Orthomolecular Medicine in Europe

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Introduction

Prerequisite to practicing orthomolecular medicine is the availability of high dose food supplements. In Europe their availability has been in jeopardy since their introduction in the 1970s. In March 2002, the European Parliament passed a directive (European law) on food supplements, exclusively for vitamins and minerals, which will be in force within approximately two years in all 15 European countries. Though general legislation in Europe is welcomed, the consequences of this new legislation is alarming. This is mainly due to the crucial role assigned by the European government to the Scientific Committee for Food (SCF). Members of this Committee are mainly conservative food scientists, who stick to the RDA amounts of food essentials and who consider the use of food supplements as needless. Therefore our utmost concern is important.

European Union

The European Union (EU) was set up after WWII. The process of European integration was launched in May, 1950, when France officially proposed to create the first concrete foundation of a European federation. Six countries (Belgium, Germany, France, Italy, Luxembourg and the Netherlands) joined in the beginning. Today the EU has 15 member states. The other nine countries are Denmark, Ireland, the United Kingdom, Greece, Spain, Portugal, Austria, Finland and Sweden (Norway and Switzerland are not yet participating in the EU). The EU itself states that European integration has delivered half a century of stability, peace and economic prosperity. It has helped to raise standards of living, built an internal market, launched the Euro currency and strengthened the Union's voice in the world.[1]

The EU strives for a free exchange of goods, people, capital and services by harmonization of legislation. It is actually a very liberal concept. To achieve this goal, European laws (directives) are made, which are, after introduction, superior to national laws. In practice, when a directive has passed through the European Parliament, the single Member States have to adapt their own laws within a limited period of time.

The main power, economically as well as politically, is situated in Germany. Thereafter France and the United Kingdom may be considered as powerful members. The southern countries, Italy, Greece and Spain, are economically, and thus politically, less strong. It is plain logic that the smaller countries also play a more modest role, like the Netherlands.

Legislation with regard to the free availability of food supplements is best regulated in the United Kingdom and the Netherlands. That is the main reason why orthomolecular medicine is practiced most openly in these countries.

Food supplements in high doses have been available in these countries since the 1970s. Initially, in Holland, free sales of these products was officially not permitted, but in 1994 a national law was passed, which legalized the free availability of food supplements, based on the principle of 'safety', not on the principle of the RDA. This difference is very important, since a law based on the RDA allows food supplements to be sold up to a dosage of, for example, three times the RDA. When a dosage exceeds this amount, the food supplement is considered to be a drug and is submitted to drug law. This is momentarily the situation in Germany and in most of the other

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European countries. This will change according to the new EU-directive of March.

A Brief History

The expansion of orthomolecular medicine is mainly dependent on the possibility to practice. Two points are crucial for this:

1. The legal permission to apply orthomolecular medicine. Contrary to the situation in the United States and Canada, where a MD can lose his license when he is not practicing mainstream medicine, this is of minor importance in the EU. MD's in Europe have a lot more freedom to practice specific therapies according to their own judgement.

2. The free availability of food supplements to prescribe. This has been the limiting factor for practicing orthomolecular medicine in most EU-countries.

Treating illnesses with high dosages of essential nutrients started approximately 30 years ago in the United Kingdom. Besides the use of food supplements by some individuals, individual MD's, inspired by some of their American colleagues, treated their patients with orthomolecular medicine. It started in the UK, probably because there was no language barrier and this country is quite oriented to the west. To a less extent, this was the situation in the Netherlands. Also in this country it started with some individual persons. From there it expanded slowly and steadily in the years thereafter.

Switzerland

A good example is how it started in Switzerland with the individual Lothar Burgerstein. In the 1980s, this businessman was ill. He learned about orthomolecular medicine in the US and decided to undergo this kind of therapy. He recovered and was so enthusiastic that he decided to start studying orthomolecular medicine. After a few years he even wrote a book in the German language, entitled 'Orthomolekulare Medizin', which was used not only by lay persons, but also by professional practitioners. Actually, it was Burgerstein who made known orthomolecular medicine in the German speaking countries, also in Germany itself. In his own country, he got permission to produce, distribute and sell high dose food supplements, according to Swiss food laws, not drug laws. He became successful in this, but his activities were restricted to his own country.

