

Court of Justice EU, 5 May 2011, Novo Nordisk v Ravimiamet



ADVERTISING LAW

Advertising for medicinal products for doctors and pharmacists:

- also extends to quotations taken from medical journals or other scientific works

In light of the above considerations, the answer to the first question is that Article 87(2) of Directive 2001/83 must be interpreted as extending also to quotations taken from medical journals or other scientific works which are included in advertisements for medicinal products directed at persons qualified to prescribe or supply medicines.

- Prohibited: claims which conflict with the summary of product characteristics; but supplemental information may be permitted.

In the light of the above considerations, the answer to the second question is that Article 87(2) of Directive 2001/83 must be interpreted as prohibiting the publication, in advertising of medicinal products directed at persons qualified to prescribe or supply them, of claims which conflict with the summary of product characteristics, but it does not require that all the claims in such advertisements are included in that summary or can be derived from it. Such advertisements may include claims supplementing the information referred to in Article 11 of that directive, provided that those claims:

- confirm or clarify – and are compatible with – that information, and do not distort it, and
- are consistent with the requirements of Articles 87(3) and 92(2) and (3) of that directive.

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Court of Justice EU, 5 May 2011

(K. Lenaerts, D. Šváby (rapporteur), R. Silva de Lapuerta, E. Juhász and J. Malenovský)
Judgement of the Court (Third Chamber)
5 May 2011 (*)

(Medicinal products for human use – Directive 2001/83/EC – Advertising – Medical journal – Information not included in the summary of product characteristics)

Information not included in the summary of product characteristics)

In Case C-249/09,

REFERENCE for a preliminary ruling under Article 234 EC, from the Tartu ringkonnakohus (Estonia), made by decision of 11 June 2009, received at the Court on 7 July 2009, in the proceedings

Novo Nordisk AS

v

Ravimiamet,

THE COURT (Third Chamber),

composed of K. Lenaerts, President of Chamber, D. Šváby (Rapporteur), R. Silva de Lapuerta, E. Juhász and J. Malenovský, Judges, Advocate General: N. Jääskinen, Registrar: R. Şereş, Administrator, having regard to the written procedure and further to the hearing on 2 September 2010,

after considering the observations submitted on behalf of:

- Novo Nordisk AS, by M. Männik, advokaat, and A. Kmiecik, solicitor,
- the Estonian Government, by L. Uibo and M. Linnam, acting as Agents,
- the Belgian Government, by A. Wespes and T. Martene, acting as Agents,
- the Czech Government, by M. Smolek, acting as Agent,
- the Polish Government, by M. Dowgielewicz, acting as Agent,
- the Portuguese Government, by L. Inez Fernandes and A. P. Antunes, acting as Agents,
- the European Commission, by M. Šimerdová and E. Randvere, acting as Agents, after hearing the Opinion of the Advocate General at the sitting on 19 October 2010,

gives the following,

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Article 87(2) 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) ('Directive 2001/83').

2 The reference has been made in proceedings between the company Novo Nordisk AS ('Novo Nordisk') and Ravimiamet (Medicines Office of the Republic of Estonia) concerning the latter's order requiring Novo Nordisk to withdraw its advertisement for Levemir (insulin detemir), on the ground that it infringed the Law on medicines (Ravimiseadus) ('RavS'), in particular the last part of Paragraph 83(3), which provides that advertisements for medicinal products may not contain information that is not in the summary of product characteristics.

Legal context

European Union law

3 Recitals forty-seven, forty-eight and fifty-two in the preamble to Directive 2001/83 state as follows:

'(47) The advertising of medicinal products to persons qualified to prescribe or supply them contributes to the information available to such persons. Nevertheless, this advertising should be subject to strict conditions and effective monitoring, referring in particular to the work carried out within the framework of the Council of Europe.

(48) Advertising of medicinal products should be subject to effective, adequate monitoring. Reference in this regard should be made to the monitoring mechanisms set up by Directive 84/450/EEC.

...

(52) Persons qualified to prescribe or supply medicinal products must have access to a neutral, objective source of information about products available on the market. Whereas it is nevertheless for the Member States to take all measures necessary to this end, in the light of their own particular situation.'

4 Pursuant to Article 11 of Directive 2001/83, the summary of product characteristics is to contain a detailed list of information, including the qualitative and quantitative composition in terms of the active substances and constituents of the excipient, knowledge of which is essential for proper administration of the medicinal product, pharmacological properties, therapeutic indications, contraindications, adverse reactions (frequency and seriousness), precautions for use, interaction with other medicaments, posology and method of administration and major incompatibilities,

5 Title VIII of Directive 2001/83, headed 'Advertising', contains Articles 86 to 88, and Title VIIIA, headed 'Information and Advertising', contains Articles 88a to 100.

6 Article 86 of Directive 2001/83 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 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.*

...

