

# CJEU RULES THAT PROVIDING FREE SAMPLES OF NON-PRESCRIPTION DRUGS TO PHARMACISTS IS PERMITTED

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Legal Briefings - By **Ina vom Feld and Behyad Hozuri**

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On 11 June, the Court of Justice of the European Union ("**CJEU**") ruled on the question of whether free samples to pharmacists of medicines may be supplied by pharmaceutical companies to pharmacists. The German Federal Supreme Court (Bundesgerichtshof) had referred questions regarding the German provisions which do not provide for supply to pharmacists. According to the judgement, free samples of non-prescription drugs may be supplied to pharmacists whereas prescription drugs may only be supplied to persons entitled to prescribe them.

## BACKGROUND

The legal dispute which led to the decision of the CJEU was an unfair competition lawsuit between two pharmaceutical companies selling non-prescription pain gel. One of the companies had supplied free samples to pharmacists "for demonstration purposes". The other company considered this to be in violation of the German Medicines Act ("**AMG**"), resulting in a breach of competition law ("unfair advantage via legal violation", "Vorsprung durch Rechtsbruch"). The action was successful in first instance and appeal. The courts concluded that Section 47 Para 3 of the AMG exhaustively listed the persons to whom free drug samples could be provided, namely specific groups, all of whom were entitled to prescribe prescription drugs. Pharmacists were not included in the list, so the courts considered the supply to them to be illegal.

# REFERRAL TO THE CJEU BY THE GERMAN FEDERAL SUPREME COURT

The Federal Supreme Court had doubts whether the German provision was in line with the Community code relating to medicinal products for human use (Directive 2001/83/EC, in the following “**Community Code**”). The respective provision regarding the supply of free samples is Article 96 Para 1 which addresses solely the supply to prescribing persons and provides for certain conditions for such supply. However, recital 46 of the Community Code excludes the provision of free samples only to the general public and recital 51 states that “*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.*”

Based on this the Federal Supreme Court referred to the CJEU firstly the question whether Article 96 para 1 of the Community Code really exhaustively limited the provision of free samples to persons entitled to prescribe, so that any provision of free drug samples to pharmacists was illegal or whether the provision of samples labelled “for demonstration purposes” to pharmacists so that they can familiarize themselves with the product was permitted. Further, and (only) in case the CJEU found the latter to be true, the Federal Supreme Court referred a second question, namely whether a reading of the German provision which excluded the giving of samples to pharmacists was still in line with the Community Code based Article 96 para 2 which gives member states the possibility to provide for further restrictions over para 1.

## RULING OF THE CJEU

The CJEU concluded based on the interplay of the provisions of the Community Code that the rules of Article 96 of the Community Code related only to prescription drugs, and were exhaustive, so that the supply of prescription drugs to pharmacists is not allowed in any case. In this regard the CJEU argued that the Community Code differentiates throughout between prescription and non-prescription drugs with prescription drugs being those which due to the dangers associated with their use need to be under the control of physicians whereas this is not the case for non-prescription drugs (Articles 71 and 72 of the Community Code). Having that differentiation in mind the CJEU sees Article 96 as tailored towards the dangers of prescription drugs which requires the supply to be limited to persons entitled to prescribe.

The CJEU on the other hand reasoned that it does not follow from Article 96 of the Community Code that the provision of samples of non-prescription drugs to pharmacists is excluded. In this regard the CJEU referred specifically to the above-mentioned recitals 46 and 51. The CJEU stated that the Community Code allows the supply of free samples to pharmacists within the framework of national law under limited conditions and under safeguarding of the goals pursued by the Community Code.

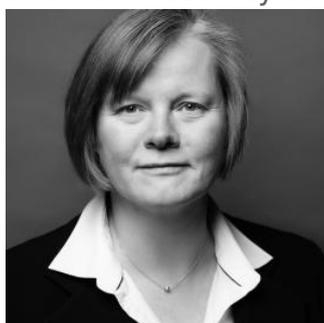
The CJEU, therefore, rules (note the official English translation of the judgment is not yet available):

“Art. 96 of the Directive 2001/83/EC (...) is to be interpreted in such a way that it does not allow pharmaceutical companies to supply free samples of prescription drugs to pharmacists. On the other hand, the provision does not hinder the supply of free samples of non-prescription drugs to pharmacists.”

It should be noted that the Attorney General’s opinion did not make this differentiation between prescription and non-prescription drugs and considered that pharmacists were completely excluded from receiving free samples. It follows from the CJEU decision that the previous interpretation of Section 47 AMG by the German courts as limiting also the supply of non-prescription drugs to persons entitled to prescribe prescription drugs was not in line with the EU Community Code. The question remains what the conditions shall be for the supply of non-prescription drugs to pharmacists, e.g. whether (with the exception of the limitation to prescribing persons) the conditions as set out in Article 96 of the Community Code shall apply *mutatis mutandis*, e.g. including a requirement of a prior written request from the pharmacist.



If you have any questions, or would like to know how this might affect your business, phone, or email these key contacts.



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