



Deloitte Legal Newsflash

Commercial

CJEU ruling prohibits the supply of free samples of prescription drugs to pharmacists

On 11 June 2020 the Court of Justice of the European Union (CJEU) ruled that, under EU Directive 2001/83, pharmaceutical companies are not allowed to distribute free samples of prescription-only medicinal products to pharmacists ([C-786/18](#)). The CJEU also specified that EU law does not prohibit the distribution of free samples of over-the-counter (“OTC”) medicinal products - for which a prescription is not required - to pharmacists.

Facts

The pharmaceutical company Novartis manufactures the medicinal product ‘Voltaren Schmerzgel’, a pain reliever gel that contains the active substance Diclofenac. In 2013, German generic manufacturer ratiopharm started distributing, to pharmacists, free samples of the medicinal product ‘Diclo-ratiopharm-Schmerzgel’, which also contains Diclofenac.

According to Novartis, the distribution of free samples carried out by ratiopharm would infringe the German Medicines Act, which lists doctors but not pharmacists among those to whom free samples of medicinal products may be distributed. The

distribution would therefore amount to the granting of prohibited advertising gifts.

As a response to ratiopharm's alleged infringement, Novartis lodged an action before the German courts. Its case was upheld by both the courts of first instance and of appeal. When the case came before the *Bundesgerichtshof* (the German Federal Court of Justice), it requested the CJEU to interpret the relevant provisions of Directive 2001/83 because of its doubts as to whether these provisions authorise pharmaceutical companies to distribute free samples of medicinal products to pharmacists.

The CJEU's findings

The CJEU starts its assessment by noting that in virtually all language versions of Article 96(1) of Directive 2001/83, the right to receive samples of medicinal products free of charge is reserved to 'persons qualified to prescribe'. On the other hand, the Court also notes that the terms of that provision do not in and of themselves allow to determine whether that restriction concerns all medicinal products defined in Article 1(2), or only medicinal products subject to prescription within the meaning of Article 1(19) of that Directive.

Continuing its assessment, the CJEU holds that the criteria that prescription medicinal products meet, as listed in Article 71(1), reflect the view that they may not be used without medical supervision because of the danger associated with their use or because of the uncertainty of their effects. The CJEU notes that prescription medicinal products can only be prescribed by persons duly 'qualified to prescribe'; that is to say, doctors trained to recognise the risks inherent in their use by a given patient. Since pharmacists are not legally authorised to prescribe medicinal products, they do not fall within the category of 'persons qualified to prescribe', but rather that of 'persons entitled to supply' within the meaning of Directive 2001/83.

In light of the objectives set out in the Directive, and in order to avoid any risk of rule circumvention on dispensing prescription-only medicinal products, the CJEU issued its conclusion. Article 96(1) of Directive 2001/83 must be interpreted as stating that only persons qualified to prescribe medicinal products (as defined by said Directive) are entitled to receive samples free of charge, with pharmacists consequently excluded from that right. The CJEU further holds that said provision does not prohibit the distribution of free samples of OTC (prescription exempt) medicinal products.

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