7 Article 87 of Directive 2001/83 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.'*

8 Article 91 of Directive 2001/83 provides:

'1. Any advertising of a medicinal product to persons qualified to prescribe or supply such products shall include:

- essential information compatible with the summary of product characteristics,*
- the supply classification of the medicinal product.*

Member States may also require such advertising to include the selling price or indicative price of the various presentations and the conditions for reimbursement by social security bodies.

2. Member States may decide that the advertising of a medicinal product to persons qualified to prescribe or supply such products may, notwithstanding paragraph 1, include only the name of the medicinal product or its international non-proprietary name, where this exists, or the trademark, if it is intended solely as a reminder.'

9 Article 92 of Directive 2001/83 is worded as follows:

'1. Any documentation relating to a medicinal product which is transmitted as part of the promotion of that product to persons qualified to prescribe or supply it shall include, as a minimum, the particulars listed in Article 91(1) and shall state the date on which it was drawn up or last revised.

2. All the information contained in the documentation referred to in paragraph 1 shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned.

3. Quotations as well as tables and other illustrative matter taken from medical journals or other scientific works for use in the documentation referred to in paragraph 1 shall be faithfully reproduced and the precise sources indicated.'

National law

10 Paragraph 83 of the RavS lays down the general requirements for advertising medicinal products. According to the Tartu ringkonnakohus (Tartu Court of Appeal), Paragraph 83(3) provides:

'An advertisement for a medicinal product must comply with the basic general requirements for advertising in the Law on advertising (Reklaamiseadus) and be based on the summary of product characteristics determined by the Medicines Office, and may not contain information which is not in the summary of product characteristics.'

11 Paragraph 85 of the RavS concerns the advertising of medicinal products to medical professionals.

According to the referring court, Paragraph 85(1) provides:

'Quotations from scientific literature used in advertisements for medicinal products directed at persons qualified to prescribe medicines, dispensers and pharmacists must be presented without alterations and together with a reference to the source. The holder of the marketing authorization must, on request, make a copy of the original source of the quotation available within three days of receipt of the corresponding request.'

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

12 In April 2008, Novo Nordisk published in the medical journal 'Lege Artis', an advertisement for Levemir (insulin detemir), a medicine available only on prescription.

13 By order of 6 June 2008, the Ravimiamet required Novo Nordisk to cease publication of the advertisements for the medicine Levemir and not to publish, in advertisements for that medicine, information which was not in its summary of product characteristics ('the contested decision').

14 According to the contested decision, the following claims, made in the advertisement for Levemir, do not comply with Paragraph 83(3) of the RavS:

- Effective blood sugar control with lower risk of hypoglycaemia;
- Body weight of 68% of patients does not increase or even decreases;
- 82% of patients inject Levemir (insulin detemir) once a day in clinical practice.

15 It appears from the summary of product characteristics, however, that:

- hypoglycaemia is precisely the most frequent side effect of Levemir;
- comparative tests with NPH insulin and insulin glargine showed that body weight rose slightly or not at all in the Levemir group, and
- Levemir is taken once or twice a day.

16 The contested decision states that the advertisement at issue is unlawful in that:

- it does not state that the risk of hypoglycaemia is lower at night;
- it claims that body weight falls, which is not stated in the summary of product characteristics, and
- the figure of 82% that is cited does not appear in the summary of product characteristics.

17 On 4 July 2008, Novo Nordisk brought an action for annulment of the contested decision before the Tartu halduskohus (Tartu Administrative Court). It claimed *inter alia* that the purpose of advertising a medicinal product to persons who are entitled to prescribe medicines is to disseminate to those persons supplementary information based on data published in scientific journals, and that it is therefore lawful to use quotations from medical and scientific literature which are not expressly stated in the summary of product characteristics.

18 By judgment of 24 November 2008, the Tartu halduskohus dismissed that action. It pointed out, in particular, that under Article 87(2) of Directive 2001/83,

all parts of an advertisement for a medicinal product must comply with the information in the summary of product characteristics and that neither Articles 91(1) and 92(1) of Directive 2001/83, nor recital 47 in the preamble to that directive, provide that information about the medicinal product which does not appear in the summary may be included in an advertisement for a medicinal product.

19 Novo Nordisk appealed against that judgment before the referring court.

20 In those circumstances, the Tartu ringkonnakohus decided to stay the proceedings and to refer to the Court the following questions for a preliminary ruling:

'(1) Must Article 87(2) of Directive 2001/83 ... be interpreted as extending also to quotations taken from medical journals or other scientific works which are included in advertisements for medicinal products directed to persons qualified to prescribe medicines?

(2) Must Article 87(2) of Directive 2001/83 ... be interpreted as prohibiting the publication in advertisements for medicinal products of claims which conflict with the summary of product characteristics, but not requiring that all the claims in advertisements for medicinal products must be included in the summary of product characteristics or be derivable from information in the summary?'

