASSOCHAM report. Whereas in the EU, the average annual growth between 2010 and 2013 was reported to be 6.5%.[5] Given the increasing popularity among population and incremental opportunity in Homoeopathic Medicinal Product (HMP) market, it is necessary that adequate measures are taken to ensure safety and quality of homoeopathic medicine and its sale regularised.

Safety and Quality

Homoeopathy is being practiced by qualified and trained professionals around the world, and medicines are prescribed using patient-centric approaches, at such dosages that cannot harm anyone directly or indirectly. It has been reported that homoeopathic treatment is safe and causes minimal to no adverse effects. This is the main reason for its popularity in the world.[6] Hahnemann too was concerned about quality and safety of medicines and stated that "*true physician must have authentic medicines in perfect condition and know they are genuine*". The different sources of medicines must be obtained in such state that their medicinal qualities are retained.[7] Homoeopathic medicines must meet the minimum standards and guarantee the high quality of medicines. There is a need to deliberate on the existing processes being followed by the industry in different countries and how these are regulated. There are the WHO guidelines on the 'Safety Issues in Homoeopathy Medicine' published in 2009; these need to be further revisited to meet out the emerging challenges of validation of existing standards of the drugs and inclusion of more drugs.[8] Homoeopathic drug standardisation is a process of implementing and developing technical standards based on the existing knowledge of the drug substance, appropriate experimentation and the consensus of different stakeholders such as practitioners, industrialists and regulators. It ensures a predefined amount of quantity, quality and therapeutic effect of each ingredient.[9] Success in homoeopathic prescribing is based on the purity and quality of raw drugs and finished products. The advancing scientific technologies in drug standardisation have enabled us to define benchmark standards that can be checked against any commercial sample, wherever necessary.[10] The quality of homoeopathic medicines can be assured by following the procedures laid down in official homoeopathic pharmacopoeias and other officially recognised documents which have defined appropriate specifications, especially for starting materials along with the standardised manufacturing procedures. The benchmark standards for raw drug plant material, the identification of source material (gross morphology of the raw drug), limit tests (for pesticide, heavy metals and fungi/bacteria) and complementary tests (foreign matter, total ash, water content, bitterness value, loss on drying and radioactive contamination) must be adhered by all the manufacturing units. Likewise, there are standards for drugs of animal origin, or human-derived origin, mineral and chemical origin along with mother tincture and finished products. Sophisticated instruments such as high-performance liquid chromatography, high-performance thin-layer chromatography fingerprinting and assays of marker compounds are being used for standardisation of homoeopathic medicines. Medicinal product cannot be considered scientifically valid if the drug tested has not been authenticated and characterised to ensure reproducibility in the manufacturing of the product. Homoeopathic drug standardisation based on scientific metrics is needed for research and reproducibility for routine clinical practice.[11] In this issue, we are publishing chemoprofiling of homoeopathic mother tincture (HT) which represents a comprehensive approach for the evaluation of quality, purity, safety and efficacy of HT. Chemoprofile of homoeopathic drug *Holarrhena antidysenterica* was standardised and compared with market samples. There is a need to undertake such studies in respect to all the existing drugs and published in pharmacopoeias to guide the industry.

Homoeopathic medicines of chemical origin have been studied due to high variability of chemical components involved. There are studies which have been conducted to investigate the oral toxicity of different homoeopathic drugs in animal experimental models as per the OECD guidelines for the testing of chemicals. The result indicated that homoeopathic drugs are safe and produce no toxicity when administered for

longer duration.[12] Evaluation of safety profile of HTs has also been studied indicating no toxic symptoms observed in tested animals.[13]

