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increasing problem of modern society shall be stopped from spreading. Nowadays 16.1% of the Spanish children aged 6-12 are obese and more than 1 out of 4 Spaniards aged 2-24 are overweight. The probability that a ten-year-old child suffers from obesity is only in Italy, Malta and Greece higher than in Spain among all European countries.

The PAOS Code is in line with the agreements made by the Spanish Ministry of Health and Consumer Affairs and the Federation of Food and Drink Industries (FIAB) that want to improve healthy diets and to promote regular physical exercise in order to avoid chronic diseases in society.

Given that children are extraordinarily vulnerable to the influence of advertisements due to their credulity and weak capacity of criticism, the PAOS Code must provide extra caution in advertisements from companies directed at this group of people.

Besides other regulations, the PAOS Code limits the use of famous or known characters in advertisements directed at minors, as well as to make advertisements in children's programmes. The presentation of the product must not take advantage of the children's trust in famous characters.

The PAOS Code especially wants to avoid children being under excessive commercial pressure. Therefore, the advertising must not make a direct appeal to minors to purchase, nor should it award the purchase, nor should it encourage them to persuade their parents or other people to purchase the advertised product. Neither should these advertisements suggest that the parents who purchase the product are better, more intelligent and more generous parents than those who do not do so. Neither should it imply that the acquisition of the product will make the child more acceptable among his/her friends.

In addition, conditions and requirements for advertising activities, draws and competitions will be determined, so that their contents are easily understandable to minors and minors are not misled.

The PAOS Code also foresees that the advertising should not promote unhealthy eating habits or lifestyles as well as unbalanced diet or a sedentary lifestyle. No product may be shown as a substitute for any of the three main meals.

The PAOS Code, whose compliance is controlled by Autocontrol (Association for the Self-regulation of Commercial Communication) has control procedures that operate even before the advertisement

is published. The PAOS Code also establishes fines that vary from € 6.000 for minor infringements to € 180.000 for serious infringements. In case of repetition of serious infringements the FIAB has the right to expel the company from the PAOS Code. This expulsion shall be made public. The readmission of the company to the PAOS Code shall only be reconsidered after the course of at least one year and once the company complies with all its obligations.

The PAOS Code came into force on 15 September 2005 and will be regularly reviewed in order to be adapted to any changes.

A Monitoring Commission was created for the compliance of the PAOS Code, which is made up of a representative from the Spanish Agency of Food Safety (AESAs) – who will chair the Commission –, three representatives from FIAB and a representative from the Spanish Advertisers' Association (AEA). This Commission will supervise the compliance, modification and updating of the PAOS Code, to which the individual consumer may address claims. *Mónica Weimann-Gómez*

## Sweden

### The LitoZin Case

#### *The medicinal product definition before the Administrative Courts of Sweden*

It is exceptionally rare for issues of medicinal product classification to reach the Swedish courts. Normally, such cases go no further than to a preliminary warning from the Medical Products Agency (MPA); such warnings are normally complied with. We therefore find it worthwhile to report on the case of the health product "LitoZin", notwithstanding the fact that judicial decision is still pending.

LitoZin is based on a powder derived from a special variety of rose-hip, the active ingredient being a substance called GOPO. It is sold in tablet and powder form as a food supplement. In a decision on 30 January 2004 the Swedish Medical Products Agency classified LitoZin as a medicinal product, prohibited further sales and ordered the seller, Örtmedicinska Institutet AB, to recall products that were already on the market.<sup>1</sup> The seller

appealed the decision, contesting that LitoZin should be classified as a medicinal product.

The substance of the case is currently awaiting decision by the County Administrative Court of Uppsala.<sup>2</sup> According to the Swedish Medical Products Act, the MPA's decisions are normally effective immediately. However, the Administrative Court of Appeal in Stockholm<sup>3</sup> has granted the seller's application for a stay of the MPA's decision pending judgment.

### The MPA's decision

In connection with the launch of LitoZin, the following statements have been included in the product information provided by Örtmedicinska Institutet AB to health product retailers:

- LitoZin was discovered by coincidence when the discoverer's aching joints were relieved following consumption of a special kind of rose-hip powder.
- The Danish national association of rheumatics are involved in the development of the product.
- LitoZin has undergone five different clinical trials.

Press advertisements for LitoZin have featured the question "How are your joints?" The LitoZin package displays dosage instructions. Furthermore, in the promotion of LitoZin frequent reference has been made to a number of published scientific studies regarding the effects of rose-hip on arthritis and aching joints.

Taking into consideration the design and impact of the marketing and presentation of LitoZin, it must be concluded that an averagely well-informed consumer must perceive LitoZin as a medicinal product.