Consideration of the questions referred

The first question

21 By its first question the national court asks, in essence, whether Article 87(2) of Directive 2001/83 applies only to advertisements for medicinal products aimed at the general public or whether it also applies to quotations taken from medical journals or other scientific works contained in advertisements for medicinal products directed at persons qualified to prescribe or supply medicines.

22 It is observed, first of all, that, as the Advocate General stated in point 30 of his Opinion, a systematic analysis of Titles VIII and VIIIa of Directive 2001/83 reveals four groups of rules. Under Title VIII of that directive, entitled 'Advertisement', the general and fundamental principles relating to advertising for medicinal products are first set out in Articles 86 to 88; next, under Title VIIIa, headed 'Information and Advertising', the detailed rules on advertising to the general public are set out in Articles 88 to 90, followed by those on advertising to health professionals in Articles 91 to 96;

and, finally, the rules concerning the obligations of the Member States and of authorisation holders and those relating to advertisements for homeopathic medicinal products are set out in Articles 97 to 100.

23 It is observed that the provisions of Title VIII of Directive 2001/83 are general in nature.

24 Thus, Article 86 of the Directive, which defines the concept of 'advertising of medicinal products' and states that it includes, in particular, the advertising of medicinal products to the general public and to persons qualified to prescribe or supply them, is a general rule applicable to any situation where it is necessary to

determine whether an activity constitutes advertising of medicinal products.

25 Similarly, it is clear from the wording and the content of Article 87 of Directive 2001/83 that that provision contains general principles applicable to all types and parts of advertising for medicinal products.

26 Firstly, the prohibition of any advertising of a medicinal product in respect of which a marketing authorisation has not been granted in accordance with Community law, as provided by Article 87(1) of Directive 2001/83, necessarily applies to all types of advertising since that authorisation procedure is obligatory for all medicinal products.

27 Secondly, it is clear that the general principles stated in Article 87(3) of the Directive, according to which advertising of a medicinal product is to encourage its rational use, by presenting it objectively and without exaggerating its properties, and is not to be misleading, are applicable to all types of advertising for medicinal products, including that directed at the general public or at health professionals.

28 As regards Article 87(2) of Directive 2001/83, interpretation of which is sought by the present question, it appears from its wording that it contains a general rule applicable *inter alia* to advertisements for medicinal products directed at the general public or at health professionals. That provision, in contrast to the provisions under Title VIIIa of that directive, does not specify that it concerns only advertising to the general public or only that directed at persons qualified to prescribe or supply medicinal products.

29 Furthermore, the wording ‘all parts of the advertising’, used in that provision, underlines the general nature of the obligation that information contained in advertising for medical products must comply with the particulars in the summary of product characteristics. Thus, that formulation encompasses quotations from medical and scientific literature, as it does any other part of an advertisement for a medical product.

30 Consequently, it follows, both from the position of Article 87 of Directive 2001/83 in its structure, and from the wording and content of Article 87, that Article 87(2) is a general rule applicable to all advertising for medicinal products, including that directed at persons qualified to prescribe or supply medicinal products.

31 Such an interpretation is consistent with the objective of Directive 2001/83.

32 Indeed, as the Court has held, advertising of medicinal products is liable to harm public health, the safeguarding of which is the essential aim of Directive 2001/83 (see [Case C-421/07 Damgaard \[2009\] ECR I-2629, paragraph 22](#), and [Case C-62/09 Association of the British Pharmaceutical Industry \[2010\] ECR I-0000, paragraph 34](#)).

33 Article 87 of Directive 2001/83 seeks to uphold that objective through the regulation of advertising for medicinal products, first, by prohibiting or limiting the use of information that could mislead the recipient or is inaccurate or unfounded, which could lead to misuse of a medical product and, second, by requiring that certain essential information be provided.

34 As all of the intervening Member States pointed out, those rules also apply to all parts of advertisements directed at persons qualified to prescribe or supply medicinal products, since, in that type of advertising too, incorrect or incomplete information can clearly endanger people’s health and thus jeopardise the fundamental objective pursued by Directive 2001/83.

35 In light of the above considerations, the answer to the first question is that Article 87(2) of Directive 2001/83 must be interpreted as extending also to quotations taken from medical journals or other scientific works which are included in advertisements for medicinal products directed at persons qualified to prescribe or supply medicines.

The second question

36 By its second question the national court asks, in essence, whether Article 87(2) of Directive 2001/83 prohibits only the publication in advertisements for medicinal products of claims which conflict with the summary of product characteristics, or whether it requires that all the claims in advertisements for medicinal products must be included in that summary or may be derivable from information in the summary.

37 As a preliminary point, it should be noted that, as is stated in the second recital in the preamble to Directive 2001/83, the safeguarding of public health is the essential aim of that directive ([Damgaard, paragraph 22](#)).

