Dietary Supplements: A Source of Regulatory Confusion

By ACSH Staff — April 13, 2009

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The market for dietary supplements is enormous, reaching an estimated $24-25 billion in the U.S. (Thurston, 2008) and £335 million in the UK (Eberhardie, 2007). This is a remarkably robust market for a wide variety of compounds that are neither foods nor medicines, and it continues to expand. Consumers often regard supplements as more "natural," or traditional and therefore safer than pharmaceutical products -- a conclusion that is often without merit. Dietary supplements occupy unique positions in the U.S. and EU regulatory schemes -- positions that are often not well understood by consumers. This misunderstanding can lead to unfortunate consequences for individuals health.

In the United States, dietary supplements were defined in the 1994 Dietary Supplements Health and Education Act (DSHEA) [1] as products (other than tobacco) that:

¢ Are intended to supplement the diet;
¢ Contain one or more dietary ingredients (including vitamins; minerals; herbs or other botanicals; amino acids; and other substances) or their constituents;
¢ Are intended to be taken by mouth as a pill, capsule, tablet, or liquid; and
¢ Are labeled on the front panel as being a dietary supplement.

This legislation also created an Office of Dietary Supplements [2] within the National Institutes of Health, which is responsible for conducting and coordinating supplement-relevant research within the NIH.

Similarly, in the EU, food supplements include foodstuffs intended to supplement the normal diet. The EU definition is more detailed about the forms supplements may take than about the actual content. It states that they are concentrated sources of nutrients (vitamins and minerals) or other substances with a nutritional or physiological effect. These substances may be marketed in capsules, pastilles, tablets, pills, pastilles, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities. (Eberhardie, 2007)
The US Food and Drug Administration (FDA) is responsible for oversight and regulation as specified in the DSHEA. In the US, supplements are regulated as foods, not as food additives or pharmaceuticals. This is more than a semantic distinction, as this categorization determines the extent to which manufacturers or suppliers must test products before they may be offered to the public.

Pharmaceutical products must undergo rigorous testing to determine first, safety, and second efficacy for the treatment of the particular health condition for which they are intended. Further, post-marketing surveillance is a source of ongoing safety information.

Purveyors of new food additives, substances such as colorants or preservatives, in contrast, must present data to the FDA demonstrating the safety of the compounds before they are added to the public food supply (such a substance that has been in long term safe use, such as salt, sugar or spices would be excluded from this requirement, and categorized as Generally Recognized as Safe or GRAS). (Rados, 2004) They do not have to undergo the extensive efficacy trials required of pharmaceutical products.

In contrast, dietary supplement manufacturers or suppliers do not have to present any premarketing safety or efficacy data to the FDA. Manufacturers supposedly will have such data to present, but are not compelled to do so before they sell their products.

If there is any question about the safety of a supplement once it is available to consumers, it is the responsibility of the FDA to show that the item is not safe when used as intended. This requirement is very difficult if not impossible to accomplish, since supplement marketers are not required to report the results of any post-marketing surveillance, and thus the FDA must rely on voluntary reports of adverse health events.

This lack of a surveillance requirement has led to a situation in which adverse effects and interactions between various supplements or between supplements and pharmaceuticals are discovered serendipitously. For example, St. John’s Wort, a popular herbal product for treatment of depression, can interact with oral contraceptives, anticoagulants, and immunosuppressive drugs. (ACSH, 2000; Markowitz et al. 2003)

Similarly, there are concerns about the appropriate regulation of supplements in the European Union. The Medicines and Healthcare products Regulatory Agency (MHRA, 2002) lists numerous areas of public health risk associated with herbal medicines. The European Food Safety Authority is responsible for the safety of food supplements under EU Directive 2002/46/EC. This Directive specifies a positive list of nutrients and sources. (Eberhardie, 2007) There are further directives relating to traditional herbal medicines -- only those with a known efficacy which have been used for 30 years, half of which have been in the EU -- are approved under EU Directive on Medicinal Products for Human Use (Eberhardie 2007; EC, 2004).

In both the EU and the United States, the categorization of dietary supplements (or food supplements) seems to be an obstacle to regulatory clarity. In the U.S., regulating supplements as foods means there is little oversight of safety or manufacturing processes.

In the EU, the definition of food supplements based on a description of their form rather than
content seems to make it difficult to determine exactly which set of regulations should apply. As Eberhardie (2007) notes, garlic may be sold as a plant, a food, or an herb; it may also be produced and sold as an herbal medicine.

Until there is clarification of how supplements should be described, regulation will likely continue to be confusing, and will not adequately protect the public health.

References


Links