

Spanish Federation of Food and Beverages Industries, FIAB (Federación de Industrias de la Alimentación y la Bebida), in order to establish such lists. Little more can be said. We hope that, in the coming months, more light will be shed on these aspects, which are of vital importance to all participants in the food manufacturing sector.

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The LitoZin Case Revisited

In this case, a consumer “health product” presented as having “a certain effect” on “joint troubles” has been held to fall outside the definition of a medicinal product.

I. Background

In issue 1/2006 of EFFL we reported on a decision by the Swedish Medical Products Agency¹ (“MPA”) to classify a “health product” called LitoZin as a medicinal product.² The decision has been on appeal to the County Administrative Court, which delivered its judgment late last year.³

II. The point at issue

The MPA based its case exclusively on the presentation of the product and on certain statements that had allegedly been made in connection with the marketing of LitoZin. The MPA did not claim that LitoZin had actual medicinal properties or effects. Consequently, the case concerned the application of the provision in the Swedish Medicinal Products Act intended to implement the definition of a medicinal product contained in Article 1.2 (a) of Directive 2001/83/EC (consolidated version):

“Any substance or combination of substances presented as having properties for treating or preventing disease in human beings”.

The case came to centre mainly on the following circumstances, which, according to the MPA, would lead an averagely well-informed consumer to perceive LitoZin as a medicinal product. Firstly, certain information had been provided in an information packet distributed to health products

retailers for the promotion of LitoZin. The promotion material stated that LitoZin had been “discovered” by chance when the discoverer’s pains and stiffness in the shoulders and other joints were suddenly alleviated following his consumption of a powder from a particular species of rosehip. Furthermore, it was stated in the packet that the Danish national association of rheumatics had been involved in the development of the product. The names and pictures of several physicians who had been involved in developing LitoZin were also included. Reference was also made to a number of scientific studies and clinical trials. Secondly, there were dosage instructions displayed on the packaging. Thirdly, press advertisements for LitoZin had been headlined with the question (in rough translation) “How are your joints?”/“What is the state of your joints?”

III. Findings of the Court

With respect to the promotion packet distributed to retailers, the court first stated that the information contained therein was relevant to the assessment of consumer perception even though it had not been communicated directly to consumers.

The court found that the story of the “discovery” of LitoZin unquestionably amounted to a claim that the product had “a certain effect on the joints”. The references to scientific studies and clinical trials which LitoZin had undergone, and to the physicians involved in its development, served to further reinforce that message, when seen in the context of the “discovery” story.

The court then went on to examine whether the claim to “a certain effect on the joints” meant that LitoZin had been presented as being capable of treating or preventing “disease”. The court noted that Directive 2001/83 contains no definition of the term “disease”, and that the ECJ in the Delattre case, C-368/88, had established that the meaning of that term must be sought in its generally accepted use, in the light of scientific knowledge.

The company had not disputed that it had presented LitoZin as having an effect on “joint trou-

¹ In Swedish: Läkemedelsverket.

² EFFL 2006:1 p. 62-64.

³ Judgment by the County Administrative Court of Uppsala län on 20 November 2006, in case 421-04.

bles". The issue therefore became whether this claimed effect of LitoZin amounted to a claim to an effect on arthrosis, arthritis or any other disease of the joints, as the MPA had argued. The court found that the concept of "joint troubles" has a wide lexical meaning, encompassing all types of troubles from the joints, such as ordinary stiffness and discomfort, as well as symptoms caused by diseases. Consequently, the court found that the expression "joint troubles" could not be considered synonymous with disease. Thus, the court did not accept the MPA's argument.

The court further noted that the company had not explicitly mentioned diseases of the joints in any context in connection with LitoZin. The advertising headline "How are your joints" / "What is the state of your joints" was considered too vague to be seen as a reference to anything other than joint troubles in a general sense. The court noted that there had been certain information appearing on the Internet, which had indicated that LitoZin was a cure for arthrosis and arthritis. However, the court, referring to the ECJ's ruling in the Ter Voort case, C-219/91, found that that information could not be attributed to the company, and therefore was irrelevant to the assessment.

In conclusion, the court held that the evidence did not prove that LitoZin had been presented as having properties for treating or preventing

arthrosis or arthritis or any other disease. Consequently, the company's appeal was granted.

IV. Comments

The judgment of the County Administrative Court in the LitoZin case seems to be irreconcilable with a recent judgment of the Stockholm Administrative Appeal Court in a similar case, which we have previously reported in EFFL.⁴ The Appellate Court there upheld the MPA's decision to classify a glucose amine product, called Artro Samin, as a medicinal product, applying the same provision of the Swedish Medicinal Products Act as in the LitoZin case. The Artro Samin judgment was based on the assessment that the product's active ingredient, glucose amine, was well known among averagely well-informed consumers as a cure for "joint troubles". Thus, the Appeal Court, unlike the County Administrative Court in the LitoZin case, considered "joint troubles" to be a "disease", in the sense required by the medicinal product definition.

The MPA has appealed the LitoZin judgment, arguing, inter alia, that it departs from the Artro Samin case. It remains to be seen whether the Stockholm Administrative Court of Appeal will stick with its previous opinion that "joint troubles" constitutes a disease in the sense of Article 1.2 (a) of Directive 2001/83/EC. In our opinion, the Appellate court should request a preliminary ruling from the ECJ on that issue. The case presently awaits decision on leave to appeal, which no doubt should be granted.

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⁴ Judgment of the Administrative Court of Appeal in Stockholm on 30 March 2006, reported as RK 7233/02. EFFL 2006, p. 184-186.