The fact that Örtmedicinska Institutet has now offered to cease marketing efforts for LitoZin cannot alter the classification of the product as medicinal.

### The parties' further arguments

Örtmedicinska Institutet contested that an averagely well-informed consumer would perceive LitoZin as a medicinal product and argued that no facts had been presented in support of this conclusion. The company submitted that the decision had no basis in Community Law, since the European Court of Justice Case Law did not indicate that the classification should be based in a "fictitious assessment of how an averagely well-informed consumer perceives a product." In any event, the company considered that its marketing in relation to consumers did not warrant medicinal product classification. According to the company, the packages were not of a "medicinal product type", nor did they contain dosage instructions. The company further argued that arthritis was a condition caused by the natural ageing process and therefore could not automatically be considered a disease. Moreover, the MPA's decision violated the constitutional right of equal treatment, as similar products on the market had not been subject to prohibition.

In the subsequent correspondence before the courts, the MPA replied to the appeal and expanded its reasoning on certain points. Thus, the MPA stated that its classification of LitoZin was based on the first criterion of the EU medicinal product definition, i.e. "Any substance or combination of substances presented for treating or preventing disease in human beings." With reference to the European Court of Justice' ruling in the Upjohn Case, C-112/89, the MPA pointed out that the purpose of this criterion is to protect consumers against using ineffective products instead of relevant, controlled medicinal products. From this the MPA concluded that the intention with a product was decisive for the classification issue. According to the MPA, the European Court of Justice' ruling in the van Bennekom Case, C-227/82, clearly indicated that there was no need to bring evidence regarding consumer perception. Instead, the competent authority was to put itself in the position of an averagely well-informed consumer and make a "fictitious assessment" of how the consumer would perceive the product. By necessity, the MPA stated, such an assessment must involve a certain degree of discretion for the competent authority. The MPA considered that it would be absurd if it were to be required to conduct market surveys in order to establish consumer perception. Quoting the Delattre

1 Decision of the Medical Products Agency on 30 January 2004, Dnr. 382:2003/57322. The company subsequently changed its name to GreenMedicine AB.

2 Länsrätten i Uppsala län Case 421-04 (pending).

3 Kammarrätten i Stockholm (Administrative Court of Appeal in Stockholm), decision on 11 May 2004 in Case 2301-04 (reported as RK 2301/04).

Case, C-368/88, the MPA further stated that Community Law on medicinal products had not progressed to the point where Member States were required to reach the same conclusions regarding the classification of medicinal products.

The MPA went on to note that the packages of LitoZin displayed statements to the effect that:

- the product has been clinically tested;
- the product is patented;
- the manufacturing method is patented; and that
- a high level content of the active substance is guaranteed.

Furthermore, the MPA noted that, in the information distributed to health product retailers, the launch of LitoZin was described as an opportunity for the health product industry to get “revenge” for the recent loss of one of its biggest selling products. According to the MPA, it would be obvious to professionals in the health product business that this was a reference to another product intended for use against arthritis: glucosamine, which had recently been classified as a medicinal product by the MPA. Retailers were also informed that LitoZin had undergone several clinical studies, five of which were double-blinds, and that the participants in one of those tests were said to have experienced significant improvement. Moreover, because of these promising results, the Danish national association of rheumatics had decided to co-fund further studies.

Taking account of these statements the MPA considered that it was obvious that LitoZin was intended as a medicinal product. This conclusion could not be altered by the fact that the product was claimed only to contain powdered rose-hip, since the mentioned marketing statements meant that the possible use of the product as a food stuff became altogether secondary. In the latter respect, the MPA also pointed out that Örtmedicinska Institutet had made marketing statements to the effect that consumption of rose-hip soup or rose-hip flour would not have the same beneficial effects as the intake of LitoZin.

### Stay of enforcement

According to the Swedish act on administrative court procedure (*förvaltningsprocesslag*, 1971:291, according to Swedish legal nomenclature), the courts may under certain conditions stay the enforcement of an appealed administrative decision. For a stay to be granted there must be a high degree

of probability that the appeal will succeed. However, this standard may be lowered where there is manifest risk that enforcement of the decision would cause considerable economic damage to an individual interest. Consequently, the court has to make a preliminary assessment of the merits of the appeal. Furthermore, the court must weigh the public interest involved against the individual interest that is likely to suffer if the decision is enforced.

