Medical pluralism, regulations and pharmacopoeia: A perspective

Pluralistic healthcare delivery is a way forward to achieve universal health coverage. Medical pluralism (MP) is defined as employment and coexistence of more than one medical system (modern and various complementary) for healthcare and illness. This is particularly prevalent in societies where one medical system alone cannot adequately meet the health needs of the entire population.\(^1\) In addition, the purpose of utilising complementary and alternative medicine (CAM) is to treat particular disease condition, just to stay healthy or both. This is also based on traditional beliefs many times in countries such as China, India and America. MP is common in America,\(^2,3\) over half (53%) of women respondents of a survey used CAM for disease conditions, especially for those involving chronic pain. MP is also common in Taiwan,\(^4\) Australia\(^5\) and Africa.\(^6\) China has adopted a unique policy of MP, whereby traditional Chinese medicine and Western biomedicine are both widely used in the healthcare system to provide optimal health outcomes to patients.\(^7\) The health systems which have scientific orientation, rational assessment of patient condition, clinical experience and evidence base should be integrated in healthcare which are pluralistic.\(^8\) Complementary medicine is sometimes referred to as integrative medicine as it is a mix of modern and traditional medicine. Homoeopathy is most popular among traditional, complementary and alternative medicine (TCAM) in the European region and the second most popular in Southeast Asian region.\(^9\) The WHO advocates widening the use of all TCAM practices within the national health system, especially in primary healthcare delivery.\(^10\) The concept, background and perspectives of MP is discussed in this issue as ‘Medical Pluralism in Europe and India: concept, historical background, perspectives’.\(^11\) The author describes the popularity of Homoeopathy based on patient dissatisfaction with conventional medicine. The holistic patient-centric approach of treatment with no side effects has led to more number of patients adopting Homoeopathy. MP has gender preponderance in female patients, as more number of women are using Homoeopathy as compared to men. The formal education of Homoeopathy and recognition in India and Germany is also discussed. The growth rate of homoeopathic pharmaceutical market has been analysed; it has grown in India, France and Germany, signifying its popularity. This has also led to organised skepticism towards Homoeopathy in several parts of the world. The objective of such misleading media reports released periodically limits the growing interest of patients in Homoeopathy and creates a negative image with arguments on its mode of action, efficacy and scientificity, the strengthening of system by providing quality care to individual patients, continuing incessantly basic and clinical research and feeding media with positive and emerging new researches in these systems can be our defence.

Regulations

With most countries having highly pluralistic healthcare delivery, the health systems involved in it need to adhere to ethical and regulatory framework. The issues relating to scientific evidence, risk and benefits, efficacy and safety may be duly addressed. The use of ineffective, poor quality, harmful medicines can result in therapeutic failure, exacerbation of disease, resistance to medicines and sometimes death. The WHO advocates that governments need to establish strong national regulatory authorities to ensure that the manufacture, trade and use of medicines are regulated effectively. Regulatory functions involve interactions with various stakeholders (e.g., manufacturers, traders, consumers, health professionals, researchers and governments) whose economic, social and political motives may differ, making implementation of regulation both politically and technically challenging. Medicine regulation incorporates several mutually reinforcing activities all aimed at promoting and protecting public health. Drug regulation should therefore include the scientific evaluation of products before registration, to ensure that all marketed pharmaceutical products meet the criteria of safety, efficacy and quality. Although these criteria are applicable to all medicines including biological products (including vaccines, blood products, monoclonal antibodies, cell and tissue therapies) and herbal medicines (also other traditional and complementary medicines), there are substantial differences in the regulatory requirements for some groups of medicines.\(^12\) The regulatory framework is well developed for homoeopathic medicinal products in countries such as Germany, France, Switzerland, the United Kingdom and India. There are defined rules for registration of new products. There is a monograph review committee that includes experts in homoeopathic pharmacy, toxicology and analytic methodology, who review safety and efficacy through Good Manufacturing Practice (GMP) guidelines. The Council is conducting pharmacognostic, physico-chemical and pharmacological studies to evaluate the safety and efficacy of the drugs scientifically and developing the quality drugs using authentic and standardised raw materials. In this issue, an article on ‘Comparative standardization study of Reserpine in Rauwolfia serpentina Homoeopathic mother tinctures manufactured by different pharmaceutical industries using HPTLC’ is included where in-house mother tincture prepared from authentic plants has been compared with the samples.
There is a suggestion that mother tincture prepared from authentic raw material shows excess amount of quantity of the active constituent i.e., Reserpin in the current experiment as compared to mother tinctures procured from the market. These results essentially point further standardisation of not only raw material but also finished products using known biomarkers. This will go a long way in improving the availability of authentic and effective drugs for the users.

The WHO has laid down standards for evaluation of active substances, safety evaluation, risk evaluation and utility evaluation of traditional medicines. The manufacturer or sponsor should validate and manage the production, processing and storage practices. A number of regulatory authorities already require quality assurance of homoeopathic medicines. Manufacturers, packagers, labellers, importers and distributors of finished homoeopathic medicines or related raw materials have to meet the relevant requirements including effective process controls, validated analytical methods, adequate buildings and good storage and sanitary conditions. Mother tincture has to comply with pharmacopoeial specifications and quality requirements including the method of preparation (reference to general procedure), appearance and description, identity tests, purity tests, procedure for stability tests and determination of content and toxic constituents. The compliance of these guidelines in homoeopathic manufacturing is essential for the acceptance of these products universally.

