

Codex Committee on Nutrition and Foods for Special Dietary Uses Proposed draft guidelines for dietary supplements

Comments from the Society for the Promotion of Nutritional Therapy

The Society for the Promotion of Nutritional Therapy (SPNT) represents some 2,000 individuals, mainly in the UK but also in ten other countries, who have a special interest in the use of special diets and nutritional products for the promotion of good health. The society aims to promote knowledge in this area, using good quality information. It has no connection with nor interests in the vitamin industry. Its members include doctors, nurses, complementary medicine practitioners, nutritional therapists, clinical scientists and lay people. Through its links with other organisations, the SPNT can count on at least 200,000 people who actively support its views.

The SPNT's definition of dietary supplements is as follows:

- 1) Preparations of vitamins, minerals, amino acids, essential fatty acids, enzymes, fibre and other factors which fulfil a useful or necessary physiological function and are found in food or synthesised within the body from food. These preparations may be chemically synthesised or natural extracts.
- 2) Concentrated plant- or animal-source preparations such as fish oils, yeast, probiotics, spirulina, kelp, royal jelly and plant or herb extracts, used to supplement the diet with the nutrients they contain, or for their health-giving properties.

The society's members have a keen interest in preserving the availability of dietary supplements currently available to them, and in championing consumer freedom of choice for the purchase of safe products in all countries. It was largely through our members' efforts that a proposed EU directive was defeated in 1992, which would have resulted in the disappearance of higher-range (supra-RDA) dietary supplements due to a virtually unanimous vote by officials from member states to class them as pharmaceutical drugs. Manufacturers confirmed that they would cease producing these products if they had to bear the cost of treating them as pharmaceuticals. Consumers were determined not to see this happen.

This short paper seeks to compare the arguments commonly used to support the pharmaceutical classification of these products, with those from the specialist consumer's perspective, in the hope that it may assist not just the UK Codex delegates but also those of other countries, in understanding and supporting the wishes of the specialist consumer.

The pro-pharmaceutical lobby

This consists exclusively of the established scientific community: government officials, academics or heads of nutrition policy units in national or international institutions or establishments. The scientific community also has a common training background based on consensus science.

At the present time, consensus science dictates that the needs of most healthy individuals are met by their country's Recommended Daily Amount or Reference Nutrient Intake for vitamins and minerals. This being so, supra-RDA dietary supplements are seen as unnecessary for healthy people. On the other hand, individuals with nutrient-responsive diseases, it is believed, should receive these nutrients from their physician, who is, it is believed, is alone capable of deciding whether these products would be beneficial. It is further believed that to ensure that only safe, effective products are used, any dietary supplements used for such medical purposes should be subjected to pharmaceutical risk:benefit evaluations. This can only be enforced by placing such products under pharmaceutical legislation. The scientific community sees itself as championing consumer safety and preventing consumers from being misled by commercial marketing campaigns.

The specialist consumer lobby

Many proponents of free consumer choice for safe dietary supplements are themselves scientists but do not necessarily agree with consensus science. It has to be admitted that consensus science is often many years behind current knowledge. For instance the link between folic acid deficiency and spina bifida was known for ten years before it was agreed that all pregnant women at risk should be recommended to take folic acid supplements. Eventually there will be a similar agreement about vitamin E supplements and heart disease. The link between smoking and lung cancer was known for 25 years before the public were advised not to smoke. Proponents of consumer freedom believe that consensus science should not be used as a weapon to stifle other, different opinions. A wealth of research - possibly several hundred thousand studies - exists to show that many individuals could benefit from taking higher-range dietary supplements. But because the results of these studies are frequently inconsistent, it tends to be assumed that the nutrients in question are not effective "medications", and the research is then marginalised by the scientific community.

However if the results are interpreted differently - if it is admitted that only those individuals suffering from a lack of or higher needs for the nutrient in question are likely to derive benefits from taking it as a supplement, then the studies would tend to support at least a temporary need for higher-range dietary supplements by a very large number of people. But to allow room for this interpretation, the possibility of widespread chronic, subclinical nutritional deficiency states in the western world has to be at least entertained.

Instead, the scientific community propagates the view that the consumer of higher-range dietary supplements is foolish, misled by clever marketing, despite the fact that this particular consumer movement has many highly qualified, extremely intelligent supporters, including doctors and clinical scientists. These individuals have studied the alternative views in great depth, and in addition often base their own views and conclusions on personal experience. In this sense they have a great deal more expertise on the safety and worth of higher-range supplements than most members of the scientific community, and, in our view rightly, believe themselves far more qualified to comment in this field.

The informed consumer is also very much aware that higher-range dietary supplements have a far better safety record than almost any other consumer product, although the anti-vitamin lobby still consistently seeks to warn against toxicity risks. In view of this safety record, the SPNT believes that safety concerns should be met by labelling criteria, not by banning products. To all intents and purposes pharmaceutical classification is equivalent to a ban because pharmaceutical licences are beyond the financial resources of an industry which is not allowed to patent its products. Product costs are high and availability low in all countries where higher-range supplements are treated as drugs under the law.

Food, medicine or just dietary supplement?

Consumer products cannot be classed as pharmaceutical just because they have been used in clinical trials or because they might be used for self-treatment. Should coffee be subjected to clinical trials because individuals use it to keep awake? Does brandy require a pharmaceutical licence because it is used as a tranquilliser?

In most countries pharmaceutical licences are only required for products which are administered (ie sold or prescribed) for the treatment of a specific disease or to alter normal physiological function for specific medical reasons. Consumer products used to supplement the diet in the hope that improved function will lead to better health, as it has done for many people, clearly cannot fall within this definition, especially if the products are not labelled with health claims.

Whether or not there is any scientifically acceptable evidence that higher-range vitamin and mineral products are capable of promoting good function is not relevant to the question of medicines classification. As with any other consumer products, the burden is on the legislator to prove that a particular product is being presented for administration as a medicine. This is usually done by considering claims made on product labels or in product literature.

Those who support medicines classification also use the argument that this affords greater consumer protection than food law. Yet a 1992 study found that 10,000 people a year are admitted into UK hospitals suffering from the side effects of prescribed medicines. A study supported by the UK government on the toxicity of dietary supplements and herbal medicines found only a handful of adverse reactions in eight years. Many of these were minor, others were caused by prescription iron tablets accidentally swallowed by children, and by Chinese and Indian ethnic medicines illegally containing mercury and lead. Products governed by food law safety criteria can be withdrawn from the market if they are not found to be as safe as food itself at levels of likely intake. What greater consumer protection can there be? In any country's legal system there is surely room for dietary supplements to have their own legislation, with regulations relating to upper limits of potency, GMP, labelling etc. Consumers believe that safety concerns can be easily met by cautionary wording on product labels. This is already the norm for all other consumer products where there is a small potential risk.

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