38 Thus, according to recital 47 in the preamble to Directive 2001/83, whilst the advertising of medicinal products to persons qualified to prescribe or supply them contributes to the information available to such persons, it should, nevertheless, be subject to strict conditions and effective monitoring.

39 Similarly, according to recital 48, advertising of medicinal products should be subject to effective, adequate monitoring.

40 The same concern can be detected in recital 52 in the preamble to Directive 2001/83, according to which persons qualified to prescribe or supply medicinal products must have access to a neutral, objective source of information about products available on the market.

41 As regards, specifically, Article 87(2) of that directive, interpretation of which is sought by the referring state, it is observed, first of all, that its wording prohibits the publication, in advertising of medicinal products, of claims which conflict with the summary of product characteristics.

42 Specifically, no part of an advertisement for medicinal products may ever suggest, *inter alia*, therapeutic indications, pharmacological properties, or other characteristics that conflict with the summary of the product characteristics approved by the competent authorities upon granting marketing authorisation for that medicinal product.

43 It is observed, however, that the European Union legislature did not specify, in Article 87(2) of Directive 2001/83, that all the information in the advertising of a medicinal product must be identical to that contained in the summary of product characteristics. That provision requires only that that information must comply with the summary.

44 In the case of advertising intended for medical professionals, which is at issue in the main proceedings, Article 87(2) of Directive 2001/83 should be read in conjunction with Articles 91 and 92 of that directive.

45 According to Article 91(1) of Directive 2001/83, any advertising of a medicinal product to persons qualified to prescribe or supply such products should include essential information that is compatible with the summary of product characteristics.

46 Similarly, Article 92(1) of that Directive states that any documentation relating to a medicinal product which is transmitted as part of the promotion of that product to persons qualified to prescribe or supply it is to include, ‘as a minimum’, the particulars listed in Article 91(1) and is to

state the date on which it was drawn up or last revised.

47 Lastly, Article 92(3) of Directive 2001/83 specifically provides for the use, in advertising for a medicinal product directed at persons qualified to prescribe or supply it, of quotations, tables and other illustrative matter taken from medical journals or other scientific works, provided that they are faithfully reproduced and the precise sources indicated.

48 In those circumstances, Article 87(2) of Directive 2001/83 cannot be interpreted as requiring that all claims in advertisements for medicinal products directed at persons qualified to prescribe or supply them should be included in that summary of product characteristics or be derivable from information in that summary. Indeed, such an interpretation would render Article 91(1) and Article 92 of that directive meaningless, since those provisions authorise the publication of supplementary information in advertisements directed at health professionals, provided that it is compatible with the summary.

49 In order to contribute, in accordance with recital 47 in the preamble to Directive 2001/83, to the information available to persons qualified to prescribe or supply medicinal products, and taking account of the greater level of scientific knowledge of those persons compared with the general public, advertising of medicinal products to such persons may, therefore, include information that is compatible with the summary of product characteristics, that confirms or clarifies the specifications contained in that summary, pursuant to Article 11 of the Directive, provided that the additional information is consistent with the requirements of Articles 87(3) and 92(2) and (3) of the Directive.

50 In other words, such information, firstly, may not be misleading and is to encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties. Secondly, it must be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned. Finally, quotations, tables and other illustrative matter taken from medical journals or other scientific works are to be clearly identified and the precise sources indicated, so that health professionals are informed of them and can verify them.

51 In the light of the above considerations, the answer to the second question is that Article 87(2) of Directive 2001/83 must be interpreted as prohibiting the publication, in advertising of medicinal products directed at persons qualified to prescribe or supply them, of claims which conflict with the summary of product characteristics, but it does not require that all the claims in such advertisements are included in that summary or can be derived from it. Such advertisements may include claims supplementing the information referred to in Article 11 of that directive, provided that those claims:

– confirm or clarify – and are compatible with – that information, and do not distort it, and
– are consistent with the requirements of Articles 87(3) and 92(2) and (3) of that directive.

Costs

52 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 (Third Chamber) hereby rules:

1. Article 87(2) 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, must be interpreted as extending also to quotations taken from medical journals or other scientific works which are included in advertisements for medicinal products directed at persons qualified to prescribe or supply medicines.

2. Article 87(2) of Directive 2001/83, as amended by Directive 2004/27, must be interpreted as prohibiting the publication in advertising medicinal products directed at persons qualified to prescribe or supply them, of claims which conflict with the summary of product characteristics, but it does not require that all the claims in such advertisements are included in that summary or can be derived from it. Such advertisements may include claims supplementing the information referred to in Article 11 of that directive, provided that those claims:

– confirm or clarify – and are compatible with – that information, and do not distort it, and
– are consistent with the requirements of Articles 87(3) and 92(2) and (3) of that directive.

