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Letter to Editor
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Nutraceuticals: Redefining a Concept

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Letter to Editor

The term “nutraceutical” comes from far: in 1989 by Stephen DeFelice, founder and chairman of the Foundation for Innovation in Medicine (DeFelice, 1989), derived it from the two words "nutrition" (indicating a food component) and "pharmaceutical" (with reference to a drug) [1].

This term identifies a food or part of a food, which can be of vegetal or animal origin and can have a potential pharmaceutical activity. Recently, a new definition of the concept on nutraceuticals has been proposed to clear the disambiguity existing between them, food supplements, and pharmaceuticals. In particular, nutraceuticals are defined as: i) for food of vegetal origin, a nutraceutical is the phytocomplex; and ii) for food of animal origin, a nutraceutical is the pool of the secondary metabolites. Both are concentrated and administered in the proper pharmaceutical form [2]. They are capable of providing proven beneficial health effects, including the prevention and/or the treatment of a disease [3].

Nutraceuticals define hence a new category, which shades the frontier between drugs and food derived products, and that could be imagined as the evolution of the concept of food supplement.

While food supplements are addressed to compensate, if any, a lack of micro/macro nutrients in the body, a nutraceutical must be safe to use, have a proven pharmacological effect, and a rationale to be used in a pathological condition.

While pharmaceuticals must follow specific legislation on efficacy, safety, production, and use in therapy to be authorized and marketed, all these rules are not, in general, followed for food supplements. Nutraceuticals, still reside in a grey area between food and food supplements, even if they are generally reported to have good safety profile with few unwanted side effects and high bioavailability [4].

A growing demand exists for nutraceuticals, and their market is rapidly increasing, nonetheless, they are experiencing a great challenge to obtain health claim substantiation due to the lack of data regarding clinical studies and safety, and also to the lack of a shared regulatory framework [5].

Their application area has been however reported in the literature as ranging from metabolic syndrome and inflammation control to Alzheimer’s disease [6-10].The addition of nutraceuticals in the daily diet could be beneficial to help to prevent the onset of pathological conditions by possibly delaying or avoiding the need to use pharmaceuticals in subjects who qualify for an alternative non-pharmacological approach to a pathological condition. Nonetheless, the limit is the lack of clear information, and often, the claimed health benefits of food supplements, often identified in the collective imagination with nutraceuticals, may not be properly substantiated by safety and efficacy information which can induce false expectations and miss the target for a product to be effective as claimed. Lacking an officially accepted and shared definition of nutraceuticals, they are also referred to as pharma-foods, and confused with food supplements. Their potential as a toolbox to be used “beyond the diet but before the drugs” to prevent and treat pathological conditions, e.g. dismetabolism is still to be acknowledged [10].

Future challenges in the area are concerned with nutraceuticals bioavailability, which affects their efficacy as disease-preventing agents, and requires further studies. The oral bioavailability depends mainly on composition and structure and only nutraceuticals which reach and distribute to the tissues and organs where they can exert their beneficial health effects are effective [11]. The bioavailability profile of nutraceuticals may influenced by a limited bioaccessibility, poor absorption, or chemical transformation within the gastrointestinal tract. It has been suggested nano/micro delivery systems using lipids, surfactants and other materials (carbohydrates, polymers, complexes and protein) to stabilize and enhance the biological activity of the bioactive compounds constituting a nutraceutical [12]. Nonetheless, the main issue concerning nutraceuticals is the lack of a shared regulation. They are actually categorized as food supplements, and the same regulation

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is applied. This generates confusion among consumers, and lack of proper information on the market. A shared regulatory framework for nutraceuticals does not exist yet.

Nutraceuticals require an appropriate description and specific classification. Food supplements and nutraceuticals are both considered to be derived from foodstuffs, which mean that in many cases, the precautionary principle valid for food is applied to food supplements, and the term nutraceutical is used for products available on the market without proper assessment by clinical efficacy data of their beneficial health effects. This does not address the issue of borderline definitions and classifications between medicinal products, food supplements and nutraceuticals [13].

While the definition of a food, food supplements, and pharmaceuticals is quite understandable, the definition of nutraceuticals is still to be accepted and shared. Trying to address the discrepancies between the definition of nutraceuticals and the regulatory aspects it is a significant challenge which must be taken in the near future. It is of utmost importance to clearly address nutraceuticals specificity of use in view of their possible applications in the pharmaceutical scenario.

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