Editorial

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Importance of Clinical trials in Ayurveda and Homeopathy

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Editorial Note

Ayurveda is a science of life of 5,000-year-old system of natural treatment which has its roots in the Vedic culture of India. More than a mere system of treating illness, Ayurveda has been enjoying a major choice of intervention throughout the world.

The Vata (movement), Pitta (digestion) and Kapha (physical form) are the fundamental energies that direct the human body. Ayurveda concentrates on these sources of energies and designs the path of treatment that is a balanced integration between the human body, mind, spirit and environment.

Homeopathy, originated in Germany in 1794, based on The Laws of Similars is a gentle and effective and advanced form of vaccination form of natural medicine that can be used to treat many conditions. Homeopathic remedies are safer and slower acting, potentized doses of substances found in nature. These medicines are prepared according to scientific principles that allow to naturally energizing body's curative immune power.

Homeopathy is amongst the latest medicines in Indian medication aiming for more research and promotion.

Drugs & Cosmetic Rules 2016

122E. Definition of new drug - for the purpose of this part, new drug shall mean and include:

A drug, as defined in the Act including bulk drug substance which has not been used in the country to any significant extent under the conditions prescribed, recommended or suggested in the labelling thereof and has not been recognized as effective and safe by the licensing authority mentioned under rule 21.

In Indian regulations, the major class of herbal products is:

a) Classical Ayurveda drugs as mentioned in the authoritative books of Ayurveda system, which are manufactured and named in accordance with the formulations described in the authoritative texts.

b) Patent or Proprietary medicine makes use of ingredients referred in formulations of authoritative texts but with intellectual intervention, innovation or invention to manufacture products different from classical medicine.

None of these classes of herbal medicines come under purview of DCGI as they do not fall into categories of new drugs. Hence, DCGI approval is not required for clinical trial of herbal products.

Ayurveda and Homeopathic medicines use a variety of products and practices. However, there aren't enough stringent clinical trials and systematic research reviews to control the drug formulations.

Various case studies conducted by the research organizations in the time period of 2010-2020 found out that, the herbs used in ayurvedic and homeopathic medicines in India and USA may cause some adverse reactions when ingested without proper doctor prescription. The herbs and products used in the proprietary ayurvedic and homeopathic medicines may contain poisonous metals such as arsenic, mercury, lead and iron. These metals when ingested in more than allowed doses may be lethal.

In Ayurvedic drugs, the problem is that, the medicine formulation is derived from the ancient books of Ayurveda. In homeopathy, the dose is fixed by the unauthorised health practitioner. The formulation dose of the same active ingredient may vary in different regions and according to the person producing the medicine. These drugs are patented and as they do not pass under DCGI, safety and efficacy tests are not done. These drugs when relased into the market, may cause adverse reactions and get completely unnoticed by the government.

With rise in the use of Ayurvedic and homeopathic medicines as a replacement of allopathic medicines, there is an immediate need to implement stringent clinical trials for the approval of these drugs and the use of these medicines. The safety and effictiveness frreports of these drugs should be periodically collected and evaluated for the safety oof the people.