

Case Notes

The Case Notes section will identify and analyse important judgments of the European courts that shape the interpretation and application of pharmaceuticals law in the European Union.

On the Distribution of Free Samples of Medicinal Products to Pharmacists: The Judgment of the European Court of Justice in Case C-786/18

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I. The Facts

Novartis manufactures and markets the drug Voltaren Schmerzgel which contains the active substance *Diclofenac*. *ratiopharm* markets the drug Diclo-ratiopharm-Schmerzgel, that contains the same active substance *Diclofenac*, which is only available in pharmacies.

In 2013, free samples of Diclo-ratiopharm-Schmerzgel – originally intended for sale – were distributed to German pharmacists in a reduced format. The packaging contained wording to the effect of ‘for demonstration purposes’.

Novartis believed that this action constituted a violation of German law for the following reasons: (i) German law does not include pharmacists among the persons allowed to receive free samples of medicinal products; and (ii) the initiative resembled the gifting of promotional items, which is forbidden by German law. Consequently, *Novartis* filed a suit requesting that *ratiopharm* be ordered to cease distribution of free samples medicinal products to pharmacists. *Novartis’* suit was judged in its favour (and affirmed by the appeal court) due to pharmacists not being included among the persons permitted to receive free samples of medicinal products. An appeal was made to the *Bundesgerichtshof* (the German Federal Court of Justice).

The *Bundesgerichtshof* found that the dispute raised issues concerning the interpretation of European Law which were vital to its resolution and submitted the following questions to the European Court of Justice (ECJ), to wit: (i) should Article 96(1) of Directive 2001/83/EC¹ be interpreted as allowing, under certain circumstances, the distribution of samples of medicinal products by the pharmaceutical in-

dustry to pharmacists; and, should that be the case, (ii) should Article 96(2) of Directive 2001/83/EC be interpreted as contrary to any national laws that forbid the distribution of free samples of medicinal products to pharmacists.²

II. Judgment of the Court

The ECJ begins by observing that Directive 2001/83/EC has two main goals: ensuring (i) the safeguard of public health, and (ii) the free movement of goods in the internal market.

On the other hand, the ECJ recalls previous decisions in which it held that (i) Directive 2001/83/EC resulted in a complete harmonisation with respect to the advertising of medicinal products in the EU, enumerating the circumstances in which Member States are authorised to enact legislation that deviates from

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1 Directive 2001/83/EC, of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L31/67.

2 In Spanish legal literature – although under Directive 92/28/EEC – this question had already been discussed, and resulted in a different decision from the one the ECJ has now reached: “By stating the following in Recital 9: ‘whereas it should be possible within certain restrictive conditions to provide samples of medicinal products free of charge to persons qualified to prescribe or supply them so that they can familiarize themselves with new products and acquire experience in dealing with them’, the CEE might be originating confusion among the persons who receive them. Notwithstanding, Article 11 is clear in allowing that such a distribution to persons qualified to prescribe take place” Cf. Nera Iráculis Arregui, *La Publicidad de Los Medicamentos* (RDCD M.2/2008) 443-444 (author’s translation).