**European Court of Justice, 2 April 2009, Damgaard**


**ADVERTISING – PHARMACEUTICAL LAW**

**Dissemination of information about a medicinal product by a third party acting on his own initiative**

- **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 independ-ently, 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 consti-tutes a form of door-to-door information, canvassing activity or inducement designed to promote the pre-scription, supply, sale or consumption of medicinal products.**

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**European Court of Justice, 2 April 2009**
(C.W.A. Timmermans, J.-C. Bonichot, K. Schiemann, J. Makarczyk and C. Toader)
JUDGMENT OF THE COURT (Second Chamber)
2 April 2009 (*)
*(Medicinal products for human use – Directive 2001/83/EC – Concept of 'advertising' – Dissemination of information about a medicinal product by a third party acting on his own initiative)*
In Case C-421/07,
REFERENCE for a preliminary ruling under Article 234 EC from the Vestre Landsret (Denmark), made by decision of 6 August 2007, received at the Court on 13 September 2007, in the criminal proceedings against
Frede Damgaard,
THE COURT (Second Chamber),
composed of C.W.A. Timmermans, President of the Chamber, J.-C. Bonichot, K. Schiemann (Rapporteur), J. Makarczyk and C. Toader, Judges,
Advocate General: D. Ruiz-Jarabo Colomer,
Registrar: C. Strömholm, Administrator,
having regard to the written procedure and further to the hearing on 9 October 2008,
after considering the observations submitted on behalf of:

– Mr Damgaard, by S. Stærk Ekstrand, advokat,
– the Danish Government, by B. Weis Fogh, acting as Agent,
– the Belgian Government, by J.-C. Halleux, acting as Agent,
– the Czech Government, by M. Smolek, acting as Agent,
– the Greek Government, by N. Dafniou, S. Alexandriou and K. Georgiadis, acting as Agents,
– the Polish Government, by T. Krawczyk, P. Dąbrowski and M. Dowgielewicz, acting as Agents,
– the United Kingdom Government, by Z. Bryanston-Cross, acting as Agent, and J. Stratford and J. Coppel, Barristers,
– the Commission of the European Communities, by H. Støvlbæk and M. Šimerdová, acting as Agents,
after hearing the **Opinion of the Advocate General at the sitting on 18 November 2008**,
gives the following
**Judgment**
1 This reference for a preliminary ruling concerns the interpretation of Article 86 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).
2 The reference was made in the context of criminal proceedings brought by the Anklagemyndigheden (Public Prosecutor) against Mr Damgaard, a journalist, who has been charged with having publicly disseminated information about the properties and availability of a medicinal product the marketing of which is not authorised in Denmark.
**Legal context**
**Directive 2001/83**
3 Recitals 2 and 3 in the preamble to Directive 2001/83 state the following:
'(2) The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health.
(3) However, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community.'
4 According to recital 40 in the preamble to the same directive:
'The provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information.'
5 Recital 45 in the preamble to that directive is worded as follows:
'Advertising to the general public, even of non-prescription medicinal products, could affect public health, were it to be excessive and ill-considered. Advertising of medicinal products to the general public, where it is permitted, ought therefore to satisfy certain essential criteria which ought to be defined.'

6 Title III of Directive 2001/83, as amended by Directive 2004/27 ('Directive 2001/83'), concerns the placing of medicinal products on the market, whilst Title IV thereof lays down rules governing their manufacture and importation. Title VII of that directive lays down rules governing wholesale distribution of medicinal products.

7 Article 86 of Directive 2001/83, the first article under Title VIII thereof, entitled 'Advertising', provides:

'1. For the purposes of this Title, "advertising of medicinal products" shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular:

– the advertising of medicinal products to the general public,

– advertising of medicinal products to persons qualified to prescribe or supply them,

– visits by medical sales representatives to persons qualified to prescribe [or supply] medicinal products,

– the supply of samples,

– the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal,

– sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products,

– sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith.

2. The following are not covered by this Title:

– the labelling and the accompanying package leaflets, which are subject to the provisions of Title V,

– correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product,

– factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims,

– information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products.'

8 Article 87 of the same directive provides:

'1. Member States shall prohibit any advertising of a medicinal product in respect of which a marketing authorisation has not been granted in accordance with Community law.

2. All parts of the advertising of a medicinal product must comply with the particulars listed in the summary of product characteristics.

3. The advertising of a medicinal product:

– shall encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties,

– shall not be misleading.'

**National legislation**

9 Paragraph 27b of the Danish Law on medicinal products (Lægemiddellov, Consolidating Law No 656/1995) provides:

'Advertising of medicinal products which may not lawfully be marketed or supplied in Denmark shall be prohibited.'

**The dispute in the main proceedings and the question referred for a preliminary ruling**

10 Hyben Total in powder and capsule form, after having been classified as a medicinal product by the Lægemiddelstyrelsen (Danish agency for medicinal products), was previously marketed in Denmark by its manufacturer, Natur-Drogeriet A/S ('Natur-Drogeriet'), as a product relieving or treating gout, gallstones, kidney disorders, bladder disorders, sciatica, bladder bleeding, diarrhoea, stomach cramps, diabetes and kidney stones. The information material on the medicinal product was prepared by Mr Damgaard. Sales of that medicinal product were halted in 1999, however, when marketing authorisation was refused.

11 In 2003, Mr Damgaard stated on his website that Hyben Total contained rosehip powder, which is supposed to relieve the pain caused by various types of gout or arthrosis, and that the medicinal product was on sale in Sweden and Norway. By decision of 16 June 2003, the Lægemiddelstyrelsen informed Mr Damgaard that those statements constituted advertising contrary to Paragraph 27b of Law No 656/1995 on medicinal products and criminal proceedings were commenced against him.

12 By judgment of 2 December 2005, the Retten i Århus (Århus City Court) (Denmark) found Mr Damgaard guilty under the aforementioned national provision and sentenced him to a fine. He appealed against that judgment before the Vestre Landsret (Western Regional Court) (Denmark), arguing in those proceedings that he was not employed by Natur-Drogeriet and had no interest in that company or in sales of Hyben Total. His activities as a journalist in the health food sector were limited to the communication, to retailers and other interested parties, of information on food supplements. Mr Damgaard did not receive any remuneration from Natur-Drogeriet for the information he disseminated concerning Hyben Total.

