



Substances used only for “recreational” purposes, which are not beneficial for health are not medicinal products

Judgement of the ECJ of 10 July 2014 in accumulated cases C-358/13 and C-181/14 on the concept of “medicinal product”

Background

This case has its origin in a criminal process followed in Germany against two persons who were accused of marketing small bags containing herbs to which synthetic cannabinoids had been added. Some of the bags included the notice that they were intended as an air freshener and not indicated for human consumption. However, the judgement states that the defendants knew that these substances had been studied by the pharmaceutical industry, and that they had shown no pharmaceutical efficacy but some psychoactive action. The judgement adds that the accused persons knew that the costumers used these bags as substitute for marihuana.

In the process against the defendants, German authorities claimed that the bags could be qualified as medicinal products, and that because the defendants had marketed them without approval, they had incurred in a criminal conduct. The defendants pleaded that the bags could not be considered as medicinal products under European law, and the German court decided to file a request for a preliminary ruling from the European Court.

The community interest of the case

The cases in which the ECJ has to decide whether a product may be qualified as a medicine or not, normally have special interest. In this case, it is shown by the fact that seven countries participated in the process.

The analysis of the Court departs from the fact that, according to the EC Code on medicines, a

“medicinal product” is any substance or combination of substances presented for treating or preventing disease in human beings and also any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings.

To determine whether the bags could fall under this definition or not, the ECJ had to construct the term “modify” contained in this definition. A literal interpretation could lead to the conclusion that any substance capable of modifying physiological functions should be qualified as a medicine, even if such modification is detrimental to the consumer. The ECJ does not follow these criteria, and relying on its previous caseload, it states that the word “modify” must be interpreted not only according to its literal significance, but also according to its context and to the purposes of the regulations on medicines. On this basis, the Court concludes that it is not sufficient that a substance may have any physiological action to be able to consider it as a medicine for legal purposes. The Court states that it is also necessary that the substance is capable of having a beneficial effect on the human body and therefore on human health.

The ECJ understands that its interpretation may result in exculpating the defendants from the criminal charges of having marketed medicines without approval, but it also concludes that the objective of penalizing the marketing of noxious substances cannot influence the definition of the concept of “medicinal product”.