In India, homoeopathic medicines are defined under Rule 2(DD) of Drugs and Cosmetics Rules, 1945. Standards of homoeopathic medicines to be complied for manufacture, sale, distribution or import are defined under Second Schedule of the Drugs and Cosmetics Act (item N.4a), import of new homoeopathic medicine under Rule 30AA and Packing and Labelling of Homoeopathic medicine under rule 32 (A). Homoeopathic Pharmacopoeia Laboratory, Ghaziabad, is to function as Central Drugs Laboratory with response to homoeopathic drugs. The current definition of Homoeopathic medicines is ‘any drug which is recorded in homoeopathic proving or therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative homoeopathic literature of India and abroad and which is prepared according to the techniques of homoeopathic pharmacy and covers a combination of ingredients of such homoeopathic medicines but does not include a medicine which is administered by parenteral route’. Standardisation studies of raw drug as well as mother tincture and finished products are essential for the preparation of any drug monograph. Besides quality evaluation, safety evaluation monograph requires utility evaluation. Thus, the indications through proving of homoeopathic medicines, are essential for final approval of monograph. Quality methodology leads to quality outcome, inadequate proving data can affect the monograph approval. Homoeopathic pathogenetic trial of Withania somnifera conducted in accordance with drug-proving protocol (revised in 2014–2015) is featured.

Even in highly regulated health systems, regulation of homoeopathic medicines may still be in an early stage. There are certain regulatory challenges such as high registration fees, standardisation of production of homoeopathic medicinal products (HMPs), manufacturing and labelling issues, transportation of homoeopathic medicines between countries and non-uniformity in the content of pharmacopoeia and monographs which needs focus and should be dealt conjointly by all regulators and policymakers. The WHO may be approached to facilitate the exchange of information. A reference list of information resources on homoeopathic medicines, including official pharmacopoeias, should be made available. The WHO could develop systems to collect and provide information to consumers on the safe use of homoeopathic medicines. The WHO needs to harmonise definitions of homoeopathic products and practices to allow classification and identification of homoeopathic products at national level. The development and regulations of homoeopathic medicinal products and pharmacopoeia in India has a major role to play in convergence of regulatory framework across the countries. In an attempt, a first ever global forum was held in New Delhi, India, on ‘World Integrated Medicine Forum on the Regulation of Homoeopathic Medicinal Products: National and Global Strategies’ which was attended by 250 delegates from 25 countries to discuss the current state of regulation of HMPs. The detailed summaries of eight interactive sessions, namely, Practitioners’ Perspectives, Regulators’ Perspectives, Pharmaceutical Industry Perspectives, Regulatory Status and Outlook in Various Countries, Homoeopathic Pharmacopoeias: Status in Main Countries, Monograph/Regulatory Requirements: Strategic Aspects, Homoeopathic Drug Development, Regulatory Innovation and Enhancing Synergies with Traditional and Conventional Medicine Systems held during the forum have been elaborated in the conference report in this issue. The forum provided a unique opportunity for regulators, practitioners and pharmaceutical representatives to discuss strategies for the regulation of HMPs, harmonisation of pharmacopoeias, labelling requirements, registration of new products, potency expiration dates, back potencies, etc., Exchange of memorandum of understanding for cooperation in the field of homoeopathic medicine between India and Homoeopathic Pharmacopoeia Convention of the United States was another highlight of the forum. Finding practical solutions to avoid duplication of evaluations, enhancing work sharing, encouraging regulatory convergence, sharing of information and optimal utilisation of limited resources were some of the action points that emerged.

**Pharmacopoeia**

With deliberations on the status of homoeopathic pharmacopoeia in main countries such as the USA, Germany, France, Brazil and India during the forum, opportunities such as harmonisation, convergence and adherence to GMPs for uniformity were discussed. The prospects of harmonisation of pharmacopoeia’s
can be argued as different countries have different standards and characteristics. However, the information needs to be refined and shared so that it may be used by manufacturers. We have published ten volumes of Homoeopathic Pharmacopoeia of India (HP1). In total, 1111 monographs and standards for 263 finished products have been published in the HPI. The ‘identically’ entitled pharmacopoeial monographs have considerable differences. Since definitions may vary between pharmacopoeias, and because of the wide range of processing techniques and manufacturing methods in various pharmacopoeias, the final homoeopathic products may show marked variability. The main homoeopathic pharmacopeias being Pharmacopoeia Française, the German Homoeopathic Pharmacopoeia, the Homoeopathic Pharmacopoeia of the United States and the HPI can give substantial inputs to each other for further growth of the system. Harmonisation of monographs and convergence is recommended as future prospects for the development of system. The Council is in process of HPI upgradation/revision in compliance with the WHO guidelines.

Further in this issue, qualitative phytochemical analysis has been performed to confirm the presence of compounds such as alkaloids, fats, steroids, tannins, flavonoids, sugars, amino acids and saponins in Allium cepa extract and its homoeopathic formulations (mother tincture, Allium cepa 30C and Allium cepa 200C). Readers will also find book review featured in this issue useful.

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REFERENCES