13 The Anklagemyndigheden, who brought the proceedings against Mr Damgaard, maintains that that dissemination of information was aimed at encouraging consumers to buy Hyben Total, irrespective of whether there was a link between Mr Damgaard and the manufacturer or seller of that medicinal product. Accordingly, that activity constitutes 'advertising' within the meaning of Article 86 of Directive 2001/83 and must be prohibited, since the marketing of that medicinal product, whose consumption that activity seeks to promote, is prohibited in Denmark.

14 Mr Damgaard contends that the information published on his website did not constitute advertising as contemplated in Article 86 of Directive 2001/83, as that concept must be construed more narrowly, that is, as

not covering door-to-door information effected by an independent third party.

15 It is in those circumstances that the Vestre Landsret decided to stay the proceedings and to refer the following question to the Court for a preliminary ruling:

'Is Article 86 of Directive 2001/83 … to be interpreted as meaning that dissemination by a third party of information about a medicinal product, including in particular information about the medicinal product's therapeutic or prophylactic properties, is to be understood as constituting advertising, 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?'

**The question referred for a preliminary ruling**

16 Recital 2 in the preamble to Directive 2001/83 states that the essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health. That aim is reiterated in the various titles of that directive, including Titles III, IV and VII thereof, the provisions of which guarantee that no medicinal product is placed on the market, manufactured or distributed without the necessary authorisations first having been obtained.

17 Similarly, in the area of information and advertising relating to medicinal products, recital 40 in the preamble to Directive 2001/83 states that the provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information. Recital 45 in the preamble to the directive further states that since advertising to the general public of non-prescription medicinal products could affect public health, were it to be excessive and ill-considered, it should therefore, where it is permitted, satisfy certain essential criteria which ought to be defined.

18 Article 87(1) of Directive 2001/83 prohibits any advertising of a medicinal product in respect of which a marketing authorisation has not been granted in accordance with Community law.

19 The public dissemination of information about a medicinal product which is not authorised in a particular Member State may, depending on the context in which that dissemination takes place, influence consumers' behaviour and encourage them to purchase the medicinal product in question, which could affect public health. As the case-file referred to the Court shows, Mr Damgaard stated on his website that Hyben Total was available in Sweden and Norway.

20 Article 86(1) of Directive 2001/83 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'. Whilst that definition explicitly emphasises the purpose of the message, it does not provide any indication as to the people who disseminate that information.

21 Thus, the wording of Directive 2001/83 does not rule out the possibility that a message originating from an independent third party may constitute advertising. Nor does the directive require a message to be disseminated in the context of commercial or industrial activity in order for it to be held to be advertising.

22 In that regard, it must be 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.

23 It is for the national court to determine whether Mr Damgaard's actions constituted a form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of Hyben Total.

24 To that end and as the Advocate General observed in point 37 of his Opinion, the situation of the author of a communication about a medicinal product and, in particular, his relationship with the company which manufactures or distributes it, are a factor which, although it may help to determine whether the communication constitutes advertising, must be evaluated together with other circumstances, such as the nature of the activity carried out and the content of the message.

25 Regarding Mr Damgaard's argument alleging infringement of his right to freedom of expression as a result of his criminal conviction, it should be borne in mind that, according to settled case-law, fundamental rights form an integral part of the general principles of law the observance of which the Court ensures.

26 Whilst the principle of freedom of expression is expressly recognised by Article 10 of the European Convention for the Protection of Human Rights and Fundamental Freedoms, signed in Rome on 4 November 1950, and constitutes one of the fundamental pillars of a democratic society, it nevertheless follows from the wording of Article 10(2) that freedom of expression is also subject to certain limitations justified by objectives in the public interest, in so far as those derogations are in accordance with the law, motivated by one or more of the legitimate aims under that provision and necessary in a democratic society, that is to say justified by a pressing social need and, in particular, proportionate to the legitimate aim pursued (see Case C-71/02 Karner [2004] ECR I-3025, paragraph 50).

27 It is common ground that the discretion enjoyed by the national authorities in determining the balance to be struck between freedom of expression and the abovementioned objectives varies for each of the goals justifying restrictions on that freedom and depends on the nature of the activities in question. When the exercise of the freedom does not contribute to a discussion of public interest and, in addition, arises in a context in which the Member States have a certain amount of discretion, review is limited to an examination of the reasonableness and proportionality of the interference. This holds true for the commercial use of freedom of expression, particularly in a field as complex and fluctuating as advertising (see Karner, paragraph 51).

28 If the information disseminated on Mr Damgaard's website, which is at issue in the main proceedings, were to be found to constitute 'advertising' for the purposes of Directive 2001/83, his conviction could be considered reasonable and proportionate, in the light of the legitimate aim pursued, namely the protection of public health.

29 In the light of all the foregoing, the answer to the question referred is that Article 86 of Directive 2001/83 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.

**Costs**

30 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

**On those grounds, the Court (Second Chamber) hereby rules:**

Article 86 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, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, 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.

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**OPINION OF ADVOCATE GENERAL RUIZ-JARABO COLOMER**

delivered on 18 November 2008 (1)
Case C-421/07
Anklagemyndigheden
v
Frede Damgaard
(Reference for a preliminary ruling from the Vestre Landsret (Denmark))

*(Medicinal products for human use – Concept of advertising – Dissemination of information about a medicinal product by an independent third party – Freedom of expression)*

**I – Introduction**

1. The question referred for a preliminary ruling from the Vestre Landsret (Western Regional Court), Denmark, provides the Court of Justice with another opportunity to specify the continually disputed limits imposed by Community law on the advertising of medicinal products.

2. The questions referred seek to have clarified whether an opinion of a medicinal product expressed by a third party unconnected with its manufacture, marketing or distribution, should be deemed to be 'advertising' for the purposes of Directive 2001/83/EC, (2) or as communication of another kind.

3. Under Articles 87 and 88 of that directive, Member States must prohibit the advertising of medicinal products the sale of which has not been authorised, those available on medical prescription only, and those containing psychotropic substances. Similarly, Member States may ban, on their territory, advertising for medicinal products the cost of which may be reimbursed.

