



Press and Information

Court of Justice of the European Union

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Judgment in Case C-786/18  
ratiopharm GmbH v Novartis Consumer Health GmbH

## **Pharmaceutical companies may not distribute to pharmacists free samples of medicinal products available only on prescription**

*Nevertheless, EU law does not prohibit the distribution to pharmacists of free samples of medicinal products for which a prescription is not required*

The pharmaceutical company Novartis manufactures the medicinal product Voltaren Schmerzgel, a pain reliever gel containing the active substance Diclofenac. It asks the German courts to prohibit the generic manufacturer ratiopharm from distributing, to pharmacists, free samples of the medicinal product Diclo-ratiopharm-Schmerzgel, which also contains Diclofenac.

Novartis claims that such distribution is contrary to German Law on medicinal products which lists doctors but not pharmacists among those to whom free samples of medicinal products may be distributed. That distribution therefore amounts to the granting of prohibited advertising gifts.

The Bundesgerichtshof (Federal Court of Justice, Germany) requests the Court of Justice to interpret the Community code relating to medicinal products for human use<sup>1</sup> ('the code') in that regard. It has doubts as to whether that code authorises pharmaceutical companies to distribute free samples of medicinal products to pharmacists.

By today's judgment, the Court holds that **the Community code relating to medicinal products for human use does not authorise pharmaceutical companies to distribute to pharmacists free samples of medicinal products available only on prescription.**

**Nevertheless, the code does not prohibit the distribution to pharmacists of free samples of medicinal products for which a prescription is not required.**

According to the Court, the code must be interpreted as meaning that only persons entitled to prescribe medicinal products subject to medical prescription, namely doctors, may receive free samples of such medicinal products, which thus excludes pharmacists. Such medicinal products may not be used without medical supervision in view of the danger that may arise from their use or the uncertainty regarding their effects.

Nevertheless, the code does not deprive pharmacists of the possibility, under national law, of receiving free samples of medicinal products for which a prescription is not required so that they can familiarise themselves with new medicinal products and acquire experience with their use.

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**NOTE:** A reference for a preliminary ruling allows the courts and tribunals of the Member States, in disputes which have been brought before them, to refer questions to the Court of Justice about the interpretation of EU law or the validity of a European Union act. The Court of Justice does not decide the dispute itself. It is for the national court or tribunal to dispose of the case in accordance with the Court's decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

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*Unofficial document for media use, not binding on the Court of Justice.*

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<sup>1</sup> 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 2001 L 311, p. 67), as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 34).

The [full text](#) of the judgment is published on the CURIA website on the day of delivery.

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