Örtmedicinska Institutet submitted that immediate enforcement of the prohibition would result in considerable economic loss for the company. The company argued that the MPA's decision was not supported by public health concerns and submitted expert opinions from two Danish medical scholars to the effect that LitoZin should be regarded as a food supplement and that Member States may reach different conclusions on whether a product should be classified as medicinal. It was not hazardous to human health.<sup>4</sup>

The MPA, argued that, since LitoZin was sold as a medicine but had not been subjected to requisite testing procedures for medicinal products, public health concerns weighed heavily against granting a stay of enforcement.

The Administrative Court of Appeal granted a stay of enforcement on the following reasons.

If the appeal proves successful, irreparable damage might result from the immediate enforcement of the decision. On the other hand, the MPA has invoked the interest of public health protection in support of immediate enforcement. At present the possibility that the appeal will be successful cannot be disregarded. The outcome of the case appears to be uncertain. On a balance of the potential damage of enforcing the decision and the countervailing interest of protecting public health, it has not been established that the latter interest outweighs the risk for economic damage that might result from enforcing the decision.

### Concluding remarks

The case contains a number of interesting classification issues. For example, the MPA's classification seems to be based its classification mainly on marketing statements that were directed to health prod-

<sup>4</sup> In Denmark LitoZin is classified as a food supplement.

uct retailers. Do such statements have the same relevance for the classification issue as marketing addressed to the consumer market? And do troubled joints in all cases qualify as a “disease” in the sense required by the medicinal product definition?

In view of the scarcity of Swedish Case Law on medicinal product classification it is hoped that the LitoZin Case will shed some much needed light on these and other issues involved. We will therefore return to the case when judgment is delivered.

*Jürgen Conzen and Petter Holm*

## The United Kingdom

### The Approach to Maximum Levels of Micronutrients

The Food Supplements Directive 2002/46/EC was adopted in June 2002 and came into effect on 12 July 2005.

Art. 5 of the directive is probably the main article with respect to the removal of barriers to trade in food supplements. This article requires that individual maximum levels are set for the permitted vitamins and minerals. These maximum levels were to be derived from scientifically assessed safe levels taking a number of factors into consideration.

To achieve the objective of maximum levels, the European Commission tasked the Scientific Committee on Foods (SCF) and their successor the European Food Safety Authority (EFSA), to undertake safety evaluations of over 30 micronutrients. The opinions on the safe upper levels for each micronutrient were published over a five year period from the end of 2000 to the end of 2005. The length of time taken to obtain all the opinions has meant that the European Commission has been unable to complete the requirements of Art. 5.

In the vacuum created by the absence of maximum levels, member states of the EU have introduced their own national controls, with a number retaining their original controls based on multiples of the Recommended Daily Allowance (RDA).

The United Kingdom (UK) has been an exponent of the principle of control of micronutrients by individually assessed maximum levels since the discussions on the directive commenced in the early 1990s. Following a dispute with the supplement

industry in 1997 over the safety of vitamin B<sub>6</sub>, the UK government instigated an Expert Group to consider the safety of all vitamins and minerals used in food supplements. The Expert Group on Vitamins and Minerals (EVM) reported in May 2003 with opinions on upper safe levels for over 30 micronutrients. In a number of cases the opinions of the EVM did not concur with those of the SCF/EFSA.

In their final report the EVM expressed concerns about the safety of high levels of intake of eleven micronutrients (4 vitamins and 7 minerals). Following discussions with the UK food supplement industry, the Food Standards Agency introduced a requirement in May 2004 for either Advisory Statements on the product labels or reformulation if the daily recommended amount of any of the eleven micronutrients exceeded a specified level, such as 1000 mg/day for vitamin C and 25 mg/day for zinc. In addition, reformulation was encouraged in the case of products containing more than 7 mg beta carotene per day and the label statement “should not be taken by heavy smokers” should appear on the labels of all products containing beta carotene.

The requirement for advisory statements was not passed into law and was considered by the Food Standards Agency to be voluntary. By the end of 2005 very few products with levels of micronutrients over specified levels carried the advisory statements on their labels.

In September 2005 the Food Standards Agency proposed to their governing Board that the concept of Advisory Statements be adopted as the UK’s position during negotiations with the European Commission and other member states on the maximum levels as required by Art. 5 of the directive.

In addition, the Board was asked to also approve an official position that there should be a two tier approach whereby the maximum levels decided by the European Commission would be used for products traded across the EU (the first tier) whilst a second tier would allow national governments the option of setting higher levels where there was evidence that dietary intakes at a national level were lower than the figures used to set the first tier, or that there was a national expert opinion that supported a higher level of safe supplemental intake.

These positions were officially adopted by the Board, but as the European Commission has not yet commenced formal discussions on maximum levels, the reaction to these proposals by other member states is not known.

*Peter Berry Ottaway*