4. The case pending before the national court is problematic in three respects, since the information disseminated refers to a medicinal product which has been banned in Denmark, posted on a Danish webpage and signed by a journalist. All these factors must be carefully considered, because they give rise to contradictory assessments. First, the fact that an unauthorised medicinal product is involved tends to support a strict approach. Secondly, the fact that Mr Damgaard, a journalist, has pleaded his right to freedom of expression calls for a more flexible approach which observes that freedom. Furthermore, the fact that dissemination took place on the Internet complicates the situation owing to the legal difficulties arising in the virtual universe of the Internet.

5. In formulating its response, therefore, the Court of Justice will have to weigh up these special circumstances, whilst bearing in mind that the criteria it lays down are liable to be extended to all kinds of medicinal products.

6. Mr Damgaard's is not an isolated case. Similar situations have arisen recently, for example, in Spain, with the statements made by Mr Sánchez Dragó about melatonin in a widely broadcast news programme (3) and also, as the representative of the Czech Government related at the hearing, with the publication in his country of a collection of stories called 'Yesterday Viagra, today Cialis'. (4)

7. I do not intend to close the intense European debate on this matter, (5) but there is no doubt that the solution adopted will help to clarify the distinction, tacitly introduced in Community legislation, between advertising and other kinds of information.

**II – Legal framework**

**A – Community legislation**

8. Directive 2001/83, which is the subject of the present reference for a preliminary ruling, was adopted

in order to codify various Community rules relating to medicinal products for human use (among them Directive 92/28/EEC). (6)

9. According to recital 2 in the preamble to Directive 2001/83, the essential aim of rules governing the production, distribution and use of medicinal products is to safeguard public health. However, recital 3 states that this objective must be attained by means which 'will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community'.

10. As regards the provisions governing information supplied to patients, recital 40 in the preamble to that directive requires that they provide a high degree of consumer protection in order that medicinal products may be used correctly on the basis of full and comprehensible information. Recital 48 therein adds that advertising should be subject to 'effective, adequate monitoring', using the monitoring mechanisms set up by the Directive on misleading advertising. (7)

11. Recital 42 also refers to the latter directive, stating that Directive 2001/83 is without prejudice to the measures adopted pursuant to Directive 84/450.

12. Title VIII of the directive at issue governs advertising of medicinal products. Article 86(1) defines it as any form of 'door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products'. The provision contains a series of promotional activities by way of example (supply of samples, sponsorship of meetings or scientific congresses) and adds that advertising may be directed at both consumers and persons qualified to prescribe.

13. Next, Article 86(2) limits the scope of Title VIII, listing certain activities to which it does not apply, including statements relating to human health or diseases, provided there is no reference, even indirect, to medicinal products.

14. Article 87(1) gives the Member States the opportunity to prohibit any advertising of a medicinal product in respect of which a marketing authorisation has not been granted in accordance with Community law; Article 87(3) prohibits misleading advertising and requires that advertising encourage the rational use of the medicinal product by presenting it objectively and without exaggerating its properties.

15. Directive 2001/83 was amended by Directive 2004/27/EC (8) because 'the definitions and scope of Directive 2001/83/EC should be clarified in order to achieve high standards for the quality, safety and efficacy of medicinal products for human use' (recital 7). Among the changes incorporated in 2004 is Title VIIIa, entitled 'Information and advertising'; it begins with Article 88a, which requires the Commission, within three years of the entry into force of Regulation No 2004/726/EC, (9) following consultations with patients' and consumers' organisations, doctors' and pharmacists' organisations, Member States and other interested parties, to present to the European Parliament and the Council a report on current practice with regard to information provision, particularly on the Internet, and its risks and benefits for patients. Following analysis of the data, the Commission, if it sees fit, is to draw up proposals setting out a strategy to ensure good-quality, objective, reliable and non-promotional information on medicinal products and other treatments and shall address the question of the information source's liability.

**B – The Danish legislation**

16. Paragraph 27b of the Danish Law on medicinal products (Lægemiddellov), introduced by Law No 280 of 6 May 1993, (10) transposed Article 2(1) of Directive 92/28 (subsequently reproduced in Article 87(1) of Directive 2001/83), expressly prohibiting 'advertising of medicinal products which may not lawfully be marketed or supplied in Denmark'.

17. The consolidated version of the Danish law on pharmaceutical products, which was in force at the time Mr Damgaard was convicted at first instance (Law No 656/1995), was repealed with effect from 17 December 2005, and replaced by the new Law No 1180 of 12 December 2005, Paragraph 64(1) of which retains the aforementioned prohibition.

**III – The main proceedings and the question referred for a preliminary ruling**

18. Hyben Total is a pharmaceutical compound manufactured by the company Natur-Drogeriet A/S. It may not lawfully be marketed and supplied in Denmark, but is freely available in Sweden and Norway, where it is classified as a food supplement.

19. Via the website www.basisinform.dk, Frede Damgaard disseminated various details about the properties of Hyben Total, (11) stating that it is sold in Norway as well as Sweden and that it contains rosehip, a plant which supposedly helps to alleviate the pain caused by some types of gout and by osteoarthritis.

20. In those circumstances, the Anklagemyndigheden (Public Prosecutor) brought criminal proceedings against Mr Damgaard for having advertised a medicinal product which is not authorised in Denmark, in violation of Paragraph 27b together with Paragraph 44(1)(1) of the Danish Law on medicinal products then in force. By judgment of 2 December 2005, the Retten i Århus (Århus City Court) found him guilty as charged and sentenced him to a fine.

21. Mr Damgaard appealed against that conviction before the Vestre Landsret (Western Regional Court), claiming that he is an independent journalist and has no connection whatsoever with Natur-Drogeriet A/S (he maintains that he is neither employed by the company nor receives any remuneration from it and that he has no interest in the company or in sales of Hyben Total). He argues that his conduct does not constitute advertising for the purposes of Directive 2001/83, since that legislation covers a narrower concept which does not extend to third parties.

22. The Public Prosecutor, on the other hand, contends that the dissemination of information about a medicinal product may be regarded as advertising if it is designed to promote its sale, irrespective of whether or not there is a connection with the manufacturers or vendors, adding that Article 86 of Directive 2001/83

differs from Article 2(1) of the directive with respect to misleading advertising.

23. The Vestre Landsret has referred the following question to the Court of Justice for a preliminary ruling pursuant to Article 234 EC:

'Is Article 86 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medical products for human use, as subsequently amended, to be interpreted as meaning that dissemination by a third party of information about a medicinal product, including in particular information about the medicinal product's therapeutic or prophylactic properties, is to be understood as constituting advertising, 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?'

