

# Medicinal products by presentation

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**Facts**

**Decisions**

**Comment**

The Supreme Court recently ruled on the line between dietetic foods and medicinal products by presentation.

## **Facts**

The claimant produced and distributed medicinal products, including over-the-counter products to fight migraines. The defendant produced and distributed through pharmacies effervescent granules under the name OMNi-BiOTiC MIGRAene (*'migraene'* being an unusual spelling of the German word for migraine), which had no marketing authorisation as a medicinal product. The defendant advertised its product in journals and newspapers with claims such as "simply smile again – despite migraine", "OMNi-BiOTiC MIGRAene has shown that it naturally reduces intensity and duration of migraine attacks and sustainably reduces the quantity of painkillers" and "OMNi-BiOTiC MIGRAene reduces intensity and frequency of migraine naturally from the belly – without adverse effects". Further, its ads referenced studies showing that the product reduced the intensity and duration of migraine attacks. In addition to the product name, the packaging stated that the granules were a "dietetic food for special medical purposes (balanced diet)" and "for dietetic treatment of migraine, heavy headache (to reduce intensity and frequency) and mental displeasure".

The claimant sued the defendant to cease and desist from:

- distributing OMNi-BiOTiC MIGRAene as a medicinal product without marketing authorisation; and
- providing misleading claims such as those mentioned above.

The defendant argued that the product was a dietetic food for special medical purposes and fulfilled all legal requirements for this qualification. The fact that a dietetic food for special medical purposes may provide effects that fall under the definition of 'medicinal products' does not automatically qualify it as a medicinal product. Further, the labelling must contain the indication "for dietetic treatment of " a disease, dysfunction or complaint.

## **Decisions**

### ***Lower-instance decisions***

The lower-instance courts<sup>(1)</sup> found that the claims "simply smile again – despite migraine", "reduces intensity and frequency of migraine", "for treatment of migraine and heavy headache" and "OMNi-BiOTiC MIGRAene has shown that it naturally reduces intensity and duration of migraine attacks and sustainably reduces the quantity of painkillers" were misleading. The courts ordered the defendant to cease and desist the distribution of the product without marketing authorisation, but dismissed the further claim to cease and desist the marketing of the product under the name OMNi-BiOTiC MIGRAene. The courts held that the product's name alone did not imply a medicinal property. The fact that the product's name contained a disease did not mean that it treated, cured or prevented said disease.

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## **Supreme Court decision**

Both parties appealed to the Supreme Court.<sup>(2)</sup> The Supreme Court dismissed the defendant's appeal, but granted the claimant's appeal.

According to Section 1(1) of the Act on Medicinal Products, implementing Article 1(2) of the Community Codex,<sup>(3)</sup> any substance or combination of substances which may be administered to humans in order to make a medical diagnosis, restore, correct or modify physiological functions, or treat or prevent diseases is considered a medicinal product. Therefore, there are two groups of medicinal product:

- those that are considered medicinal products because of their real function; and
- those that do not have such function, but are presented in such a way as to pretend that they have such function (ie, medicinal product by presentation).

To qualify as a medicinal product, the subjective purpose behind the product is sufficient. It is the public's understanding of the advertising – and not the advertiser's intention – that is decisive.<sup>(4)</sup> Further, medicinal products by presentation are subject to the Act on Medicinal Products – in particular, they cannot be distributed without marketing authorisation according to Section 7(1) of the act.

The Supreme Court previously held that a product cannot qualify both as a food (for specific medical purposes) and as a medicinal product by presentation.<sup>(5)</sup> If a product is marketed as a medicinal product, only the Act on Medicinal Products applies.<sup>(6)</sup> Further, EU Regulation 609/2013<sup>(7)</sup> does not provide otherwise: Article 9(5) of the regulation expressly provides that labelling, presenting and advertising foods according to Article 1(1) must not attribute to such foods the properties of preventing, treating or curing a human disease, or imply such properties.

The claimant correctly argued that the product name OMNi-BiOTiC MIGRAene indicated a pharmaceutical effect, because it suggested that the product could cure or treat the disease clearly indicated in its name. The impression that the product had a curative effect was also created through its sale as effervescent granules and distribution through pharmacies.

Moreover, the qualification by the lower-instance courts contradicted the Supreme Court's early jurisprudence that a product name – in connection with the product's presentation and all other circumstances – may indicate a pharmaceutical effect if a disease is prominently emphasised.<sup>(8)</sup> This view is shared in Austrian literature.<sup>(9)</sup> The average consumer understood that OMNi-BiOTiC MIGRAene – independent from the spelling in capital and lower letters – was a product that could prevent migraines or headaches, due to its presentation as effervescent granules and distribution through pharmacies. This understanding was supported by the product's design, which also indicated that the product could cure or treat headaches. Therefore, the defendant was also ordered to cease and desist the use of the product name OMNi-BiOTiC MIGRAene.

## **Comment**

The Supreme Courts held its ground and maintains strict control over health and disease-related claims for foods. Further, this decision keeps a close watch on the thin line between dietetic foods and medicinal products.

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## **Endnotes**

(1) *LG für ZRS Graz*, February 12 2016 (39 Cg 130/15i), OLG Graz April 7 2016 (5 R 40/16 s).

(2) *Oberster Gerichtshof*, October 25 2016 (4 Ob 117/16h).

(3) Directive 2001/83/EC of the European Parliament and the Council of November 6 2001 on the Community Code relating to medicinal products for human use.

(4) European Court of Justice, November 15 2007 (C-319/05; ECLI: EU: C: 2007: 678).

(5) *Oberster Gerichtshof*, May 19 2015 (4 Ob 76/15b).

(6) *Oberster Gerichtshof*, May 19 2015 (4 Ob 76/15b).

(7) EU Regulation 609/2013 of the European Parliament and of the Council of June 12 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control.

(8) *Oberster Gerichtshof*, February 18 1986 (4 Ob 301/86).

(9) Ciresa, *Arzneimittelwerberecht* margin number 67; Rauer, *Kosmetikwerbung und der schmale Grat hin zum Präsentationsarzneimittel*, PharmR 2014, page 509.

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