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Medicinal product advertising law and sweepstakes campaigns by mail-order pharmacies

Tie-in transactions with prescriptions?

The pharmaceutical market is booming. For quite some time now, this market has no longer been strictly controlled and devoid of competition. At the same time, the national legislator is—understandably enough—interested in preventing any kind of improper influence on consumers when it comes to their individual health. German ideas of what the concept of controlled trade in pharmaceuticals should entail are far less liberal than those of some of its European neighbours. It is therefore not surprising that cross-border trade in medicines is a particularly sensitive area of competition law. The European Court of Justice (ECJ), in its judgment dated 24 July 2021 (C-190/20) had to decide whether a mail-order pharmacy can be legally prohibited from offering a sweepstakes to recruit customers where entering the sweepstakes is contingent on filling a prescription for a prescription-only medicine.

The case

The decision was based on a German legal dispute. The North Rhine Chamber of Pharmacists (Apothekerkammer Nordrhein), which is tasked with monitoring pharmacists' compliance with their professional duties, took action against DocMorris, a mail-order pharmacy based in the Netherlands. This same mail-order pharmacy had already been a defendant in cases brought by various German associations in the past. According to the ECJ, the operation of a mail-order pharmacy is permissible in principle, even if this business model contradicts the traditional German approach to selling pharmaceuticals because it does not offer the possibility of an on-site personal consultation. In this specific case, however, the issue was not the operation of the mail-order pharmacy as such, but a sweepstakes that DocMorris advertised in March 2015. The main prize was to be an e-bike worth €2,500; other prizes offered were high-quality electronic toothbrushes. To enter the sweepstakes, a consumer needed to send in an order form for a prescription medicine and the corresponding prescription to DocMorris by post.

The North Rhine Chamber of Pharmacists held this to be a violation of the German Drug Advertising Act (Heilmittelwerbegesetz, HWG) and therefore considered the action to be an anti-competitive practice. The Chamber unsuccessfully applied to the Frankfurt/Main Regional Court (Landgericht) for an injunction to stop the defendant from advertising the sweepstakes. The Regional Court concluded that the HWG was not applicable at all in the specific case, as EU law took precedence. However, the Frankfurt/Main Higher Regional Court (Oberlandesgericht) upheld the action on appeal. In its appeal to the Federal Court of Justice (Bundesgerichtshof, BGH), DocMorris sought the reinstatement of the judgment of first instance. Like the Higher Re-

gional Court, the BGH assumed a violation of the general prohibition of advertising pursuant to Section 7(1)(1) of the HWG. The sweepstakes would entice pharmaceutical consumers to forego a personal consultation at the pharmacy, creating an "abstract danger" of improperly influencing patients. Nevertheless, the BGH was not completely convinced of the regulations of the HWG being compatible with EU Directive 2001/83 on the Community Code relating to for medicinal products for human use. In the event that a specific case falls within the scope of this Directive, the HWG may be non-applicable. Unlike the HWG, the Directive does not contain any specific provisions on advertising for pharmaceuticals in the form of a sweepstakes. The BGH therefore stayed the proceedings and referred the following question to the ECJ for a preliminary ruling:

"Is it consistent with the provisions of [...] Directive 2001/83 for a national provision (in this case, Section 7(1)(1) of the HWG) to be interpreted as prohibiting a mail-order pharmacy established in another member state from soliciting customers by advertising a prize draw where participation in the draw is linked to the submission of a prescription for a prescription-only medicinal product for human use [...]?"

The judgment

This question was essentially answered in the negative by the ECJ. The ECJ first clarified that Directive 2001/83 referred only to advertising for certain medicinal products, but not to advertising for online sales as such. The sweepstakes held by the mail-order pharmacy could, however, at most be regarded as an advertising measure for the entire product range of DocMorris, since the prize offered was not a specific different pharmaceutical but a completely different commodity. The offending campaign therefore did not fall within the scope of the Directive, so that the Directive would not preclude the application of the HWG in this specific case.

Inken Huschke

But the ECJ also examined, beyond the specific questions referred to it, the compatibility of the HWG provision with other EU law. However, in the end, the court was unable to establish a violation. The scope of application of Directive 2000/31 (the eCommerce Directive) was not affected, since the advertisement was not for an electronically provided service, but for sales by mail order. The ECJ thus concluded that the ban on holding sweepstakes to advertise the sale of pharmaceuticals by mail order was not in agreement with harmonized European law. Any such regulations would therefore fall within the legislative realm of the individual member states.

In doing so, however, they would—as always—have to ensure that the European fundamental freedoms are protected. Looking at the present case, the guarantee of free movement of goods in particular was relevant. However, according to the ECJ, no violation of this fundamental freedom was recognized in the case at hand, since the HWG regulation refers to advertising the sale of pharmaceuticals by mail order as such, independently of whether the pharmaceuticals originated in Germany or in some member state. In this respect, trade between member states would not be impeded. The ECJ thus concluded that Union law did not preclude the application of the HWG as a national provision.

Summary and outlook

The sweepstakes held by the mail-order pharmacy was therefore an advertising measure to be assessed in accordance with national law, in this case the HWG. No provisions of EU law were relevant in this context. Consequently, in its final ruling dated November 18th, 2021, the Federal Court of Justice concluded that advertising the sweepstakes constituted a violation of the prohibition of advertising gifts pursuant to Section 7(1)(1) of the HWG, in effect rejecting the appeal by the mail-order pharmacy. This judgment is likely to have gone some way towards countering any fears on the part of pharmacists' Chambers that the German pharmaceuticals market would increasingly be dominated by foreign mail-order pharmacies such as DocMorris. The result of the ECJ ruling is to strengthen on-site sales of pharmaceuticals by pharmacies at physical locations. The German legislator continues to have the power to protect this business model, at least in connection with the advertising of the entire range of pharmaceuticals sold. In this respect, mail-order pharmacies domiciled in other European countries must comply with the stricter German regulations.

Comparable advertising bans also exist for medical devices, so the ruling must be applied in this area as well.

Contact address

Inken Huschke
Scientific Assistant
Law Offices of Ratajczak & Partner mbH
Berlin · Duisburg · Essen
Freiburg i.Br. · Cologne · Meißen · Munich · Sindelfingen

Posener Straße 1
71065 Sindelfingen · Germany
Phone: +49 7031 9505-27
Fax: +49 7031 9505-99
huschke@rpmed.de