**IV – Procedure before the Court of Justice**

24. The reference for a preliminary ruling was lodged at the Court Registry on 13 September 2007.

25. Written observations were lodged by Mr Damgaard, the Commission and the Danish, Belgian, Greek, Polish and United Kingdom Governments.

26. At the hearing held on 9 October 2008, the representatives of Mr Damgaard, the Kingdom of Denmark, the Czech Republic, the Hellenic Republic, the Republic of Poland, the United Kingdom of Great Britain and Northern Ireland and the Commission attended the hearing and presented oral argument.

**V – Analysis of the question referred for a preliminary ruling**

27. The Community legislation on advertising of medicinal products has given rise to a wide range of doubt amongst the national courts as to how to interpret those rules.

28. In these preliminary reflections, two very important decisions of the Court of Justice, referred to repeatedly in the case-file, must be mentioned, as they constitute case-law references which are essential for deciding this case. The first is the judgment in Gintec, (12) which examined the treatment to be given under Directive 2001/83 to statements of third parties in connection with the advertising of medicinal products, and held that Member States may prohibit the use of such declarations only if the requirements of Article 87(3) of that Directive are not met. The second is the judgment in Ter Voort, (13) which denied that the dissemination of information about the therapeutic properties of a medicinal product by 'a third party acting on his own initiative and completely independently, de jure and de facto, of the manufacturer or the seller' constituted a 'presentation' for the purposes of the Community definition of a medicinal product. The similarity between the wording of that judgment and the words chosen by the Vestre Landsret when drafting its question for a preliminary ruling is obvious, although in the Ter Voort case it was not clarified whether there was advertising within the meaning of the directive, as it is in the present case.

29. In accordance with that case-law, the referring court asks the Court of Justice whether Article 86 of Directive 2001/83, when it defines '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', encompasses information about the therapeutic or prophylactic qualities of a product disseminated by an independent third party acting on his own initiative.

30. The question is of great importance, since Directive 2001/83 prohibits any advertising of medicinal products which have not been authorised and those sold on medical prescription only. It is therefore necessary to go beyond the literal content of the reference for a preliminary ruling in order to ascertain whether the Community legislature wished to prevent any dissemination of information about those two categories of medicinal products or whether, on the contrary, it chose to leave some types of popularisations outside the scope of the directive.

**A – Advertising and information are different concepts**

31. First of all, it is necessary to define the concepts of 'advertising' and 'information' in respect of medicinal products, between which the Community legislation clearly differentiates, especially since the amendment introduced in 2004 by Directive 2004/27, which added Title VIIIa, entitled 'Information and advertising'. The meaning of those terms is not explained, but it is emphasised that there may be information about medicinal products which is non-promotional in nature. Article 88a, the first article under that new title, stresses the need to ensure that there is objective, good-quality and reliable information and provides for the Commission to a draw up a report on current practice in the field – particularly on the Internet – and its risks and benefits for patients, including proposals for a strategy, addressing in particular the question of the information source's liability.

32. The Commission's report, notified to the European Parliament and to the Council in the final days of 2007, (14) states that it is necessary to ensure the clarity of that conceptual duality, which it expressly acknowledges when it states that, 'since 1992 Community legislation clearly differentiates between advertisement and information on medicines'.

33. The Commission states that '[p]atients have become more empowered and proactive users of healthcare, increasingly seeking information about their illnesses and treatment options including medicines'. It is concerned, moreover, that individuals turn more frequently to the Internet in their investigations; for these reasons, it ends by reiterating that it is necessary to create a framework which provides citizens of the Member States of the European Union with 'understandable, objective, high-quality and non-promotional information about the benefits and the risks of their medicines, and which maintains the confidence of citizens, regulators and healthcare professionals'.

34. In contrast to the provisions governing advertising, those relating to information have not been harmonised. The Member States are therefore free to

adopt any approach they like in this sphere, provided that they do not infringe the Community rules on advertising laid down in Directive 2001/83. As the Commission points out in its report, there are wide variations in national legislation on this point; some apply very restrictive rules, while others allow the supply of non-advertising information.

35. These legal divergences make it difficult for the Community Court to carry out its current task: to draw a clear boundary between advertising and mere information about medicinal products for human use, in the light of Directive 2001/83. Furthermore, the two concepts are so interdependent that it is impossible to separate them, as requested in the question referred for a preliminary ruling, by resorting to a single criterion.

**B – Drawing the boundaries of the two concepts**

36. The Vestre Landsret asks whether 'advertising' under Article 86 of Directive 2001/83 includes the promotion of the therapeutic or prophylactic benefits of a medicinal product by a third party acting on his own initiative and independently, de jure and de facto, of the manufacturer and the seller.

37. In my view, the situation of the author or of the spokesman and, in particular, his relationship with the company which manufactures or distributes the medicinal product, are a factor which, although it may help to determine whether the communication constitutes advertising, must be evaluated together with other circumstances, such as the nature of the activity carried out and the content of the message. The question referred for a preliminary ruling therefore deserves a rather more qualified reply.

**1. Directive 2001/83 defines the concept of 'advertising of medicinal products' in the light of the purpose of the message**

38. The appropriate starting point for the analysis is the wording of Article 86(1) of Directive 2001/83, under which advertising of medicinal products means any form of 'door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products'. It is clear from the provision at issue that the fundamental criterion for separating advertising from mere information lies in the objective pursued: if the intention is to promote 'the prescription, supply, sale or consumption' of medicinal products, there will be advertising for the purposes of the directive; if, on the other hand, 'purely' informative material is being disseminated without promotional intent, it will not come within the Community rules on advertising of medicinal products.

39. The crucial element is thus the deliberate and direct intention of the party who issues the message. I disagree on this point with the position of the Czech Government, whose representative argued at the hearing that it was necessary to assess the concept of advertising according to objective factors, such as the ability of the information to promote the consumption of a product. In my view, when Article 86(1) refers to an activity 'designed to promote' certain conduct, it refers to the volition which guides the action and is, therefore, rooted in subjective criteria.

40. Article 86(2) of the Directive excludes certain kinds of dissemination from Title VIII, probably because it would be complicated to use them with that intention to promote: this is the case with labelling and accompanying leaflets (which are, however, subject to the provisions of Title V); correspondence needed to answer a specific question about a particular medicinal product, even where accompanied by non-promotional material; information relating to pack changes, trade catalogues and price lists; and 'statements relating to human health or diseases', provided , in these last two cases, that there is no reference, even indirect, to medicinal products.

