Court of Justice of the European Union
PRESS RELEASE No 84/14
Luxembourg, 12 June 2014

Press and Information

Advocate General's Opinion in Joined Cases C-358/13 and C-181/14
D and G

According to Advocate General Bot, products consisting of aromatic herbs and synthetically produced cannabinoids and which are sold exclusively for recreational purposes are not medicinal products

In order to be classified as a medicinal product, a substance or combination of substances must be intended to prevent or treat an illness

An EU directive[1] defines the concept of 'medicinal product by function' 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**'.[2]

Between 2010 and 2012, D and G sold mixtures of aromatic herbs containing various synthetically produced cannabinoids. The latter consist of psychoactive substances intended to reproduce the effects of cannabis when they are smoked. At the time, the German Law on combatting narcotics did not allow prosecution for the sale of those substances. The German authorities therefore sentenced D and G to custodial sanctions on the basis of the Law relating to medicines, concluding that they had marketed a 'dubious medicinal product'.

The case having been brought before it, the Bundesgerichtshof (Federal Court of Justice, Germany) asks whether, in spite of the risks to human health, the combination of substances at issue may be classified as a 'medicinal product', in so far as, although it does, as the directive provides, modify human physiological functions by exerting a pharmacological action,[3] it does not produce any therapeutic benefit for humans.

In his Opinion today, Advocate General Yves Bot considers that the concept of 'medicinal product' referred to in the directive is not capable of covering a combination of substances such as that at issue. Such a combination of substances is, admittedly, capable of modifying human physiological functions, but **its use for purely recreational purposes is intended neither to prevent nor treat an illness**.

First of all, the Advocate General points out that the issue is not to prevent the medical use of narcotics, which remains essential for pain relief, but to restrict the marketing of psychoactive substances consumed by humans for exclusively recreational purposes, the consumer seeking, in this instance, psychic effects associated with the consumption of cannabis.

In support of his arguments, Mr Bot relies first of all on the definition of the concept of 'medicinal product by presentation' covered by the directive, since that concept makes reference to the product's 'properties for treating or preventing disease in human beings'. Mr Bot considers next

[1] 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).
[2] Article 1(2)(b) of the directive.
[3] Synthetically produced cannabinoids affect the human central nervous system and create risks for human health in so far as they interfere with vital functions of individuals such as concentration and attention, exacerbate certain mental health problems such as anxiety and depression and cause psychiatric effects such as hallucinations and paranoia and a potential risk of abuse and addiction. Those psychoactive effects can even lead to suicidal tendencies.

that the criterion relating to the 'modification of physiological functions' cannot be interpreted independently of its context or of the intended medical use of the substance or combination of substances at issue. The directive uses not only the verb 'to modify', but also the verbs 'to restore' and 'to correct', those verbs referring to an improvement of human organic function or the restoration of human physiological functions, which implies the existence of a medical or therapeutic benefit. Advocate General Bot notes, moreover, the Court's settled case-law according to which the use of a medicinal product must 'be intended to prevent or treat disease'.[4]

In addition, the Advocate General considers that the directive, based on the protection of public health and the free movement of goods within the EU, precludes the marketing of substances presenting risks for human health similar to those presented by narcotics the use of which has no medical application.

By regulating the marketing authorisation, manufacture, importation, labelling and the distribution of medicines, the directive seeks to allow the marketing and free movement of safe and effective products, the composition of which has been analysed, the indications, contra-indications, risks and adverse reactions of which have been assessed and the posology, the pharmaceutical form and the method of administration have been determined. Those rules are therefore not applicable to a combination of substances intended, in reality, to be excluded from the market because it lacks any medical benefit and presents risks to human health.

Furthermore, Mr Bot considers that the sale for purely recreational purposes of new psychoactive substances is clearly outside the legal economic sphere of the internal market. He notes in that regard that, in accordance with the Court's case-law, 'narcotic drugs that are not distributed through channels strictly controlled by the competent authorities to be used for medical and scientific purposes are, because of their very nature, subject to a prohibition on their being imported and offered for sale in all the Member States'.[5]

Although it is understandable that, confronted with a legal vacuum, Germany sought to apply legislation relating to medicinal products in order to be better able to control and prevent the marketing of those new substances, Advocate General Bot concludes that such an aim is not however capable of warranting a broad interpretation, indeed a distortion, of the concept of 'medicinal product'. He considers, consequently, that only enforcement measures based on the control of narcotics are suitable in order to respond to the appearance of psychoactive substances on the market. In that regard and in the interests of clarity, he recommends that the legal basis of texts currently being drafted be clearly linked with the area of freedom, security and justice.

NOTE: The Advocate General's Opinion is not binding on the Court of Justice. It is the role of the Advocates General to propose to the Court, in complete independence, a legal solution to the cases for which they are responsible. The Judges of the Court are now beginning their deliberations in this case. Judgment will be given at a later date.

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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[4] Case C-319/05 *Commission* v *Germany*.
[5] Case C-137/09 *Josemans*. See also Press Release no 121/10