Regulatory Issues

The current regulatory framework and its requirements for homoeopathic medicines differ from country to country. There are regulations for HMPs, either as part of complementary and traditional medicine or conventional medicine, with some countries having an official document regulating its production and quality, such as the Homoeopathic Pharmacopoeia of the United States, the Homoeopathic Pharmacopoeia of India, the Brazilian Homoeopathic Pharmacopeia and the European Homoeopathic Pharmacopeia. Indian regulatory framework has homoeopathic medicines covered under the provisions of the Drugs and Cosmetic Act, 1940, Rules 1945.[14] In Germany, a substantial market consisting of both small- and medium-sized companies exists with 1235 licensed homoeopathic products, 1033 licensed anthroposophic products and over 3000 registered homoeopathic/anthroposophic products, whereas in France, methods for producing homoeopathic stocks were standardised and published in the French Pharmacopoeia since 1983, currently registered HMPs are reimbursed in France up to 30% of cost. In Switzerland, a simplified registration process exists for homoeopathic products without a specific therapeutic indication (currently around 12,000 marketed products).[15]

Global acceptance of Homoeopathy is dependent on the safety, quality and efficacy of its medicines. The regulatory framework must be harmonised so that the difficulty arising out of disparate rules and regulations may not inhibit the overall development of Homoeopathy worldwide. The Council had organised the World Integrated Medicine Forum (WIMF) for HMPs in 2017 with objective of facilitating an effective dialogue among all stakeholder practitioners, drug manufacturer and regulators. The outcome of which was published in conference report.[15] In this issue, we are publishing a report of feedbacks received from the participants of the first WIMF. To further the recommendations and discussion of the first WIMF, now the second forum on Regulation of Homeopathic medicinal products- Advancing global collaboration is being organised in January 2019.

Future Prospects

The awareness about the quality and safety of homoeopathic medicine as an essential requirement must be present among practitioners, clinicians and especially the students of Homoeopathy. Understanding about the quality and safety methods of preparing homoeopathic medicine, standardisation techniques may be incorporated in the homoeopathic curriculum. There are over 250 medical colleges in India where pharmacy is being taught as a subject however, not much focus is laid on the facilities available in Pharmacy Laboratory of institutions. It is time that strengthening of infrastructure in colleges, especially the Pharmacy Laboratory is done so that revolutionary work in the field of drug standardisation can be undertaken, manufacturer and medical colleges must collaborate to by scholars and, undertake this arduous task. The homoeopathic industry must also strengthen their Research and Development Department with adequate infrastructure and catalyse the clinical trials of the HMPs. Lately, efforts are made to inculcate the good manufacturing practice and good clinical practice, making amendments in rules and minimising the regulatory standards. Several studies are required to be undertaken to demonstrate the pharmacological actions of different medicines used in Homoeopathy in laboratory settings. In this issue, the outcome of study undertaken at R. C. Patel Institute of Pharmaceutical Education and Research, Shirpur, India, of a commonly used homoeopathic medicine *Thuja* in dilution is being published, wherein its antiarthritic effects in Complete Freund's Adjuvant-induced arthritis[16] have been shown.

The current issue also includes a pilot study undertaken to study the usefulness of Homoeopathy as an adjuvant therapy to standard conventional care in stroke patients.[17] The results of this study were encouraging and opened avenues for further controlled trial. Besides these, two case reports on the role of Homoeopathy in infertility and hypothyroidism are being published for the practitioners to replicate the success stories. Further, to address the recent challenge faced in research publication, Predatory Journals, we are reprinting an article titled 'A Downside on Research and Hampering the Impact and Relevance of Scientific Outcome'.[18]

Dr. Upma Bagai, who was professor and chairperson, Department of Zoology, Panjab University, Chandigarh, passed away on 8 September 2018. She has undertaken significant research in immunology and chemotherapy of the malaria parasite *Plasmodium,* especially in Homoeopathy she has done significant research which has been published in international journals and cited many times. She and her team has evaluated antimalarial efficacy of *China*, *Chelidonium majus*,[19] *Malaria Co Nosode* and *Eucalyptus* through *in vitro* and *in vivo models* against *Plasmodium berghei.*[20] Activity of these drugs was also compared to the standard antimalarial, chloroquine and artemisinin. With profound grief, we write her obituary in this issue.

As the year ends, we are grateful to our reviewers and are acknowledging them in this issue for their valuable feedback and enriching inputs to the journal. I wish all the readers a very happy new year.

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