41. This list in Article 86(2) provides important indicia for interpreting the definition of advertising given in Article 86(1), but it is not exhaustive, as there might be cases of non-promotional information not included in the list.

42. Pursuing this idea, we might ask whether a pharmaceutical company is advertising when it informs health personnel about the correct administration of one of its products, if a doctor gives his patient product information to assist with how to take a medicinal product (for example, because of the complexity of its dosage) or publishes a scientific work on a pharmacological advance.

43. In my view, in all these situations, although a medicinal product is mentioned, it is necessary to examine whether the dissemination had the promotional objective referred to in Article 86 of Directive 2001/83. As I have explained above, the party issuing the information and the context in which it is disseminated it may provide relevant criteria for the assessment.

**2. The Directive does not preclude the advertising message coming from an independent third party**

44. Returning to the question which has been referred for a preliminary ruling, the directive, taken literally, does not preclude extending the concept of advertising to dissemination by an independent third party. An offer of information or inducement made by a person unconnected with the company which manufactures or distributes the medicinal product may be in the nature of advertising if it is designed 'to promote the prescription, supply, sale or consumption of medicinal products'. Article 86 of the Directive stresses the purpose of the activity and is not concerned with the party called upon to carry it out.

45. Usually, the 'promotion' of a medicinal product is ensured by someone who, owing to his direct or indirect relationship with the manufacturers or distributors, benefits from an increase in sales, but the scope of the aforementioned Article 86 also allows for a message originating from a person encouraging the consumption or prescription of a medicinal product in order to satisfy any non-economic aspiration to be held to be advertising. (15) Therefore, advertising of a medicinal product might be effected by someone who does not

manufacture, distribute or market it and who is unaffected by fluctuations in sales.

46. I disagree on this point with the observations made by the European Commission in these proceedings. In its pleadings it claims, referring to Article 86(1) of Directive 2001/83, that the Community legislature did not intend to regulate the dissemination of information about medicinal products by independent third parties. After explaining what is meant by 'advertising of medicinal products' in Title VIII, that article states that the concept includes advertising both to the general public and to persons qualified to prescribe and, to illustrate this, it refers to (16) certain activities, such as visits by medical sales representatives, supplies of samples, or sponsorship of promotional meetings or scientific congresses.

47. The Commission adds that the examples given in Article 86(1) involve tasks which have to be carried out by the holder of the authorisation or other groups of persons interested in the marketing of the medicinal product. However, someone who is not directly concerned with the marketing may sponsor a promotional meeting or scientific congress, such as those referred to in that article. Furthermore, the wording of recital 53 (17) (to which the Commission also refers in its pleadings) is merely intended to ensure that the information supplied by the companies is reliable, but it does not rule out that it may originate from other sources.

48. Nor do I agree with the Polish Government's submission that Article 98(3) of Directive 2001/83, in providing that the Member States may not prohibit the co-promotion of a medicinal product by the holder of the marketing authorisation and one or more companies nominated by him, is seeking to limit the number of persons authorised to advertise for medicinal products; this interpretation goes beyond the letter and spirit of that article.

49. That being said, without prejudice to the foregoing, the directive is based on the premise that statements by third parties represent something other than advertising (Article 90 is very instructive in that regard, as I shall explain later), and that perception underlies a number of judgments of Court of Justice (as in Gintec and Ter Voort, referred to above).

50. Article 90 of the directive prohibits, in advertising to consumers, any material which 'refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products' (Article 90(f)), and the inclusion, in improper, alarming or misleading terms, of 'claims of recovery' (Article 90(j)). In both cases, reference is made to information which has that promotional impact, but they are treated as separate from advertising in the strict sense of the term. The Directive expressly excludes those two kinds of statements from advertising to the general public, but says nothing as to their being disseminated independently and used in advertising to persons qualified to prescribe.

51. The Court of Justice interpreted Article 90 in the judgment in Gintec, stating in paragraph 37 that the achievement of the objective of Directive 2001/83 would be compromised were a Member State to be able to extend the obligations laid down therein and introduce an absolute and unconditional prohibition, not expressly provided for by that directive, on the use in the advertising of medicinal products of references to statements from third parties, whilst that directive prohibits their use only where they contain specific material or come from certain designated persons.

52. The Court of Justice confirmed, on this point, my Opinion in that case, where I affirmed that Directive 2001/83 does not contain an outright abstract ban on advertising using statements of non-professional third parties or any relevant statements, but it does prohibit statements which are in some way 'unusual and, because they are inappropriate, exaggerated or excessive ("improper"), worrying or perturbing ("alarming") or potentially deceptive ("misleading"), encourage uncontrolled consumption' (points 47 and 69).

53. I also pointed out in that Opinion that, in accordance with the judgment in Deutscher Apothekerverband, (18) the Member States must not censure what Directive 2001/83 does not reject and that, since that directive, 'which offers a high level of protection of human health, is directed at eliminating disparities in national provisions relating to the advertising of medicinal products by introducing a common regime which guarantees their free movement within the single market, it would be inconsistent to interpret the exceptions broadly' (point 45).

54. I consider, in line with the above, that, if the Member States may prohibit the revelations of third parties in advertising of medicinal products intended for the general public only in the circumstances described in Article 90 of the directive, it would be unacceptable for those statements to be completely prohibited for medicinal products which are unauthorised or available only on prescription, simply because they were considered to be a variant of advertising activity.

