

Healthcare & Life Sciences - Austria

Pneumococci vaccination campaign

Contributed by [Preslmayr Attorneys at Law](#)

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Introduction

In compliance with Title VIII of Directive 2001/83/EC – which relates to the advertising of medicinal products for human use⁽¹⁾ – the Medicinal Products Act⁽²⁾ provides a set of restrictions in this regard.

According to Section 50(1) of the act, the advertising of medicinal products includes all activities that seek to canvass the market, obtain information or market research or generate a need, with the aim of increasing prescriptions, administration, sales or consumption of medicinal products.

In particular, this includes advertising medicinal products to both the public and persons qualified to prescribe or supply them. Statements relating to human health or diseases do not qualify as medicinal advertisements, provided that they make no reference (even an indirect reference) to medicinal products. Moreover, Section 51(1) prohibits advertising medicinal products to the public that:

- are available by medical prescription only;
- are not subject to prescription, but have the same name as a medicinal product that is subject to prescription; and
- are registered homeopathic medicinal products.

However, according to Section 51(2), these restrictions do not apply to vaccination campaigns carried out or supported by an Austrian territorial authority.

Facts

The first defendant, *Österreichischer Verband der Impfstoffhersteller* (ÖVIH) – an association of vaccine producers – together with two companies producing vaccines, organised an advertising campaign regarding pneumococci aimed at the general public. ÖVIH placed ads in print media and on television. The print ads referred to the "friendly support" given by the two vaccine producers and the television spots contained similar content, using the headline: "For adults over 50, pneumococci are a concern." Alongside these ads, ÖVIH sent information packs to physicians and pharmacists with the headline: "Pneumococci are a concern for your patients over 50!"

At the same time, the second defendant (one of the two vaccine producers) advertised its vaccine Prevenar 13, which is subject to prescription, in a vaccination campaign in a professional journal for pharmacists and physicians. The ad ran from September 1 2012 to February 28 2013. In addition, the second defendant sent patient information to physicians, informing them that pneumococci are bacteria that may cause dangerous and lethal diseases. The information did not specify that it was intended only for persons qualified to prescribe or supply medicinal products, not for patients.

The names of the vaccines were not mentioned in the patient information that ÖVIH sent to physicians, but were mentioned in the second defendant's ad in the medical journal.

In Austria, only two pneumococci vaccines have marketing authorisation. The 2013 Ministry of Health vaccination scheme recommended vaccination against pneumococci for adults aged 50 and older. According to the health authorities, only 255 cases of invasive pneumococci diseases occurred in 2012, 21 of which were fatal.

The claimant, *Verein für Konsumenteninformation* – an association for the protection of consumers – sued the defendants, demanding that the ads be stopped. In its opinion, the ads created the impression that pneumococci are constantly circulating among the population and the risk of a pneumococci infection increases at the age of 50. The claimant alleged that the campaign was

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financed by the second defendant, which advertised its vaccine in the medical journal. In a flyer distributed by the second defendant, patients were informed that pneumococci are bacteria that may cause dangerous and lethal diseases. Since the vaccine must be prescribed, it cannot be advertised to the public. Thus, the claimant argued that in the absence of support from a territorial authority, the exception in Section 51 did not apply. Further, the claimant alleged that the exception in Section 50(2) also did not apply, because the campaign provided no legitimate information regarding health or diseases and, at the very least, contained an indirect reference to a medicinal product.

Decisions

Court of first instance

The court of first instance⁽³⁾ dismissed the claim on the basis that the campaign did not establish a connection with an individual vaccine and therefore the exception in Section 50(2) applied. Further, the ad in the medical journal addressed qualified persons and the flyer sent to physicians did not mention the vaccine produced by the second defendant.

Court of appeal

The court of appeal granted the claim,⁽⁴⁾ holding that the reference to the danger of pneumococci diseases for individuals aged 50 and older without indicating the low statistical probability of an infection, in conjunction with the reference to the "friendly support" of the campaign by the second defendant, qualified as an indirect advertisement of the vaccine. Although the ad in the medical journal addressed qualified persons only, it could not be considered alone. The court held that the public information, which recommended that a physician or pharmacist be consulted, also had to be considered, as physicians and pharmacists were addressed in the medical journal.

