

CJEU, C-786/18: pharmaceutical companies cannot distribute to pharmacists free samples of drugs that are available only upon prescription

The decision of the Court of Justice of the European Union ('CJEU') of 11 June 2020 in case C-786/18 concerns the interpretation of art. 96 of Directive 2001/83/EC of 6 November 2001, containing a community code relating to medicinal products for human use.

Article. 96, § 1, provides for the **possibility of exceptionally delivering free samples to the persons authorized to prescribe them**, in compliance with a series of constraints indicated in the provision itself.

Furthermore, pursuant to § 2, Member States can **further limit the distribution of samples of certain medicinal products**.

According to the German Federal Court of Justice (*Bundesgerichtshof*), the body that made the request for a preliminary ruling to the CJEU, it was necessary to clarify the interpretation of the rule and, in particular, whether art. 96 exhaustively dictated the rules on the distribution of free samples of drugs, excluding pharmacists from the distribution itself. The *Bundesgerichtshof* had been asked to make a decision because Ratiopharm, a German company which had been ordered - at the request of the competitor Novartis - to cease the free distribution of samples of a drug (Diclo-ratiopharm-Schmerzgel) to pharmacists, had challenged the second instance decision, which confirmed the ban imposed at first instance.

The referring court **therefore asked whether art. 96, § 1, of the Directive must be interpreted as meaning that, under certain conditions, it authorizes pharmaceutical companies to distribute free samples of drugs also to pharmacists** and, if so, **whether Article 96, § 2, permits the existence of a national provision which prohibits the delivery of free pharmaceutical products to pharmacists**.

In the decision at issue, the CJEU recalls that, when interpreting a provision of EU law, account must be taken not only of the text of the provision itself, but also of its **context** and of the **purposes pursued** by the legislation to which it belongs:

- As for the textual interpretation of the provision, if on the one hand it seems uncontroversial that the right to receive free samples concerns only "*persons qualified to prescribe*"; on the other hand, it is not clear whether these samples also concern over the counter drugs or only those subject to prescription.
- As for the context, the CJEU preliminarily recalls that, based on art. 70, § 1, of the Directive, when the authorities authorize the placing on the market of a medicinal product, they must specify whether or not it is subject to medical prescription, which is necessary in cases where it is believed that there may be a danger of use and / or uncertainty about the effects of the medicine. In the event that the prescription is necessary, this can only come from the "*authorized persons to prescribe*", *i.e.* doctors, who are trained to keep under control any danger and uncertainty. On the other hand, pharmacists are "*authorized to supply*" as opposed to prescribe drugs. This difference is also relevant with respect to promotional activities, for which it can be concluded that the advertising of non-prescription drugs is allowed, albeit within the limits indicated by the Directive (see articles 88, §§ 1 and 2, 89 and 90). It follows that art. 96, § 1, cannot cover all drugs, including those not subject to prescription, but only those subject to prescription, as they are potentially dangerous.

- As for the purposes, protection of public health is the ultimate objective of the Directive, as shown in recital 2, which states: *“The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health”*

It therefore follows that **only those that are authorized to prescribe such drugs under the Directive (i.e., doctors) have the right to receive free samples of such prescription drugs.**

Therefore **pharmacists, who are not authorized to prescribe, do not enjoy this right.** However, **pharmacists have the right to receive free samples of over the counter drugs.**

The Court therefore concludes that art. 96, § 1, of the Directive *“must be interpreted as meaning that it does not authorize pharmaceutical companies to distribute free samples of drugs that are available only on prescription to pharmacists. On the other hand, this provision does not preclude the free distribution to pharmacists of drugs that do not need a prescription”* [free translation from Italian, as this decision is not available in English yet].

The CJEU did not deem it necessary to answer the second question of the Bundesgerichtshof - if Article 96, § 2, allows for the existence of a national provision that prohibits the delivery of free pharmaceutical products to pharmacists - in light of the negative answer given to the first question.