55. The judgment in Ter Voort, also cited above, added, in paragraph 31, that 'the dissemination of information about the product, in particular about its therapeutic or prophylactic properties, by a third party acting on his own initiative and completely independently, de jure and de facto, of the manufacturer or the seller does not constitute by itself a "presentation" within the meaning of the directive', since it does not reveal an intention on the part of the manufacturer or the seller to market the product as a medicinal product. The findings of the Court in Ter Voort cannot simply be transferred over and applied to the present case, because in that case it was necessary to ascertain whether the statements of a third party constituted a 'presentation' of a product, whereas here it is necessary to determine whether those statements constitute 'advertising' for the purposes of Directive 2001/83. However, it is telling that the Court of Justice refused to hold that the dissemination of information by a third party con-

stituted 'presentation' of a product, in the absence of an intention to market the product. (19)

56. Following the foregoing explanations, it should be emphasised that the wording of Article 86 of Directive 2001/83 does not allow a distinction to be drawn a priori between statements which are advertising and which are merely informational solely on the basis of who the author is, since advertising of a medicinal product may emanate from the manufacturer, the seller or someone wholly unconnected with either of them, whose actions are prompted by other interests. Be that as it may, although the communication by an independent third party of information about a medicinal product may possibly be regarded as advertising within the meaning of the directive, its precise classification must be made after an overall assessment of a number of factors, such as the existence of a link between the author of the dissemination and the pharmaceutical company, a matter which, although it is not a determining factor, is a particularly important indication, because a third party does not often provide information about a medicinal product for a promotional purpose. Together with this criterion relating to the person, it is necessary to weigh up the signs provided by another two circumstances: first, as I have already said, whether the message is promotional; and, secondly, whether the activity is of a commercial nature.

**3. The directive does not require that the advertising of medicinal products be in the context of commercial or industrial activity**

57. Mr Damgaard's representative maintains that, in accordance with recital 42 of Directive 2001/83, (20) the concept of advertising referred to in Article 86 must be interpreted on the basis of the definition of that term provided by the Community legislation on misleading advertising. Article 2(1) of Directive 84/450 (21) reduces that definition to the making of a representation 'in connection with a trade, business, craft or profession'. If this additional requirement were added to medicinal products, that would rule out the possibility of regarding the dissemination of information by an independent third party as advertising.

58. According to the United Kingdom Government, the directive on misleading advertising should be the 'model' for the definition of advertising of medicinal products in Directive 2001/83; it bases its argument on a historical commentary of the latter Directive and on the travaux préparatoires for its precedent, Directive 92/28.

59. The Commission's directive proposal contained a definition of advertising of medicinal products which reflected that of the directive on misleading advertising and was therefore limited to advertising in connection with a trade or business. During the draft proposal procedure, the European Parliament suggested broadening the scope of the directive by adding non-commercial activities. The approved text did not adopt the reference of the directive on misleading advertising or the wording suggested by the Parliament in its amendments, which were rejected.

60. The United Kingdom infers from those legislative vicissitudes that the Community legislature sought to apply the concept of advertising in the aforementioned directive on misleading advertising to the pharmaceutical sector.

61. This perception of the directive is incorrect, since the legislature's silence reveals that it was aware of the undesirability of providing a clear and categorical response in the area of provisions on advertising. It is probably for this reason that the directive removed the reference to the requirement that advertising had to be in connection with a trade or business and also ruled out extending it to non-commercial circles. In short, the omission in the directive to reproduce the definition of advertising given in Directive 84/450 and the Directive on television broadcasting activities (22) (which also contains the factor of the connection with a trade or business) was wholly intentional. It was necessary to take a less categorical, more nuanced approach, like the one I am attempting to outline in this Opinion. (23)

62. Moreover, under the principle of lex specialis generalibus derogat, (24) the directive on misleading advertising does not apply where there is a specific legislative provision. The Court of Justice held, in paragraph 31 of its judgment in Gintec, that Directive 2001/83 contains specific rules on the advertising of medicinal products and therefore constitutes a special rule as compared with Directive 84/450. Consequently, although the latter directive will apply in cases of misleading advertising, in the sphere of medicinal products there is an autonomous definition of advertising.

**4. Preliminary corollary**

63. Following the preliminary observations above, it is possible to put forward a few conclusions:

64. In the first place, in order to classify the dissemination of information about a medicinal product as advertising, it is necessary to ascertain whether it was designed to promote the prescription, supply, sale or consumption of the product.

65. Secondly, the links between the author of the dissemination and the pharmaceutical company and also the industrial or commercial context in which the information appeared are significant indications that it constitutes advertising, although a message from an independent third party might constitute advertising for the purposes the directive and the definition of 'advertising of medicinal products' in Article 86 must not be modelled on the generic concept of advertising in other Community rules.

66. In any event, it is for the Vestre Landsret, since it has direct knowledge of the facts in the main proceedings, to assess whether Mr Damgaard is independent of Natur-Drogeriet A/S and whether the information which he put online on his website was promotional. To that end, it is appropriate to ascertain, for example, whether the logo of the brand, product or company was featured, and to examine the information provided on strictly commercial aspects (such as the price and sales points) of Hyben Total.

**C – The protection of the right to freedom of expression**

67. In addition to the above, the Danish court must weigh up Mr Damgaard's right to express freely his opinion, since, as the Court of Justice held in Lindqvist, (25) it is for the national authorities and courts to make sure that the interpretation of Community law they select does not infringe the fundamental rights protected by the legal order of the Union or the other principles of Community law, such as the principle of proportionality.

68. According to settled case-law, fundamental rights form part of the general principles of law observance of which is guaranteed by the Court of Justice, which is guided by the constitutional traditions common to the Member States and international instruments relating to the protection of human rights to which Member States have given their cooperation or signature. (26)

69. These principles were embodied in Article 6(2) EU, which provides that '[t]he Union shall respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 ["ECHR"] and as they result from the constitutional traditions common to the Member States, as general principles of Community law'.

70. Freedom of expression forms part of the body of constitutional law of each of the Member States (27) and is enshrined in Article 10 of the ECHR and Article 11 of the Charter of Fundamental Rights of the European Union. (28) There are many judgments of the Court of Justice which uphold the right to freedom of expression within the Community. (29)

71. The European Court of Human Rights has emphasised the great importance of this freedom, stating that it constitutes 'one of the essential foundations of [a democratic] society, one of the basic conditions for its progress and for the development of every man'. (30) Thus, the protection it affords is applicable not only to '"information" or "ideas" that are favourably received or regarded as inoffensive or as a matter of indifference, but also to those that offend, shock or disturb the State or any sector of the population'. (31)

72. As the Court of Justice pointed out in Cwik, freedom of expression '[enables] expression to be given to opinions which differ from those held at an official level'. (32)

73. Those judicial decisions are of particular importance to the present case, which concerns the dissemination of information about an unauthorised medicinal product.

74. In my Opinion in Gintec, I have no doubt that Directive 2001/83, sensitive to the concern of the EC Treaty to safeguard health, promotes the correct and rational use of medicinal products. That intention, however, must allow some margin for the specific features of freedom of expression, since the protection afforded by that right also extends to statements which the health authorities may consider a threat to the aforementioned objective of safeguarding health.