Signatures

Opinion of Advocate General Jääskinen delivered on 19 October 2010 (1)

Case C-249/09

Novo Nordisk AS

v

Ravimiamet

(Reference for a preliminary ruling from the Tartu Ringkonnakohus Estonia)

(Medicinal products for human use – Directive 2001/83/EC – Advertisement in a medical journal going beyond the information given in the summary of product characteristics – Persons qualified to prescribe)

1. This reference for a preliminary ruling concerns the interpretation of Article 87(2) 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 ('Directive 2001/83'), (2) so far as concerns the content of advertisements for medicines.

2. The Tartu Ringkonnakohus (Tartu Regional Court) raises the question, in relation to quotations from medical journals or other scientific works, of the applicability and scope of the requirement that all parts of the advertising to persons qualified to prescribe or supply medicinal products ('the professionals') must comply with the particulars listed in the summary of product characteristics ('the summary') referred to in Article 87(2) of Directive 2001/83.

I – Legal framework

European Union law (3)

3. Recitals 47, 48 and 52 of Directive 2001/83 concern the advertising of medicinal products to professionals. They provide as follows:

'47. The advertising of medicinal products to persons qualified to prescribe or supply them contributes to the information available to such persons. Nevertheless, this advertising should be subject to strict conditions and effective monitoring, referring in particular to the work carried out within the framework of the Council of Europe.

48. Advertising of medicinal products should be subject to effective, adequate monitoring. Reference in this regard should be made to the monitoring mechanisms set up by Directive 84/450/EEC.

...

52. Persons qualified to prescribe or supply medicinal products must have access to a neutral, objective source of information about products available on the market. Whereas it is nevertheless for the Member States to take all measures necessary to this end, in the light of their own particular situation.'

4. Article 11 of Directive 2001/83, which concerns the summary of product characteristics, defines extensively and exhaustively the information which must be included in the summary, inter alia the composition and information knowledge of which is essential for proper administration of the medicinal product, information useful for therapeutic purposes, contra-indications, the frequency and seriousness of undesirable effects, posology and method of administration and major incompatibilities.

5. According to Article 23(3) of Directive 2001/83, the holder of the marketing authorisation is forthwith to supply to the competent authority any new information which might entail the amendment of the particulars or documents referred to in Article 11.

6. Title VIII of Directive 2001/83 relating to advertising contains Articles 86 to 88 and Title VIIIa entitled

'Information and Advertising' contains Articles 88a to 100.

7. Article 86(1) of Directive 2001/83 provides:

'... "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 medicinal products,
- ...

8. Article 87 of Directive 2001/83 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.'

9. Articles 88 to 90 of Directive 2001/83 concern advertising to the general public although Article 88a concerns information on medicinal products.

10. Articles 91 to 96 of Directive 2001/83 concern advertising to professionals.

11. Article 91 of Directive 2001/83 provides:

'1. Any advertising of a medicinal product to persons qualified to prescribe or supply such products shall include:

- essential information compatible with the summary of product characteristics;
- the supply classification of the medicinal product.

...

2. Member States may decide that the advertising of a medicinal product to persons qualified to prescribe or supply such products may, notwithstanding paragraph 1, include only the name of the medicinal product, or its international non-proprietary name, where this exists, or the trademark, if it is intended solely as a reminder.'

12. Article 92 of Directive 2001/83 provides:

'1. Any documentation relating to a medicinal product which is transmitted as part of the promotion of that product to persons qualified to prescribe or supply it shall include, as a minimum, the particulars listed in Article 91(1) and shall state the date on which it was drawn up or last revised.

2. All the information contained in the documentation referred to in paragraph 1 shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned.

3. *Quotations as well as tables and other illustrative matter taken from medical journals or other scientific works for use in the documentation referred to in paragraph 1 shall be faithfully reproduced and the precise sources indicated.*

National law

13. Paragraph 83 of the Ravimiseadus (Law on medicines, 'the RavS') lays down the general requirements for advertising medicinal products. According to the national court, Paragraph 83(3) provides:

'An advertisement for a medicinal product must comply with the basic general requirements for advertising in the Reklaamiseadus (Law on advertising) and be based on the summary of product characteristics determined by the Ravimiamet, and may not contain information which is not in the summary of product characteristics.' (4)

14. Paragraph 85 of the RavS concerns the advertising of medicinal products to persons qualified to prescribe medicines, dispensers and pharmacists. According to the national court, Paragraph 85

(1) provides:

'Quotations from scientific literature used in advertisements for medicinal products directed at persons qualified to prescribe medicines, dispensers and pharmacists must be presented without alterations and together with a reference to the source. The holder of the marketing authorization must, on request, make a copy of the original source of the quotation available within three days from receipt of the corresponding request.'

II – The main proceedings and the questions referred for a preliminary ruling

15. Novo Nordisk A/S ('Novo Nordisk') published, in April 2008 in the medical journal *Lege Artis*, No 4 (72), an advertisement for the prescription medicine Levemir (insulin detemir).

