Functional food: A growing and not clearly controlled market with a risk potential ranging from a food to a drug

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In the observational report by H. U. Bachmann and A. Hoffmann published in this issue [1] the investigators describe the interaction of a functional food (L-Carnitin) with an oral anticoagulant (acenocoumarol). This case exemplifies the risk that functional foods may have pharmacological effects and that there is a potential risk of interaction even when these foods are consumed with no therapeutic intention [2]. In the event of such an incident, diagnosis becomes more difficult.

We have to face the reality that:

- both healthy and ill people do not perceive functional foods as drugs, even after several inquiries
- there are no standardized international regulations with a clear dividing line between the definition of a functional food and a drug
- the turnover and the distribution track is incalculable / not easily estimated and therefore the consumer can not be correctly informed
- a growing market segment for lifestyle and sports is a matter of fact

From the point of view of the specific products the difference between a functional food and a drug is not clearly defined and is not easy to classify.

The aggressive marketing and advertising of functional foods in segments with a high financial margin, such as sports, fitness and lifestyle, continues with no regard to ethical considerations or responsibility. This is in stark contrast to the ethical constraints placed on pharmaceutical marketing.

I do not generally disapprove of the observed trend. We know that functional foods have many potential benefits, for example a decrease in the LDL-level of cholesterol, a positive effect on the growth and the structure of bones and protection from caries. I want merely to enforce the need and the duty of those concerned to inform people of the ingredients of functional foods. I would like to see the development of a culture of discussion and interest, which allows the conclusion that "(valuable) functional foods" can be considered to be drugs when taken in high doses.

Experience during the last years has shown that "natural ingredients" [3] such as health foods [4, 5] are no longer considered completely harmless.

The published observational report shows clearly that we have only reached the tip of the iceberg. It is absolutely necessary to go into greater specific details and to develop further background knowledge especially in cases of uncertainties.

For example, magnesium is good for the structure and health of bones. In high doses it may be laxative or it may have an effect on vascular system tonus or on skeletal muscle tone.

Vitamins in therapeutic doses are essential, in high doses mostly useless and (possibly) dangerous. A certain doctor recommends vitamins in high doses against practically any form of cancer. Such information is of no use to anybody and misleads patients, often causing him or her to postpone seeking serious medical advice.

As a consequence and as a basis for future improvement, firms dealing with such products are asked to perform their duty to inform patients correctly. Public authorities are also faced with the challenge of controlling functional food products and their turnover according to international guidelines (www.fda.gou/medwatch).

The following positive example demonstrates the importance of correct and swift information. Some time ago the interaction between hypericum and cyclosporine, describing the complications in transplantation medicine was published as a single case report [5]. The public authorities reacted in an exemplary and quick manner. The turnover of products containing the ingredients of the hypericum plant was limited immediately and signs warning of the potential risk of interaction became compulsory. Some products were only able to remain on the market following appropriate modifications and others were completely forbidden [6].

The community of medical professionals should always bear in mind the fact that functional food can be regarded as a drug when taken in high doses. The following documentation on an interaction between L-Carnitine and Acenocoumarol should remind us that more attention needs to be paid to this topic. Let us keep our eyes open.

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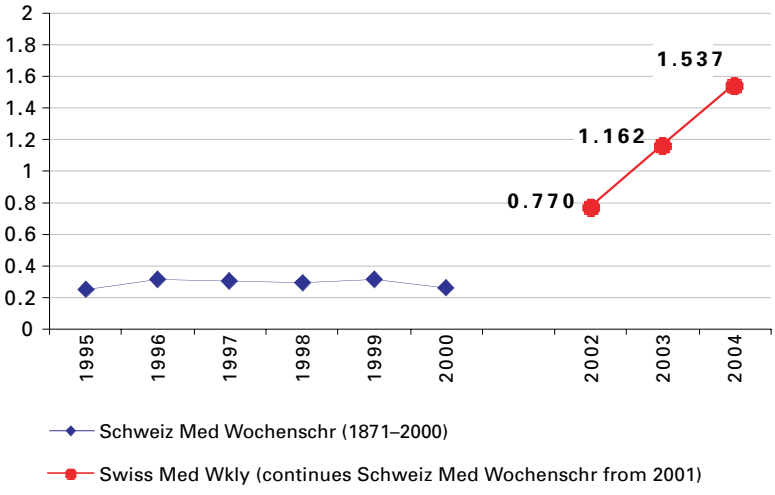

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