



## **Mixtures of herbs containing synthetic cannabinoids consumed as a marijuana substitute are not medicinal products**

In today's judgment, the Court of Justice finds that under EU law<sup>1</sup> the term medicinal product does not include substances such as mixtures of herbs containing synthetic cannabinoids which have the effect of simply modifying physiological functions but are not such as to have any beneficial effects, either immediately or in the long term, on human health, are consumed solely to induce a state of intoxication and are, as such, harmful to human health.

That is the Court's response to questions submitted by the Bundesgerichtshof (Federal Court, Germany), which, in two sets of criminal proceedings, is required to decide whether the sale of mixtures containing synthetic cannabinoids used as a marijuana substitute may give rise to criminal law proceedings on the ground of the unlawful sale of unsafe medicinal products. Two vendors of such mixtures (Mr D and Mr G) have been convicted of the sale of unsafe medicinal products by lower courts. Mr D was handed a suspended sentence of one year and nine months imprisonment, Mr G was sentenced to four years and six months imprisonment and a fine of €200 000. At the material time, synthetic cannabinoids did not fall under the German law on narcotic drugs, so that the German authorities were unable to instigate criminal law proceedings on the basis of that law.

The consumption of the synthetic cannabinoids in question generally induces a state of intoxication which may range from intense excitement to hallucinations. They may also cause nausea, intense vomiting, heart-racing, disorientation, delusions and even cardiac arrest. The synthetic cannabinoids have been tested by the pharmaceutical industry in pre-experimental studies. The series of tests were discontinued at the first experimental/pharmacological stage: it was apparent that the desired health effects of those substances could not be achieved and considerable side effects were foreseeable due to the psychoactive effects of the substances.

Given the objective of EU law of attaining a high level of human health protection and the context in which the term 'medicinal product' occurs, the Court concludes that that term does not include substances which simply have the effect of modifying physiological functions but are not such as to have any immediate or long-term beneficial effects on human health.

The Court observes that, according to the Bundesgerichtshof, the mixtures in question are consumed not for therapeutic but for purely recreational purposes and that they are, as such, harmful to human health. In view of the objective of attaining a high level of human health protection, the need for a consistent interpretation of the term medicinal product and the need to weigh any harmful effects a product may have against its therapeutic effects, such substances cannot be classified as medicinal products.

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<sup>1</sup> The term 'medicinal product' is defined, inter alia, in Article 1(2)(b) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 34). Under that provision, a medicinal product is defined as 'any substance or combination of substances which may be used in or administered to human beings with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis'.

The fact that that conclusion may mean that the marketing of the substances at issue is not subject to any criminal law sanction cannot call the Court's finding into question.

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**NOTE:** A reference for a preliminary ruling allows the courts and tribunals of the Member States, in disputes which have been brought before them, to refer questions to the Court of Justice about the interpretation of European Union law or the validity of a European Union act. The Court of Justice does not decide the dispute itself. It is for the national court or tribunal to dispose of the case in accordance with the Court's decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

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The [full text](#) of the judgment is published on the CURIA website on the day of delivery.

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