75. The Court of Justice referred to the need to weigh up all the rights and issues at stake in Lindqvist, in which criminal proceedings were brought against a Swedish catechist for having set up a number of Internet pages containing information about herself and 18 of her colleagues in the parish, including their names and, in some cases, their family circumstances, telephone numbers and other details, without first obtaining their consent. In so far as is relevant to the present case, the Court of Justice stressed that 'Mrs Lindqvist's freedom of expression in her work preparing people for Communion and her freedom to carry out activities contributing to religious life have to be weighed against the protection of the private life of the individuals about whom Mrs Lindqvist has placed data on her internet site'.

76. Freedom of expression may be subject, under Article 10(2) of the ECHR, 'to such formalities, conditions, restrictions or penalties as are prescribed by law' and, in particular, to those which are necessary, in a democratic society, for the protection of health.

77. However, the Court of Justice, in its judgment in Connolly, required these limitations to be interpreted restrictively, adding that '[a]ccording to the Court of Human Rights, the adjective "necessary" involves, for the purposes of Article 10(2), a "pressing social need" and, although "[t]he contracting States have a certain margin of appreciation in assessing whether such a need exists", the interference must be "proportionate to the legitimate aim pursued" and "the reasons adduced by the national authorities to justify it" must be "relevant and sufficient"'. (33)

78. The key factor, then, is the proportionality of the restriction on the right. This was stated by the Court of Justice in Karner, (34) which, because it concerned advertising restrictions, has a certain similarity to the case now under consideration; there Court held that, when the exercise of the freedom 'does not contribute to a discussion of public interest and, in addition, arises in a context in which the Member States have a certain amount of discretion, review is limited to an examination of the reasonableness and proportionality of the interference. This holds true for the commercial use of freedom of expression, particularly in a field as complex and fluctuating as advertising' (paragraph 51).

79. In the present case, it is for the Vestre Landsret to assess whether bringing criminal proceedings against Mr Damgaard constitutes a disproportionate interference such as to infringe his right to freedom of expression or whether, on the contrary, that measure is essential to the achievement of the objectives of protecting health and promoting the proper use of medicinal products pursued by the Community legislation, since that freedom of expression does not extend to the pursuance – in the guise of dissemination or provision of therapeutic information – of advertising activities which, at the present time, are prohibited under Community law.

80. Advertising deserves the protection of Article 10 of the ECHR (35) in that it makes no distinction according to whether the type of aim pursued is profit-making or not; (36) however, the discretion of the Member States to impose limitations is wider in this

field, and restrictions are sometimes imposed in order to prevent unfair competition or false and misleading advertising. In some circumstances, the dissemination of objective and truthful advertising may be suppressed in order to protect the rights of others or rights arising out of the specific features of a particular commercial activity or profession. (37)

81. Finally, we must not forget that Mr Damgaard has relied on his position as a journalist, (38) a matter which it is for the national court to verify and which, if it is true, must be taken into account, since it would afford him a greater degree of protection of the right to freedom of expression. This is apparent from the case-law of the European Court of Human Rights, which, in The Observer and The Guardian v United Kingdom, (39) held that when national authorities adopt measures likely to dissuade the press from imparting information on matters of legitimate public interest, the Court is called upon to carry out a careful review of the proportionality of those measures. This is a logical consequence of the role of 'watchdog' conferred on the media in a democratic society, enabling public opinion to monitor the public authorities. (40)

**VI – Conclusion**

82. In the light of the foregoing considerations, I propose that the Court of Justice give the following reply to the question referred by the Vestre Landsret:

(1) Article 86 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medical products for human use, as amended, is to be interpreted as meaning that dissemination by an independent third party of information about a medical product, including, in particular, its therapeutic or prophylactic properties, is to be considered to be advertising if it is designed to promote the prescription, supply, sale or consumption thereof.

(2) A lack of connection between the author of the information and the sellers or manufacturers of the medicinal product and the non-commercial or non-industrial nature of the activity of that independent third party may, however, be strong indications that a message does not have promotional content.

(3) It is for the national authorities and courts, which are responsible for applying the legislation that transposes Directive 2001/83 into national law, to ensure the correct balance between, on the one hand, the objectives of protecting health and promoting the rational use of medicinal products and, on the other, the right of the party concerned to freedom of expression, taking into account the special protection afforded to the party concerned, if it is established that he is a journalist.

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1 – Original language: Spanish.

2 – 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).

3 – In February 2008, when the aforementioned television presenter made those statements, melatonin was not authorised for sale in Spain, but was freely available in other Member States as a food supplement (the news item may be consulted at http://actualidad.terra.es/sociedad/articulo/abogacia_estado_sdrago_2268719.htm). The similarity with Mr Damgaard's case ends here because, to my knowledge, the investigations carried out by the abogacia del Estado (legal department) of the Spanish Ministry of Health did not lead to any proceedings, probably because it was already planned to authorise that hormone.

4 – 'Viagře už odzvonilo, teď je tady Cialis'. In 2004 a fine of CZK 200 000 was imposed on the author and editor of those short stories.

5 – The current state of opinion is reflected in the public consultation opened recently by the European Commission, which may be found on its webpage: http://ec.europa.eu/enterprise/pharmaceuticals/patients/patients_key.htm.

6 – Council Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use (OJ 1992 L 113, p. 13), repealed by Directive 2001/83.

7 – Council Directive 84/450/EEC of 10 September 1984 relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising (OJ 1984 L 250, p. 17).

8 – Directive of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83 (OJ 2004 L 136, p. 34).

9 – Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1). Directive 2004/27, when wording Article 88a of Directive 2001/83, refers in error to 'Directive 2004/726/EC'.

10 – Lov nr 280 af. 6. maj 1993 om ændring af lov om lægemidler m.v.

11 – At the hearing, Mr Damgaard's representative answered my questions concerning the website, explaining that it provided information about many products, and mentioned the price of Hyben Total.

12 – Case C-374/05 Gintec International [2007] ECR I-0000.

13 – Case C-219/91 Ter Voort [1992] ECR I-5485, paragraph 31.

14 – Communication from the Commission to the European Parliament and the Council concerning the Report on current practice with regard to provision of information to patients on medicinal products in accordance with Article 88a of Directive 2001/83, as amended by Directive 2004/27 (COM(2007) 862 final).

