OMICS International
conferenceseries.com

Pharmaceut Reg Affairs 2015, 4:3
http://dx.doi.org/10.4172/2167-7689.S1.019

5th International Conference and Exhibition on

Pharmaceutical Regulatory Affairs

August 03-05, 2015 Orlando, USA

Potential endocrine disruptors in herbal medicine: A second look at regulatory issues

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Background: Herbal remedies have been used for several years by people from diver cultures and climes. Prior to the advent of modern medicine, use of herbal medicine was the only available treatment known to mankind. The World Health Organization (WHO) in 2005 had reported that significant percentage of the world population rely heavily on herbal medicine to meet their basic health needs. The same report showed that the use of herbal medicine throughout the world exceeded that of conventional drugs by two to three times. In Africa, over 90% of individuals rely on herbal medicine. The voracious use of herbal medicine by different people is premised on the belief that herbal drugs are safe and may be consumed at any quantity without side effects. Other reasons are availability and accessibility at minimal cost. However, use of traditional medicine is not only limited to developing countries, but extensive use of herbal products has also been reported among people in the developed nations. In the United States, a survey by the National Center for Complementary and Alternative Medicine revealed that the use of herbal therapy or natural products other than vitamins and minerals was the most common especially when all other forms of traditional medicine were excluded. Recent analysis of a named herbal medicine using GC/MS, NMR and FTIR analysis showed the presence of potential estrogen disruptors (PED). Potential endocrine disruptors are exogenous chemicals or mixtures of substances which interfere with normal endocrine functions thereby resulting in adverse hormonal function either in an intact organism, the offspring or the entire population. High prevalence in non communicable diseases such as cancer, infertility and cardiovascular diseases have all been linked to either the presence of Estrogen Disruptors (EDs) or Potential Endocrine Disruptors (PEDs). The economic burden caused by EDs/PEDs is high. How should the regulation of herbal remedies be improved especially in the developing countries in order to reduce the adverse effects caused by these chemicals? This shall be the focus of this presentation.

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Drug regulations in India- A critical analysis

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The regulation of medicines in UK probably began in the fifteenth century to make sure that they were not contaminated or defective. 'Medicinal Products' are defined as 'any substance or combination of substances presented as having properties for treating or preventing disease in human beings.' Before making any medicine in the market clinical trials are necessary not only in India but in the entire world. A clinical trial is a scientific investigation to evaluate the effect of new drugs or vaccines other than health interventions, by administering these to human volunteers. Generally, clinical trial has three phases before manufacture of drugs. In the beginning of the current century Drug Industry was practically non-existent in India and pharmaceuticals were being imported from abroad. After the First World War manufacturing of drugs started in India. To control the manufacture, distribution and sale of drugs and medicines the Government passed the following two Acts. a) The Poisons Act, 1919; b) Dangerous Drugs Act, 1930. The Government also adopted The Opium Act, 1878. Drugs Act was passed in the year 1940. By passing Narcotic Drugs and Psychotropic substances Act in the year 1985 it repealed all previous Acts. The other Acts which are regulating the manufacture, sale, import, export and clinical research of drugs and cosmetics are as follows: a) The Drugs and Cosmetics Act, 1940; b) The Pharmacy Act, 1948; c) The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954; d) The Medicinal and Toilet Preparations (Exercise Duties) Act, 1956; e) The Drugs (Prices Control) Order, 1995 (Under the Essential Commodities Act).

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