

The difference between drugs and nutritional supplements

In the assessments of risk associated with the intake of nutritional supplements we often see that such supplements are confused with drugs. In Norway, regulations are in place to ensure that nutritional supplements are safe and reliably marketed. Products in which the content of vitamins and minerals exceeds the maximum values defined by the regulations are classified as pharmaceuticals.

■ Nutritional supplements are intended as additions to the diet. The products should contain concentrated sources of vitamins, minerals or other substances with a nutritional or physiological effect. Nutritional supplements are regulated in detail by the applicable regulations (Kosttilskuddsfor-skriften) (1).

High dosages must be classified as drugs

The benefits of nutritional supplements are a source of constant debate (2, 3). Debates have included whether large doses of vitamins and minerals in the form of nutritional supplements may have undesired health effects (4). A much-quoted example is a study by Ristow et al. showing that supplements containing 1,000 mg vitamin C and 267 mg vitamin E can obstruct induction of molecular regulators for insulin sensitivity and the endogenous antioxidant defence during physical exercise (5). The Norwe-

gian regulations define minimum and maximum limits for the various vitamins and minerals. The maximum limit for vitamin C and vitamin E are 200 mg and 30 mg respectively. According to an overview article by Hathcock et al., even higher supplements than these are considered safe (6). There are few studies available on the equivalent doses obtained through foods.

«It is illegal to claim that nutritional supplements can prevent, heal or alleviate diseases, symptoms of diseases or pain»

Products containing vitamins in amounts that exceed the maximum limit are available in Norway, but these are classified as prescription-free drugs and are intended for use over a restricted period of time in consultation with a doctor for treatment of vitamin deficiency. This contrasts with nutritional supplements, which are normally used as additions to the diet over a longer period of time.

Sweden has different regulations. These define no maximum limits, and their nutritional supplements therefore contain far higher doses of nutrients. Outside of Europe, for example in the U.S., the daily recommended intake may be different from the values used in Norway. The discussion

Do we need nutritional supplements?

Nutritional supplements contain nutrients that can also be ingested through a healthy diet. According to the regulations, it is illegal to claim or to render the impression that a balanced and varied diet in general will not provide a sufficient supply of vitamins and minerals (1). The Directorate of Health has defined the recommended intake of various vitamins, minerals and other nutrients (7). If the diet does not provide these, nutritional supplements can increase the body's level of them, and thereby prevent symptoms of deficiencies.

The Norwegian dietary recommendations advise people with a very low energy intake (< 6.5 MJ/d or < 1 550 kcal/d) to use a multivitamin/mineral supplement (8).

This applies in particular to elderly persons who have a small food intake. In addition, people of dark complexion and people who are little exposed to sunlight should take a daily supplement of 10 µg of vitamin D in addition to what is ingested through food (8). The EU's food safety authority, EFSA, is currently reviewing health claims for the various nutrients.

Dishonest suppliers

It is illegal to claim that nutritional supplements can prevent, heal or alleviate diseases, symptoms of diseases or pain. Such marketing of a nutritional supplement entails its classification as a drug. Dishonest suppliers who market their products with such claims contribute to spreading misconceptions about nutritional supplements.

There are also examples of producers who mix undeclared drugs and/or unapproved active substances and herbs into their products. The industry is collaborating with the Association of Herbal Manufacturers and Retailers to put a stop to these

actors, but currently there are no appropriate schemes that can be used to remove these products from the market. Hopefully, the publication of the EU regulations for health claims will provide more definitive guidelines and simplify these efforts. Publication of the regulations is expected in late 2012.

Quality variations

Quality assurance and full traceability of ingredients are essential to ensure consumer safety. In addition, manufacturers of nutritional supplements need a broad knowledge of the bio-availability of the active ingredients and their effects to be able to make high-quality products. There are major variations in the body's uptake and the effect of the active ingredients depending on the form in which they are supplied. The regulations on nutritional supplements have appendices that are intended to ensure that the chemical compounds used as a source of vitamins and minerals are safe and present in a form that the body can absorb. I therefore maintain that nutritional supplements from reliable Norwegian suppliers will not contain doses associated with negative health effects, and that they therefore constitute an appropriate and safe alternative for those who fail to ingest the recommended amounts of nutrients by way of their daily diet.

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