

Editor Speak

Dear Readers,

Homeopathic Drug Regulation

The Central Council for Research in Homeopathy, the apex research body in India, is organizing a global meet to evolve national and global strategies on regulation of Homeopathic medicinal products at Delhi on 23rd - 24th February, 2017. Homeopathic medicine regulation is one of the major challenges in almost all countries. This was one of the topics discussed in the Rio conference of the LMHI in 2015. As such this meet is a land mark event in Homeopathic drug regulation.

Homeopathy is a medical system practiced widely in several countries for over two centuries. Certain reports emanating from few of these countries show intolerance to the system, citing inadequate clinical evidences. The parameters and tools to measure the clinical evidences in biomedicine differ from that of Homeopathy, which largely rely on holistic and *vitalistic* principles. It is a known fact that most of the clinical evidences shaped for the bio medical products are by the drug manufacturers having a commercial interest in those products. In Homeopathy there are two distinct categories of preparations, the classical one that follows the drug proving as the basis for its therapeutic efficacy and another set which are marketed on empirical evidences. Both of these are categorized as Homeopathic medicines for drug regulations. Thus it is evident that there exist certain fixed guidelines for clinical evidence relating to classical medicines where as such no rules exist for the Homeopathic products. One major cause for the embarrassing reports of lack of clinical evidence is poor drug regulatory measures of the Homeopathic products.

Homeopathy was a popular complimentary system in the United Kingdom. The Science and Technology Committee Report by the UK Parliament in 2010 concluded that the Medicines and Healthcare products Regulatory Agency (MHRA) should not allow **homeopathic product** labels to make medical claims without evidence of efficacy. As they are not medicines, **homeopathic products** should no longer be licensed by the MHRA. In Australia, the National Health and Medical Research Council report on Homeopathy in 2015 says that there was no reliable evidence from research in humans that homeopathy was effective for treating the range of health conditions. The report says they could not find either homeopathy caused greater health improvements than placebo, or caused health improvements equal to those of another treatment. The Food and Drug Administration, USA, issued public notice on March, 2015 expressing intention to revisit their regulations on **homeopathic products** manufactured and marketed without prior approval. The Russian Academy of Sciences has become the latest body to declare homeopathy has "no scientific basis" and endangers people who believe it to be effective.

We respond to such reports more so on emotional terms rather than analytical means. These are reports based on unscientific studies, improper evaluation and also motivated by vested interest. In all these reports no distinction was made on tons of evidences exist on the effectiveness of classical preparations which are in strict sense homeopathic medicine and the claims labeled on the homeopathic products. In fact no claims are labeled on classical homeopathic medicines.

Demand for homeopathic treatment increased resulting in flooding market with varieties of products. Commercialization brought down ethical usage. Use of classical preparations is coming down and formulations, combinations, externals, health products and cosmetics are marketed more. All these are categorized under Homeopathic Medicine as far as drug regulations are concerned. The present crisis is mainly because

of irrational use of the word Homeopathic Medicine. There is a need to define what a Homeopathic medicine is and what a Homeopathic product is. Unless a distinction made between the homeopathic medicines, which are otherwise considered safe and effective and the homeopathic products marketed mainly for commercial benefits, the future of Homeopathy is at stake. Hope the global meet shall evolve strategies to meet this challenge.

Tragically, except Government of India, no other major Government encourages scientific studies on clinical advantages or effectiveness of Homeopathy. The onus of proving clinical effect of Homeopathic medicine and homeopathic products lies with the Government. The apex research council should not shy away from the responsibility of validating the clinical and therapeutic advantage of the Homeopathic products also through scientific protocols.

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