

The Role of Documented Long-Term History of Use of Herbal Medicines for Their Efficacy and Safety and Market Authorization in the World

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Since antiquity in the beginning of mankind the use of herbal medicines has offered an effective medicine for the treatment of human and livestock illnesses. Herbal medicines form the oldest and still the most widely used system of healthcare in the world still in use today. It is used in all societies and is common to all cultures in the world. In recent years, an increasing number of people have been choosing herbal medicines and/or products over modern medicines in order to improve their health conditions, either singly or in combination with others. Herbal medicines are staging a prominent comeback and herbal “renaissance” is occurring all over the world. According to the World Health Organization (WHO), more than 80% of the world's populations are using herbs for basic healthcare needs.

For many, traditional medicine is the first resort of call, and practitioners of traditional medicine have played an important role in the treatment and management of human illnesses. The World Health Organization (WHO) defines herbal medicines as herbs, herbal materials, herbal preparations, and finished herbal products that contain whole plants, parts of plants, or other plant materials, including leaves, bark, berries, flowers, and roots, and/or their extracts as active ingredients intended for human therapeutic use or for other benefits in humans and sometimes animals [1].

The World Health Organization's General guidelines for methodologies on research and evaluation of traditional medicine does not require proof of efficacy and safety through pre-clinical studies and clinical trials for herbal medicines with the history of long-term traditional use [2]. Safety and efficacy information is therefore substantiated through literature sources based on the long-term traditional use of the product in communities or a well-established use. Long-term traditional use refers to herbal medicines that have a history of use for several decades without reports of toxicities [2]. The regulation of herbal medicines by regulatory authorities in European countries, United States of America, China, India, Thailand and Japan follows the WHO's General guidelines for methodologies on research and evaluation of traditional medicine which does not require proof of efficacy and safety through pre-clinical studies and clinical trials for herbal medicines with the history of long-term traditional use [2].

The European Union Directive 2004/24/EC allows the registration of traditional herbal medicines under a Traditional Use Registration (TUR) scheme, whereby a documentation proving long-term traditional use as stipulated in Article 16c of the Directive: ‘...[If] the medicinal product in question, or a corresponding product has been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the Community [EU-member states]’ then it can qualify as a ‘traditional herbal medicinal product’ (THMP).

China has become the biggest producer as well as exporter of herbal medicines, accounting for 30% of total world trade by value in 1991, followed by Korea, USA, India and Chile [3]. Singapore and Hong Kong have emerged the main re-exporters of medicinal plants in Asia. Japan, USA, Germany, France, Italy, Malaysia and Spain are now the major markets of herbal medicines. Hamburg is the world trading centre in medicinal plants. About 53 countries supply medicinal plants to Germany, of which important ones are India, Argentina, former Yugoslavia, Greece, China, Poland, Egypt, Hungary, Czech Republic, Democratic Republic of Congo, Albania, the Netherlands and France [3].

Considering the African traditional medicine which have existed since time immemorial, in fact long before the advent of modern medicine. It has continued to be used, in the treatment of diseases and illness, by more than 80% of the Africa's indigenous populations especially in rural and peri-urban areas of sub-Saharan [4]. Despite being the world's richest and oldest medical system, African traditional medicine has remained a cropper and the least developed and established traditional medicine system in the world as well as the most undeveloped, informal, with lack of overall acceptance and integrations by most of the Ministries of Health in the continent.

The World Health Organization's General guidelines for methodologies on research and evaluation of traditional medicine [2] and the Guidelines for registration of traditional medicines in the WHO African Region, AFR/TRM/04.1[5] have not well domesticated and enforced by the majority of African countries. The distrust between modern and traditional health practitioners also seems to be high in Africa than in the developed and developing countries that are officially promoting herbal medicines [4]. Use of herbal medicines is expected to rise globally. This upward trend is predicted not only because of



population explosion, but also due to increasing popularity for herbal medicines as being effective with fewer side effects[6].

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