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## Advertising of medicinal products versus freedom of expression of a journalist European Court of Justice Decision dated 2 April 2009 (C-421/07) 'Frede Damgaard'

### **Legal context**

Seized within the framework of a preliminary ruling procedure, the European Court of Justice ("ECJ") recently had the opportunity to specify the definition of advertising of medicinal products as provided for by Directive 2001/83/EC of 6 November 2001 on the Community Code relating to medicinal products for human use ("Directive 2001/83/EC").

As a reminder, please note that Article 86(1) of Directive 2001/83/EC defines the concept of advertising of medicinal products as "any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products (...)."

However, Article 86(2) of said Directive excludes from the scope of the advertising of medicinal products "information relating to human health or diseases, provided that there is no reference, even indirect to medicinal products."

### **Factual context**

The situation at stake was the dissemination, on a journalist's website, of information related to the pain-relieving effects of a medicinal product in certain diseases such as certain categories of gout or arthrosis.

At the time of the dissemination, in 2003, the concerned product was forbidden in Denmark but was on sale in Sweden and Norway.

The journalist was condemned on the basis of Danish legal provisions prohibiting advertising for medicinal products that are not lawfully marketed in Denmark.

The journalist appealed against that judgment before the Regional Court of Appeal, contending that the disseminated information could not be considered as advertising since he had no interest in the sales of the concerned product.

He also asserted that such a condemnation was against the principle of freedom of expression acknowledged by Article 10 of the European Convention for the Protection of Human Rights and Fundamental Freedoms.

The Danish Regional Court of Appeal stayed the proceedings and referred the case to the ECJ for a preliminary ruling.

The question referred to the ECJ was whether or not the dissemination by a third party of information about the medicinal product's therapeutic or prophylactic properties must be understood as constituting pharmaceutical advertising in the meaning of Article 86(1) of Directive 2001/83/EC.

### **Rationale**

The ECJ started its reasoning by observing that the definition provided by Directive 2001/83/EC expressly puts the emphasis on the purpose of the spread message, but it does not give any criterion as to the person disseminating the information.

The ECJ deduces from this observation that the wording of Directive 2001/83/EC does not rule out the possibility that a message coming from an independent third party may constitute advertising.

Indeed, the ECJ stated that "even where it is carried out by an independent third party outside any commercial or industrial activity, advertising of medicinal products is liable to harm public health, the safeguarding of which is the essential aim of Directive 2001/83."

Consequently, the ECJ rules that it is for the national courts to determine whether or not the content of the disseminated message of an independent party constitutes advertising in the meaning of Directive 2001/83/EC.

The ECJ, however, adds that, in addition to the content of the message spread, the national courts must consider the relationship of the author with the company manufacturing or distributing the concerned product and the nature of the activity carried out by the author.

Concerning the freedom of expression, the ECJ recalls that such a freedom may be subject to certain restrictions justified by the public interest.

The ECJ highlights that, should the concerned national court consider that the information published on a journalist's website constitutes advertising for purposes of Directive 2001/83/EC, the protection of public health would be a legitimate justification to restrict the freedom of expression.

Consequently, the Court ruled that:

"Article 86 of Directive 2001/83/EC is to be interpreted as meaning that dissemination by a third party of information about a medicinal product, including its therapeutic or prophylactic properties, may be regarded as advertising within the meaning of that article, even though the third party in question is acting on his own initiative and completely independently, de jure and de facto, of the manufacturer and the seller of such a medicinal product. It is for the national court to determine whether that dissemination constitutes a form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products."

### **Parallel with French case-law**

With a "little" delay, this ECJ preliminary ruling turns out to be in line with the case-law of the French Civil and Administrative Supreme Courts dating back to 1971 and 1979<sup>1</sup>.

Indeed, the French Supreme Courts held that any publication praising the merits of a medicinal product must be considered as advertising whatever its author, and no matter if the manufacturer of the said medicinal product did not ask or pay for such publication.

Accordingly, the first-line criterion is the content of the message, and mainly the presence or the absence of any element encouraging the prescription, supply, sale or consumption of medicinal products.

Decision "*Frede Damgaard*" (C-421/07) aims at giving some criteria to distinguish between advertising and information.

It should be remembered that the Proposal "amending Directive 2001/83/EC on the grounds of information to the general public on medicinal products subject to medicinal prescription" [SEC(2008)2667, SEC(2008)2668] proposes that pharmaceutical companies can disseminate, either directly or indirectly through a third party, information on their prescription-only medicinal products to the general public under specific conditions. The border between advertising and information will certainly give rise in the future to further interpretation issues and litigations.

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<sup>1</sup> Decision of the French Supreme Court (Cour de Cassation) dated 13 January 1971, JCP G 1971,II, 16932 ; Decision of the Supreme Administrative Court (Conseil d'Etat) dated 15 March 1979, Bull. Ordre, n° 222, p. 604.

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