



“Guidelines” may have an interpretative value, but the judicial criteria will always prevail

Judgment of the ECJ of 6 September 2012, Case C-308/11, Kreussler, on the concept of medicinal product

On 6 of September, the Court of Justice of the European Union pronounced one more judgment on the concept of medicinal product, on when a product must be considered as such and may only be marketed after having received the appropriate authorization.

Fitting certain products in European regulations on medicinal products is a complex issue, and the European Union judges have worked on this matter in many cases over the past years. The judgment that we refer to, however, stands out because the Court, apart from ruling on the concept of pharmacological action, offers us a lesson on law that is worth remembering.

The case arose in Germany when two competitors that marketed mouthwashes containing chlorhexidine got involved in a dispute regarding whether these products had to be considered as medicinal products or if they could be marketed as cosmetic products. A court of Frankfurt decided that the product could be considered a cosmetic product as it did not have a pharmacological action, and it pointed out that its decision was based on the criteria exposed in a guidance document adopted by the European Commission. According to the Court, this document stated that there is a pharmacological action only if there is interaction between the molecules of a substance and a human cellular constituent.

In European and Spanish pharmaceutical law there are many documents of this type, to which sometimes we refer as "soft legislation". They are documents that may have an

interpretative value, that express the criterion of the administration at a certain moment, and that, as such, may be relied on as against the administration.

However, the value of these documents must be limited to this. The Court of Justice reminds in its judgment that a guidance document such as this one is not a legal binding act, nor is it a legal act that is enforceable against individuals with force of law. In the European context, the judgment says, these documents may be useful for the interpretation of the provisions of European law and help to ensure that they are uniformly applied, but this does not take away the fact that only the Court of Justice has the jurisdiction to give a binding interpretation of European Union law.

In short, Luxemburg orders the German courts to apply the criteria set out by the European case law when they pass a judgment on the concept of pharmacological action. By the way, the Court concludes that in order to consider that a substance has a «pharmacological action» it might be sufficient if it produces an interaction between its molecules and any cellular constituents present in the human body. Moreover, the judgment recalls that before qualifying a product as a medicinal product multiple factors must be taken into account, which always requires a case-by-case analysis.