15 – From the definition given in the Directive, for example, it is difficult to deny that the campaigns frequently launched by public authorities to encourage the consumption or prescription of generic medicinal products are in the nature of advertising. Nevertheless, in order to respond to the concerns of the United Kingdom Government, it need only be stated that the fact that these campaigns are in the nature of advertising

does not lead to their prohibition in all cases. There can be no objection to the promotion of generic medicinal products which do not adhere to specific active principles, because, under Article 86(2), they fall outside the scope of Title VIII of the Directive. Likewise, promotions directed at persons qualified to prescribe are not unlawful, even in the case of generic products sold only on prescription, since the Directive only prohibits advertising of that kind of product when it is directed at the general public. Lastly, Article 88(3) of the Directive gives the Member States the power to ban advertising of products the cost of which may be reimbursed; some exceptions may thus be tolerated.

16 – As I deduce from the use of the expression 'it shall include in particular', which appears in the article.

17 – 'Each undertaking which manufactures or imports medicinal products should set up a mechanism to ensure that all information supplied about a medicinal product conforms with the approved conditions of use.'

18 – Case C-322/01 Deutscher Apothekerverband [2003] ECR I-14887.

19 – The Community definition of 'medicinal product' does not indicate whether that presentation is the responsibility of the manufacturer or the seller.

20 – 'This Directive is without prejudice to the application of measures adopted pursuant to [Directive 84/450/EEC] …'.

21 – That provision has been reproduced verbatim in Article 2(a) of Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising (OJ 2006 L 376, p. 21), which codifies Directive 84/450 and its successive amendments.

22 – Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by Law, Regulation or Administrative Action in Member States concerning the pursuit of television broadcasting activities (OJ 1989 L 298, p. 23).

23 – In Deutscher Apothekerverband, cited in footnote 18 above, where the issue was whether a website selling medicinal products contained advertising directed at the general public, Advocate General Stix-Hackl similarly recommends a case-by-case analysis, when she states that '[t]he assessment is based essentially on the objective impression given to consumers by the overall appearance of the website' (point 211 of the Opinion).

24 – As regards the rule for the preferential application of the specific rule, see Case C-136/96 Scotch Whisky Association [1998] ECR I-4571.

25 – Case C-101/01 Lindqvist [2003] ECR I-12971, paragraph 87.

26 – Inter alia Joined Cases 60/84 and 61/84 Cinéthèque and Others [1985] ECR 2605.

27 – For a comparative study of the rules governing freedom of expression in several European constitutions, see Skouris, W. (Ed.), Advertising and constitutional rights in Europe, Nomos Verlagsgesellschaft, Baden-Baden, 1994.

28 – Solemnly proclaimed by the European Parliament, the Council and the Commission in Nice on 7 December 2000 (OJ 2000 C 364, p. 1) and adopted on 12 December 2007 in Strasbourg. The Treaty of Lisbon, which at the time of completion of this Opinion is pending ratification, plans to amend the wording of Article 6 EU, paragraph 1 of which will read as follows: 'The Union recognises the rights, freedoms and principles set out in the Charter of Fundamental Rights of the European Union ..., which shall have the same legal value as the Treaties'.

29 – Case C-288/89 Collectieve Antennevoorziening Gouda [1991] ECR I-4007, paragraphs 22 and 23; Case C-368/95 Familiapress [1997] ECR I-3689, paragraphs 24 to 26; Case C-235/92 P Montecatini v Commission [1999] ECR I-4539, paragraph 137; Case C-273/99 P Connolly v Commission [2001] ECR I-1575, and Case C-274/99 P Connolly v Commission [2001] ECR I-1611; Case C-340/00 P Commission v Cwik [2001] ECR I-10269; and Case C-112/00 Schmidberger [2003] ECR I-5659. In point 111 of his Opinion in Schmidberger, Advocate General Jacobs refers specifically to Article 11 of the Charter.

30 – Judgments of the European Court of Human Rights in Handyside vUnited Kingdom [1976] Series A, No 24, § 49; Appleby and Othersv.United Kingdom, Reports of Judgments and Decisions 2003-VI; Müller and Others [1988] Series A, No 133, § 33; and Vogtv.Germany [1995] Series A, No 323, § 52.

31 – Judgment of the European Court of Human Rights in Handyside, § 49.

32 – Cwik, paragraph 22.

33 – Case C-274/99 Connolly, cited above, paragraph 41. See also Case 5/88 Wachauf [1989] ECR 2609; Case C-177/90 Kühn [1992] ECR I-35; Case C-22/94 Irish Farmers Association and Others [1997] ECR I-1809; and Joined Cases C-20/00 and C-64/00 Booker Aquaculture andHydro Seafood [2003] ECR I-7411. As regards the Strasbourg case-law, see the judgments in Vogt v Germany, § 52, and Wille v Liechtenstein [1999], Reports of Judgments and Decisions 1999-VI, § 61 to 63.

34 – Case C-71/02 Karner [2004] ECR I-3025.

35 – See, on freedom of expression in the European commercial sphere, Twomey, P.M., 'Freedom of expression for commercial actors', in Neuwahl, N.A. and Rosas, A., The European Union and Human Rights, Martinus Nijhoff Publishers, 1995.

36 – Judgment of the European Court of Human Rights in Casado Cocav.Spain [1994] Series A, No 285-A, § 35.

37 – Judgment of the European Court of Human Rights in Marka Intern Verlag GmbH and Klaus BerrmannvGermany [1989] Series A, No 165, § 34. The United States Supreme Court, following a long series of uncertain precedents, has concluded that the First Amendment also applies to advertising, although the Constitution 'accords less protection to commercial speech than to other constitutionally safeguarded forms of expression' (Bolger v Youngs Drug Products Corp., 463 U.S. 60 (1983)).

38 – At the hearing, Mr Damgaard's lawyer reaffirmed her client's experience as a journalist specialising health, dietetics and nutrition.
39 – Judgment of the European Court of Human Rights in The Observer and The Guardian v.United Kingdom [1991] Series A, No 216, § 59.
40 – Sarmiento, D., Mieres, L.J. and Presno, M., Las sentencias básicas del Tribunal Europeo de Derechos Humanos, éd. Thomson-Civitas, Madrid, 2007, p. 81.