

Efforts are needed to tap into the potential of nutraceuticals

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A growing demand exists for nutraceuticals, which seem to reside in the grey area between pharmaceuticals and food. The products are thought to provide medical or health benefits "beyond the diet, but before the drugs". A new review published in the *British Journal of Clinical Pharmacology* looks at the potential of nutraceuticals, stressing the need for a proper definition of nutraceuticals and clear regulations to ensure their safety.

In the review article, a team led by Ettore Novellino, PhD and Antonello Santini, PhD, of the University of Napoli Federico II in Italy, states that nutraceuticals with proven efficacy and health benefits substantiated by clinical data could be used as powerful tools to prevent and treat medical conditions, especially in individuals who may not yet be eligible for conventional pharmaceutical drugs. Therefore, it is of utmost importance to have a proper and unequivocal definition of nutraceuticals, to conduct clinical studies on their safety and efficacy, and to have standardized regulations for their use. In addition, nutraceuticals require a specific classification apart from food supplements and pharmaceuticals.

The authors propose the following definition for nutraceuticals: the phytocomplex of a vegetable or the pool of secondary metabolites from an animal. Both are concentrated and administered in a pharmaceutical form and are capable of providing beneficial health effects, including the prevention and/or treatment of a disease.

"Nutraceuticals, in the collective imagination of the consumer, tend to be



confused and wrongly identified with many other products available on the market on the basis of potential health-benefits," said Dr. Novellino. "An evaluation of the safety, the mechanism of action, and the effectiveness of nutraceuticals—and substantiating this with clinical data—is the central point that differentiates nutraceuticals from food supplements."

Dr. Santini added that the growing demand and interest in nutraceuticals justifies the need for a restructuring of the entire regulatory framework that differentiates nutraceuticals from <u>food</u> supplements. "We propose a regulatory system that is similar to the one used for drugs, which is more rigorous and more complex than the one commonly accepted for <u>food</u> <u>supplements</u>," he said. "It is important for consumer protection that national authorities and regulatory agencies require manufacturers to provide data to support any claim in the labels of products when the term nutraceutical is used."

More information: "Nutraceuticals: opening the debate for a regulatory framework" *British Journal of Clinical Pharmacology* (2018). DOI: 10.1111/bcp.13496

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