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Strengthening Homoeopathy with Standards: The BIS initiative

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Abstract
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GUEST EDITORIAL

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The WHO's *Traditional Medicine Strategy 2014–2023* advanced the safe and effective use of traditional and complementary medicine (T&CM) by emphasising regulation, research, and the systematic integration of T&CM products, practices, and practitioners into national health systems.[1] Key initiatives included the development of standards, norms, and technical documents such as guidelines on the quality and safety of both codified and non-codified practices, internationally recognised terminology, and benchmarks or training manuals to support professional practice.

WHO surveys have highlighted the widespread use of Homoeopathy in nearly 100 countries across all continents, while also underscoring the need for more robust data to strengthen its evidence base for safety and effectiveness, thereby supporting its appropriate use and integration.[2] With the global rise in demand for homoeopathic medicines and the rapid expansion of the international market, WHO has issued safety guidelines to ensure the quality of homoeopathic medicinal products.[3]

The most recent *WHO Traditional Medicine Strategy* further advocates the establishment of appropriate regulatory mechanisms for all forms of traditional medicine. This requires the identification and adoption of norms and standards, the development of clear rules, industry education, and the promotion of mutual understanding across the supply chain—from manufacturers and suppliers to end-users.[4]

In India, healthcare standardisation has evolved as a continuum, progressing from ancient wisdom to modern regulatory frameworks, a trajectory reflected in the institutionalisation of Homoeopathy. The statutory era formally began with the enactment of the *Drugs and Cosmetics Act and Rules, 1940*, which laid the legal foundation for quality control. This framework was significantly strengthened with the establishment of the *Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H)* under the Ministry of Ayush, mandated to formulate quality standards for Ayush drugs by publishing and updating their pharmacopoeias, including the *Homoeopathic Pharmacopoeia of India (HPI)*.[5]

Under the *Drugs and Cosmetics Act and Rules*, all homoeopathic pharmaceutical industries are legally bound to comply with HPI monographs. The Central Drugs Standard Control Organization (CDSCO) serves as the central authority regulating all categories of drugs, including Homoeopathy. Compliance with pharmacopoeial standards—covering identity, purity, and strength of drugs, as well as permissible limits for heavy metals, pesticide residues, and microbial load—is mandatory. These requirements are reinforced by Good Manufacturing Practices (GMP), ensuring accredited production, packaging, and distribution. Consequently, India has developed a relatively robust regulatory framework for Homoeopathy.

Globally, Homoeopathy is primarily regulated through official pharmacopoeias, such as those in the European Union, the United States, and several other countries. However, implementation remains challenging due to inconsistencies across pharmacopoeias and diversity in regulations, import–export requirements that often fail to recognise pharmacopoeial monographs as valid standards. There is scope for creating a committee at the level of International Standards Organisation (ISO) looking after the standardisation of homoeopathy. The publication of the European standard EN 16872:2016 on services of medical doctors with additional qualification in Homeopathy provides strong regional evidence that consensus-driven standardisation for Homoeopathy is achievable.[6]

In line with the current needs, the Ministry of Ayush has launched a new initiative for standardisation in the Homoeopathy sector through India's national standards body, the Bureau of Indian Standards (BIS). This step marks a crucial advancement toward harmonisation, global recognition, and strengthened regulatory coherence in Homoeopathy.

BIS is advancing standardisation across diverse sectors, including Ayush, through a dedicated department. Within this framework, the *Homoeopathic Sectional Committee* has been constituted to address the standardisation of Homoeopathy, encompassing both traditional and modern aspects of products and services. The committee works in close collaboration with stakeholders—regulatory authorities, scientific and educational institutions, and industry representatives—to develop comprehensive, evidence-based standards that are aligned with national and international guidelines.

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Indian standards are formulated through a transparent, inclusive, and consensus-driven process, ensuring active participation of all stakeholders. To date, 22 Indian Standards have been published. These cover a wide range of areas, including:

- Standardised terminology in Homoeopathy to promote clarity and consistency in professional communication
- Standards for globules, sugar of milk, and non-medicated tablets
- Specifications for selected raw herbs and their hydro-alcoholic extracts
- Quality norms for glass and plastic containers used in the preparation and dispensing of medicines

This marks the beginning of a new era in enhancing the quality of homoeopathic medicinal products (HMPs) and practices. The published standards are available for adoption by the industry, which can seek BIS certification to validate compliance and strengthen credibility.

Recognising the importance of enhancing awareness about these standards among homoeopaths, researchers, and academia, a range of knowledge dissemination initiatives are being undertaken. These include workshops for college faculty, technical presentations, and publications.[7,8] To further propagate the knowledge contained in the Indian Standards, this Journal has initiated a series of comprehensive write-ups, each issue featuring at least one standard. The previous issue introduced the Indian Standard on plastic containers and closures for dispensing homoeopathic pharmaceutical preparations.[9] In the present issue, we provide an overview of the Indian Standard for globules (IS 18947:2024), widely used in homoeopathic practice, which will be of value to all stakeholders.

Standards deliver multiple benefits to the industry by promoting improved quality, greater efficiency, and enhanced safety of products and services. They facilitate market access, strengthen consumer confidence, and drive innovation and sustainability. BIS certification further reinforces trust in homoeopathic products by ensuring quality at both the raw material and manufacturing levels. Unlike pharmacopeial standards, which are primarily familiar to practitioners, the BIS *ISI mark* is easily understood by patients, thereby fostering wider acceptance of certified products and helping to filter out substandard ones from the market. This approach not only aligns industry practices with regulatory frameworks but also enhances public confidence in homoeopathic medicines.

In the context of global trade, and in the absence of international standards, BIS—as India's national standards body—plays a pivotal role in establishing criteria for assessing imported and exported goods. From the import of exotic raw herbs to the export of homoeopathic products manufactured in India, these BIS-developed standards are poised to play a significant role in the years ahead.

I warmly invite readers to engage with this ongoing series in the *BIS Discussions* section and welcome their valuable feedback and perspectives.

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