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Opinion

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Herbal medicines (and adverse effects): to be or not to be?

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There are some substantial differences between allopathic drugs and herbal medicines; however, at least from a certain point of view (apart from the fact that plants are a natural source of substances that have been used by humans during tens of thousands of years), their effectiveness and safety should be evaluated based on a similar approach, without making a difference between these two types of products. Both are real medicines, and both should be subject to formal and demanding requirements from the regulatory authorities before being placed on the market.

Pharmacovigilance is defined by the World Health Organization (WHO) as the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem.[1] In the field of the human medicines, regulatory agencies are responsible for protecting the public health by assuring the safety, efficacy, and security of human drugs, including biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation. These agencies are also responsible for advancing public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines to maintain and improve their health.[2] These concepts are naturally and directly applied to allopathic medicines and also to medicinal herbs, but the latter are often not considered in the clinical practice. Many times health or drugs authorities worldwide probably do not agree with these principles, and consequently the general population and health-care professionals generally do not have sufficient knowledge on this topic.For instance, every year in the United States there are more than 100,000 deaths from Food and Drugs Administration-approved, correctly prescribed medicines. This makes the medical system the third leading cause of death in the US, after heart disease and cancer.[3] But how many deaths occur due to medicinal herbs consumption or errors associated with improper use? Really, we do not exactly know.

The WHO estimates that, on average, around 75% of the population in developing and developed countries rely on or frequently use traditional medicine as the primary method for health care needs.[4]

There is considerable information on adverse effects of medicinal plants, including pharmacovigilance reports, interaction articles, clinical assays, occasional case reports, reviews, and others, but these do not seem to be enough. Although the use of medicinal herbs is actually very important throughout the world, and is clearly increasing, in comparative terms, only about 0.15% of the available information on adverse effects/events from reliable scientific sources is related to the use of herbal medicinal.[5] This, however, does probably not reflect the real situation of the incidence of adverse effects of medicinal herbs in public health, but only shows the numbers of pharmacovigilance reports, most of which are voluntary ones. For many patients, the use of herbs is not regarded in the same way as the administration of other kinds of modern medicines, even if, with the use of the plants, the goal of the person is to combat illness or injury, improve or modify a physiopathological status, or relieve a specific symptom.

A lot of important scientific evidence on medicinal herbs and adverse effects has been accumulated over the past 30 years. Although scientific studies about ethnomedical, anthropologic, and chemical aspects as well as actions and active components of thousands of plants abound in the scientific literature, the gap between this basic knowledge and the adequate clinical use is immense.[6-9] Recent developments in the control and regulation of traditional medicine in Japan as well as China are good examples of how the scientific community is able to work to achieve the goal to accomplish the requirements of stringent formal regulations.[10]

In order to be (or not to be) universally accepted as a therapy in the world of modern medicine, and without losing the traditional essence, the medical use of herbs should be suitably and strictly studied and controlled. As yet there is no medical and social awareness of the importance of this issue. The strength of the dominant/leading healthcare system in the world is based, partly, on its capacity to investigate and show its own weaknesses. There are, of course, other marketing and economical strategies, but just to research its scope and limitations has made it stronger. As in many other clinical settings and scientific fields, also in this area a strong decision on implementation

of health politics related to the education in and correct use of medicinal herbs, added to close clinical follow-up and research is essential to consolidate the safe use of natural products.

Conflict of interests

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