Changing Times

In the European countries, the last decades a similar pattern as in Switzerland was observed. It started with a few individuals and grew little by little. The initiators were mainly inspired by orthomolecular medicine and were closely operating with orthomolecular practitioners. They made the public aware of the power of nutritional medicine. A lot of support came from journalists who wrote about this subject for magazines, mainly directed towards women. For many years, the availability of food supplements was dependent on small firms, almost exclusively in the UK and the Netherlands. In the other countries, efforts were also made, but sales were limited by national laws, restricted to low doses of vitamins and minerals. Trade across the borders was done, especially from the Netherlands.

This 'movement' started in the 1970s and was the birthplace of the food supplement business of today. It has resulted, in the Netherlands (with 16 million citizens), in food supplement sales of $375 million (1997), $425 million (1998), $1.875 million (2001). About 25% of the Dutch population is using food supplements now.

Nowadays, the biggest company in food supplements worldwide is Royal Numico, a Dutch-based multinational. Decades ago, it started as a local dairy company. Thereafter, it specialized in baby nutrition and nutritional products in hospitals (enteral and parenteral nutrition). The last decade, it not only bought small food supplement firms in

Europe, but also the American companies GNC and Rexall Sundown. This way, Numico became the biggest food supplement supplier in the world. The Swiss-based pharmaceutical concern Hoffmann la Roche may be considered as one of the very first firms to go into nutritional substances as producer of raw materials like vitamin C. Other companies which became active in this field the last years are traditionally chemical concerns, like BASF (German) and DSM (Dutch).

This change, from small firms to a large scale business, ended up, inevitably, in a European legislation on March 13 this year.

The New EU Directive

Without going into detail with regard to the realization of this directive, it may be said that it took a lot of lobbying from the pro food supplement organizations to get this directive shaped as it is now. It is far from perfect, but, considering all economical and political counter forces, it was most probably the most attainable outcome.

The starting point was that it tended to become a directive based on the 'RDA principle' as now is the situation in Germany and most other countries. Fortunately, in 2001, the principle of safety was proposed by the European Commission as basis for the directive.

The second crucial point was the option between a 'positive list' or a 'negative list' of vitamins and minerals and their combinations. A 'negative list' would have been preferred, since this implicates that all vitamins and minerals and their compounds are allowed. A particular substance is banned from this negative list, when it has toxicity or unwanted side effects. However, also under pressure of current scandals concerning food safety (mad cow disease, dioxin in chickens, mouth and claw disease), finally the EU Parliament decided to choose for a 'positive list': only vitamins, minerals and their combinations which have been proven safe, are permitted. This means two things:

1. The safety of a substance must be judged.

2. The upper safe limits has to be established for all substances.

These two conditions makes this legislation very alarming, since the Scientific Committee on Food (SCF) is in charge to execute these two points. It is hoped that a amendment of the European Parliament on the directive, that urges the Committee to be reasonable in their decisions, will have effect.

Implications of the Directive

The implication of this new EU-legislation is that the free availability of vitamins, minerals and their combinations in the United Kingdom and in the Netherlands will become more restricted, when this EU-directive comes into force (within about three years). On the other hand, in other countries, including Germany and France, vitamins, minerals and their combinations, when on the positive list, become available now at higher dosages. Whereas in these countries, vitamin C nowadays is permitted to be freely sold at a maximum of approximately 200 mg, this will become 1000 mg.

Positive List

List 1 (p. 174) shows which substances are on the positive list now. We see that some substances, such as Vanadium, are essential for orthomolecular practice, but missing. This mineral is also missing on the list of substances, which manufacturers plan to submit to the SCF for approval. This list became public at the time the directive passed the European Parliament (List 2, p. 175). It depends on the SCF, in how far this Committee judges that enough safety data are available to put a substance on the positive list. Recently, the European Commission has asked the SCF to review the upper levels of daily intakes of vitamins and minerals and also to provide the basis for the establishment of safety factors.[2] We have to wait which yardsticks the SCF will use.