16. By order of 6 June 2008, the Ravimiamet (Medicines Office), a government body whose mandate is to protect public health by monitoring the medicinal products and medical equipment used in Estonia, required Novo Nordisk to cease publication of the advertisement for the medicine Levemir ('the contested decision'), on the ground that it did not correspond to the summary, and not to publish in advertisements for that medicinal product information which was not in the summary.

17. The contested decision declares that the following claims made in the advertisement for the medicine in question do not comply with Paragraph 83(3) of the RavS:

- 'Effective blood sugar control with lower risk of hypoglycaemia';
- 'Body weight of 68% of patients does not increase or even decreases';
- '82% of patients inject Levemir (insulin detemir) once a day in clinical practice'.

18. On the other hand, it is apparent from the summary that:

- hypoglycaemia is precisely the most frequent side effect of Levemir;

- comparative tests with NPH insulin and insulin glargine showed that body weight increased slightly or not at all in the Levemir group;

- Levemir is taken once or twice a day.

19. The contested decision criticises the applicant on the ground that:

- it is not stated in the advertisement that the risk of hypoglycaemia is lower at night
- the claim made in the advertisement that body weight falls has no basis in the summary;
- the figure of 82% stated in the advertisement does not appear in the summary.

20. On 4 July 2008, Novo Nordisk brought an action for the annulment of the contested decision before the Tartu Halduskohus (Tartu Administrative Court). It claimed inter alia that the purpose of the advertising of a medicinal product to persons who are qualified to prescribe medicines is to disseminate to those persons supplementary information based on data published in scientific journals, and that it is therefore lawful to use quotations from medical and scientific literature which are not expressly used in the summary.

21. By judgment of 24 November 2008, the Tartu Halduskohus dismissed the action. It pointed out, in particular, that, under Article 87(2) of Directive 2001/83, all parts of an advertisement for a medicinal product must be consistent with the information listed in the summary and that the opportunity to include in an advertisement for a medicinal product information about the medicinal product which does not appear in the summary is also not granted by Articles 91(1) or 92(1) of Directive 2001/83 or by recital 47 in the preamble to that directive.

22. Novo Nordisk lodged an appeal against that judgment before the Tartu Ringkonnakohus (Tartu Regional Court).

23. The national court decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'1. Must Article 87(2) of Directive 2001/83/EC be interpreted as extending also to quotations taken from medical journals or other scientific works which are included in advertisements for medicinal products directed to persons qualified to prescribe medicines?

2. Must Article 87(2) of Directive 2001/83/EC be interpreted as prohibiting the publication in advertisements for medicinal products of claims which conflict with the summary of product characteristics, but not requiring that all the claims in advertisements for medicinal products must be included in the summary of product characteristics or be derivable from information in the summary?'

III – Analysis

A – The first question referred for a preliminary ruling

24. The first question concerns, in essence, whether Article 87(2) of Directive 2001/83, which provides that all the parts of the advertising must be consistent with the summary, applies to quotations taken from medical journals or other scientific works which are included in

advertisements for medicinal products directed at professionals.

25. The Commission and the Governments of the Member States which have intervened are unanimous in their view that Article 87(2) of Directive 2001/83 covers quotations from medical journals or other scientific works. Novo Nordisk has not expressly tackled this question.

26. In my view, this question does not pose any particular difficulty.

27. The interpretation proposed by the Member States seems to me to be supported by arguments drawn from the origin of Directive 2001/83 and by its objective and structure.

28. First of all, as regards statements made by third parties to the general public, I would point out that, according to the case-law of the Court of Justice, *inter alia* in *Gintec*, Directive 2001/83 does not prohibit them. (5) Although the judgment in *Gintec* concerns advertising to the general public, the conclusion it draws also applies to advertising to professionals.

29. Secondly, Directive 2001/83 expressly acknowledges that quotations taken from medical journals or other scientific works may be used to promote a medicinal product to professionals. (6)

30. A systematic analysis of Titles VIII and VIIIa of Directive 2001/83 reveals four groups of rules. Articles 86 and 87 of Directive 2001/83 contain general principles relating to all advertising, whereas the detailed rules on advertising to the general public appear in Articles 88 to 90 of that directive, and those on advertising to health professionals in Articles 91 to 96 thereof. The provisions of Articles 97 to 100 concern the obligations of the Member States and of the authorisation holders and the application of the provisions on advertising to homeopathic medicinal products.

31. Although the introduction of Article 88a and Title VIIIa have to a certain extent broken the cohesion of the scheme of the provisions on advertising in Directive 2001/83, I have no doubt that Articles 86 and 87 have general scope as regards the advertising of medicinal products. Such an interpretation is corroborated by the history of the directive, since its Article 86 was originally Article 1 in Chapter 1, entitled ‘Definitions, scope and general principles’, of Directive 92/28, (7) which applied to the whole of Directive 92/28. Articles 86 and 87 are therefore applicable to all advertising of medicinal products (with the exception, laid down in Article 100(1), of the application of Article 87 (1) to homeopathic medicinal products).

