

## Concerns about Quality and Safety of Dietary Supplements

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Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), released by US federal legislation, dietary supplement is a preparation belonging to foods that is intended for digestion and cannot replace a meal or the diet. It may contain vitamin, mineral, herb or other botanical, amino acid or concentrate, metabolite, constituent, extract, or combination of any ingredient listed above. DSHEA indicates manufacturers as subjects responsible for ensuring the quality, evaluating the safety and labeling of their products [1]. Despite the control over the quality of dietary supplements held by manufacturers and Food and Drug Administration some concern about quality and safety of this kind of products arise. Firstly, despite a huge advertising campaigns showing the potential benefits produced by dietary supplements, many consumers do not distinguish dietary supplements from drugs. What is more, although dietary supplements should contain just food ingredients showing only nutritional effects, they are produced in forms of tablets and capsules, in packages which resemble medications. Hence, in many cases, people expect rather pharmacological than nutraceutical effects exerted by dietary supplements. And indeed, at a given dose, some dietary supplements may have pharmacological effects, and such preparations are so-called "borderline products" [2]. The legal framework for supplements varies among countries [1-4]. Even inside the European Union, where production of dietary supplements is regulated by Directive 2002/46/EC (which refers to food supplements, specifically vitamins and minerals; EC, 2002) and Regulation 1924/2006 (which refers to nutrition and health claims; EC, 2006) the Member States shall determine the requirements for dietary supplements. Products which are legally commercialized in the one country as dietary supplements may be considered medicines in other country. And if in case of medicines manufacturers need to comply with all the obligatory requirements for a medicine product, such requirements do not apply to dietary supplements. The DSHEA states that manufacturers do not have to gain approval, or register their products with the FDA, they are also not obliged to obtain FDA approval to release the product on the market [1]. This means that consumers can only trust the Good Manufacturing Practices implemented by manufacturers, who are not legally required to provide evidence that their product is safe or effective. Consequently, not without a reason, researchers still investigate many aspects of dietary supplements (quality, safety, adulterations, health benefits, interactions), especially since the interest in such products is not decreasing. According to a consumer survey conducted by Grand View Research Inc., the market of dietary supplements is still growing with largest Asia Pacific accounting for 47.7% of the total share in 2015 and the botanical supplements are the leading segment [5]. In Poland, number of new dietary supplements reported to State Sanitary Inspection in 2016 reached over 8800 preparations, whereas in 2012 it was just near 4000 [6]. Giving such interest and spending more money on dietary supplements consumers should be aware of risks associated with careless administration of these products, especially since the responsibility for the negative effects of taking dietary supplements may not be passed on to the manufacturer. A poor manufacture practices were frequently revealed by researchers reporting the amount of active compound different than labeled value [7], presence of degradation or oxidation products exceeding maximum levels established by international standards of quality [8], presence of medicines or banned substances [9], various compositions of a given dietary supplements with the same batch number or changes in the chemical composition of the formulations resulting in inadequate labelling [8]. What is more, some association of liver injury and administration of herbal dietary supplements has been reported [10]. Many other possible side effects resulting from administration of preparations of questionable quality may be revealed in the near future. The solution for this problem should be changing a legislation, but this is not profitable. Hence, increasing the society awareness can be a good initiative which should be supported by scientific community.

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