Manufacturers

Another negative point with regard to this positive list is that manufacturers only will submit substances which will be profitable. This implicates that it is very difficult for 'orphan nutrients' to come on the European market. Another disadvantage of this positive list is that it inhibits innovative activities.

For example, a substance such as NADH is not on the list. In the liberal countries, the United Kingdom and the Netherlands, this substance is freely available now. When the directive goes into operation, this substance will be taken off the market, unless the manufacturer and/or the distributor considers this substance economically interesting enough to submit a safety dossier to the SCF. However, this will cost a lot of money, which has to be earned back by the supplier. Of course, in the end the SCF has to decide to put NADH on the positive list. Thus the position of NADH is doubtful. Concerning vitamin B_3, although already on the positive list as nicotinic acid or nicotinamide, still the upper safe levels have to be established. Thus, uncertainty remains for this vitamin remains.

Blueprint

Another problem arises. The here mentioned legislation is limited to vitamins and minerals. For other substances, like coenzyme Q10, alpha-lipoic acid, L-carnitine, etc, no regulation has been made yet. This just passed legislation on vitamins and minerals, however, will serve as a blue print for these less researched substances. This also applies to herbs, which have less of a safety profile than vitamins and minerals have. So admission of these substances will even be more problematic and doubtful.

Conclusion

The first orthomolecular practitioners and the small scale food supplement businesses paved the way, decades ago, for the general public and for the big companies to go into the food supplement market. This change was actually wanted by these pioneers–expanding the awareness and the scale of orthomolecular medicine. This development is inevitable. Certainly, there are advantages–money for research, modernization of legislation, better quality control, protection of the consumer–but without doubt there are disadvantages–dependence on big business and regulatory governmental institutions, less flexibility and slower innovation. In Europe, this means that there are new players: the big companies and the SCF, to which the European Parliament has delegated its responsibility concerning the availability of food supplements. The only thing the consumer/patient is able to do is to watch and to stay alert. Very alert!

References

1. http://europa.eu.int/abc-en.htm
2. http://europa.eu.int/comm/food/fs/sc/scf/out80_en.html

List 1. Vitamins and Minerals on the Positive List (General)

Vitamin A
Vitamin C
Vitamin D
Vitamin E
Vitamin K
Vitamin B_1
Vitamin B_2
Vitamin B_3
Vitamin B_5
Vitamin B_6
Folic acid
Vitamin B_{12}
Biotin
Calcium
Magnesium
Iron
Copper
Iodine
Zinc
Manganese
Sodium
Potassium

Selenium
Chromium
Molybdenum
Fluoride
Chloride
Phosphorus

List 2. List of Substances Planned to be Submitted to the SCF
Boron chelate - Numico
Calcium-aminoacid-chelate - Orthica (will stimulate suppliers)
Calcium aspartate - Bio-Life (will stimulate suppliers)
Calcium orotate - Bio-Life (will stimulate suppliers)
Cholecalciferol-Cholesterin GlaxoSmithKline
Chromium nitrate - Roche
Chromium orotate - Bio-Life (will stimulate suppliers)
Chromium yeast - Numico
Chromiumpicolinate - Orthica (will stimulate suppliers)
Chromium polynictinate - Interhealth
Copper orotate - Bio-Life (will stimulate suppliers)
Copper oxide - Roche
Iron oxide - Roche
Iron pidolate - Roche
Manganese orotate - Bio-Life (will stimulate suppliers)
Magnesium ascorbate - Roche
Magnesium orotate - Bio-Life (will stimulate suppliers)
Magnesium trisilicate - Roche
Magnesium-amino-acid-chelate - Orthica (will stimulate suppliers)
Potassium aspartate - Roche
Selenium yeast - Numico
Selenomethionine - Orthica (will stimulate suppliers)
Silicon dioxide - Numico/BAH
Potassium molybdate - Numico/Roche/GlaxoSmithKline
Thiamine monophosphate - Roche
Tocopherols (other than alpha) - Numico
Zinc glycerophosphate - Roche
Zinc-amino-acid-chelate - Orthica (will stimulate suppliers)
Zinc orotate - Bio-Life (will stimulate suppliers)
Zinc picolinate - Numico

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