32. Moreover, I consider that the Commission, in its proposal, intended that Article 87(2) should apply both to advertising to the general public and to advertising to health professionals. As the Commission has pointed out, a provision similar to that of Article 87(2) of Directive 2001/83 was already included in Article 2(2) of Directive 92/28. The statement of reasons of that proposal stated:

‘With the exception of certain common principles and generalities (Article 2), the proposal for a directive

provides for separate systems for advertising to the general public and advertising to ... professionals’. (8)

33. That conclusion is confirmed by the objective of Article 87(2) of Directive 2001/83, the essential aim of which is to safeguard human health. (9) More specifically, the objective of the provisions on the advertising of medicinal products is to achieve a balance between making information available to professionals (10) and monitoring advertising to ensure that the information it contains is neutral and objective. (11)

34. For these reasons, the expression ‘all parts of the advertising’, in Article 87(2) of Directive 2001/83, must be interpreted as including quotations taken from medical journals which appear in an advertisement for a medicinal product directed to professionals.

35. A different interpretation excluding such quotations from the scope of Article 87(2) would be problematic because it would amount to allowing pharmaceutical undertakings to use quotations taken from medical journals or scientific works to influence the image of their medical product on the market, even if that information is not consistent with the verified and monitored particulars included in the summary, which would be contrary to the objective of Directive 2001/83.

36. In the light of the foregoing, it must be concluded that quotations from medical journals or scientific works appearing in advertisements directed at professionals fall within the scope of Article 87(2) of Directive 2001/83.

B – The second question referred for a preliminary ruling

37. As regards the second question, the parties unanimously take the view that claims which are incompatible with the summary cannot be included in an advertisement for a medicinal product. Therefore, the real problem in the present case is knowing whether the directive precludes the inclusion in advertisements of additional information which does not appear in the summary or is not derivable from it.

1. Preliminary observations

38. The question concerns Article 87(2) of Directive 2001/83. However, in my view, it must be interpreted in conjunction with Articles 91 and 92 of that directive, because it concerns more specifically advertising directed at professionals. I would add that I consider that, in the light of the broad definition given to ‘advertising’ in Article 86 of Directive 2001/83, the provisions of Article 92 of the directive also apply to posters and notices, even though the wording of paragraph 1 of that article states that it applies above all to the promotion of medicinal products by medical representatives.

39. Article 87(2) provides that the advertising of a medicinal product must ‘comply’ with the summary. Articles 91 and 92 expressly state that advertising directed at professionals must include essential information ‘compatible’ with the summary.

40. It is apparent from the wording of the national provision, and from the observations of the parties, that a whole series of interpretations is possible, *inter alia* that all the claims made in an advertisement for a medicinal product must be included in the summary, or that all

the claims made in the advertisement must be included in the summary or be derivable from it, or again that any claims are permitted provided that they are not incompatible with the summary.

41. In my view, what there is here is a sequence of interpretative alternatives rather than clear, mutually exclusive choices. Many cases may be covered by several of those interpretations. For example, advertising on the basis of information in the summary by using synonymous terms might be covered by both the first and the second interpretations envisaged, whereas mentioning a clinical trial giving more accurate results than the parameters cited in the summary might fall under both the second and third interpretations.

42. I would add that the absence of any contradiction, in terms of formal logic, between the product characteristics listed in the advertisement and the summary is too weak a criterion for consistency. Logically, the proposition 'A or B' is not inconsistent with the proposition 'A'; in fact, it can be deduced from it. However, it seems clear to me that the addition of new alternative therapeutic indications, which are not in the summary, is inconsistent with it, even if there is no contradiction in terms of formal logic. (12)

2. Freedom of commercial expression and the principle of proportionality

43. Before establishing an appropriate approach, it is necessary to look more closely at two aspects which, according to Novo Nordisk, support the third hypothesis. Novo Nordisk maintains that the principle of proportionality and the fundamental right to freedom of expression, which also applies to commercial communications, require that only information which is incompatible with the summary is to be prohibited.

44. It is true that the European Court of Human Rights extended to companies and other corporate entities certain rights and freedoms which the Court of Justice also applies in its caselaw.