Moreover, the Court of Appeal held that patients could research the name of the vaccine, either by asking a physician or pharmacist or by searching the Internet. Therefore, the court held that the campaign illegally advertised a medicinal product to the public.

Supreme Court

The Supreme Court overturned the court of appeal's ruling and reinstated the court of first-instance decision.⁽⁵⁾ According to the Supreme Court, in order to assess the effect that the ads had on the public, the ads addressed to the public had to be considered in conjunction with the patient information sent to physicians. In the court's view, there was no need to consider the second defendant's ad for its vaccine in the medical journal, as it was not addressed to patients.

The court held that an ad seeks to increase the sale of a particular medicinal product if it is clear to which medicinal product the ad refers,⁽⁶⁾ regardless of whether the name of the product is expressly mentioned. In this case the ads and the patient information sent to physicians mentioned neither a specific medicinal product nor the active ingredient or specific effect of the product. The reference to the second defendant as a supporter of the ads and the patient information may have led consumers to believe that the second defendant had an economic interest and thus may be the producer of a respective vaccine; but according to the court, this did not qualify as an ad for a specific medicinal product.

Section 50(2) excludes general statements relating to human health and diseases from the prohibition on advertising medicinal products to the public, provided that they make no reference (even an indirect reference) to medicinal products. The fact that a medicine must be prescribed ensures that a potential inducement to use a certain medication through objective information is not immediately turned into a purchase decision. The final decision regarding whether a medicinal product will be administered to a patient remains with the attending physician. That said, it is possible for a physician to prescribe a different medicine from that originally intended on the request of an informed patient, so such information may have a minor effect on sales. However, this possibility is not sufficient to ascribe an advertising intent to the producer of a medicinal product. Moreover, there is no risk to a patient's health if more than one pharmaceutical is considered a viable treatment option.

The court thus concluded that the potential advertising intent of the second defendant did not impair doctors' impartiality.⁽⁷⁾ The court further held that the information on the dangers of pneumococci for certain individuals was not an advertisement for a specific vaccine, even if the patient information clearly suggested that receiving a vaccination and consulting a physician were recommended. The information campaign did not induce patients to buy the defendant's vaccine. To rule otherwise would suggest that any objective information offered to the public about vaccinations and vaccination campaigns would constitute an illegal advertisement to the public.

Finally, the court held that the impression that a vaccination against pneumococci may reduce health risks was favourable and complied with the recommendations in the government's 2012 and 2013 vaccination plans.

Comment

Health information must always steer a middle course between addressing possible health problems and concerns and avoiding undue influence on individuals.

Advertising to the public includes not only ads, television spots and generally accessible websites, but also patient information, compliance brochures, press releases and other press information, provided that these materials directly or indirectly refer to a medicinal product. Such a reference can be assumed if an ad mentions either the medicinal product's name or its active ingredient. Without a

direct or indirect reference to a medicinal product, an ad is not considered a method for increasing sales, but rather a permitted statement relating to human health or diseases.

In this case, since none of the ads accessible to the public contained a direct or indirect reference to a particular medicinal product, the Supreme Court was right to dismiss the claim. Nothing in the Medicinal Products Act prohibits a pharmaceutical company from advertising a medicinal product to healthcare professionals in parallel with a permissible information campaign addressed to the public.

The exception on advertising vaccination campaigns to the public is limited to campaigns supported by an Austrian territorial authority, whereas Article 88(4) of the Community Code exempts vaccination campaigns by industry, provided that the competent authority approves them. The implementation of Article 88(4) by Section 51(2) of the Medicinal Products Act is thus not fully compliant with the Community Code.

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Endnotes

(1) Directive 2001/83/EC of the European Parliament and of the Council of November 6 2001 (OJ L 311, 28.11.2001, p. 67-128).

(2) BGBl 185/1983 as amended.

(3) Commercial Court Vienna, September 30 2013 (19 Cg 53/13k).

(4) Appellate Court Vienna, March 31 2014 (5 R 235/13).

(5) Supreme Court, October 21 2014 (4 Ob 96/14t).

(6) As already stated by the Supreme Court on June 12 2007 (4 Ob 81/07a) – Femara – ÖBl 2007/64, 287.

(7) As already ruled by the European Court of Justice on May 5 2011 (C-316/09 [32 ss, 36 ss]).

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