(13) Union law and the Charter of Fundamental Rights of the European Union ('the Charter') are to the same effect. Article 10 of the European Convention for the Protection of Human Rights and Fundamental Freedoms (14) and Article 11 of the Charter concern freedom of expression, which also includes commercial expression. (15)

45. However, the European Court of Human Rights also makes a distinction between the level of protection conferred on natural persons on the one hand and legal persons on the other. (16)

46. Accordingly, the European Court of Human Rights has held that 'overriding considerations of public health, on which the State and the European Union have, moreover, legislated, may take precedence over economic concerns, and even over certain fundamental rights such as freedom of expression'. (17)

47. As regards the advertising of medicinal products, the Community legislature weighed up the requirements arising from the need to protect public health, on the one hand, and the freedom of commercial expression, on the other, and achieved a balance which is defined in Directive 2001/83. (18) In my view, the protec-

tion of public health must take priority in the interpretation of the provisions concerned. Therefore, I do not think there are grounds for adopting an alternative approach which would maximise freedom of expression in the commercial communications of pharmaceutical laboratories and minimise the scope of the restrictions on advertising as a rule for interpreting Directive 2001/83.

48. Such an approach is likewise not justified by the principle of proportionality. In Union law, this principle applies, first and foremost, to judicial review of the scope of obstacles to the fundamental freedoms and to the acceptable scope of Union activities. (19) It requires that the measures concerned satisfy criteria of aptitude, necessity and proportionality *stricto sensu*, that is to say, that they hinder as little as possible the exercise of the fundamental freedoms and that they leave as large as possible a margin for decision at national level.

49. In my view, the principle of proportionality *stricto sensu* does not apply to the balancing of two fundamental freedoms, namely, the right to health (20) and freedom of expression, if it is conceived as a requirement to minimise the former and maximise the latter. Here, the purpose of the application of the principle of proportionality is to attach weight to the relative importance of the two fundamental rights rather than to minimise the obstacles to freedom of commercial expression caused by the measures relating to the advertising of medicinal products adopted by the Union legislature in order to safeguard public health. Public health must be safeguarded in order to guarantee the fundamental rights, human dignity, the right to life and the right to physical and mental integrity referred to in Articles 1 to 3 of the Charter. (21)

50. In the system of fundamental rights, the right to life is the foremost and must take precedence over the fundamental rights of freedom of action. (22) Freedom of commercial expression is not at the heart of that fundamental right. Therefore, the Union legislature has a wide discretion with regard to the level of protection granted to public health and it is therefore not required to restrict itself to the minimum necessary to protect freedom of expression. The argument that the principle of proportionality requires the adoption of a restrictive approach with regard to the interpretation of the limitations on the advertising of medicinal products is therefore, in my view, unfounded.

3. The purpose of the requirement of compliance

51. As regards the expression 'must comply' in Article 87(2) of Directive 2001/83, the first interpretation proposed, that every claim made in the advertisement for a medicinal product is in the summary, seems to me too restrictive, in the light of Article 87(2), and also of Article 91(1), which require that the information provided in the advertisements complies with and is even compatible with, but not wholly identical to, the information given in the summary. Furthermore, recital 47 of Directive 2001/83 provides that the advertising of medicinal products to professionals contributes to the information available to such persons.

52. Above all, the wording of Article 91(1) and of Article 92 seems to indicate that Directive 2001/83 allows the dissemination of additional details by means simply of information or by means of advertising to health professionals. Those provisions would be meaningless if the advertising could refer only to information contained in the summary.

53. The second interpretation proposed, according to which all the claims made in the advertisement must be included in the summary or be derivable from it, and also the third interpretation, according to which any claim is allowed provided that it is not incompatible does with the summary, give a broader definition of the scope of Article 87(2) of Directive 2001/83. The difference from the first interpretation lies, in my view, in the fact that it is possible to give information which is additional to the summary of the product characteristics, which is precluded by the second interpretation, but allowed by the third interpretation if the information is not inconsistent with the summary.

54. I think the third interpretation is the most persuasive as a point of departure. It seems to me that there may be essential or useful information about the medicinal products which does not appear in the summary of product characteristics but which is nevertheless compatible with it. However, the mere absence of inconsistency between the summary and the advertisement seems to me too weak a criterion.

55. Such an interpretation, which makes it possible to use, in the advertisement, new information which does not appear in the summary or which is not derivable from it, subject only to the condition that it is not inconsistent with the summary, raises the problem that scientific studies vary in quality and validity and sometimes reach different, or even inconsistent, conclusions. If such an interpretation were adopted, pharmaceutical undertakings could select and use in advertisements the study most favourable to their medicinal products, without the control afforded by the information included in the summary, which is part of the procedure for authorising marketing. That could seriously undermine the objectivity and neutrality of information which professionals receive from such sources, contrary to the objective of Titles VIII and VIIIa of Directive 2001/83. (23)

56. Consequently, restrictions as to the type of information which may be used in advertising to professionals and which is not included in the summary are necessary, even if the approach which allows the inclusion of further information not included in the summary in advertising to professionals is adopted.

57. The interpretation of Article 87(2) of Directive 2001/83 must balance the protection of public health, (24) by means of effective monitoring of advertising, (25) and the objective of providing professionals with neutral, objective sources of information about medicinal products available on the market. (26)

58. So far as concerns the classification of the restrictions referred to above, I shall guard against using expressions which add no conceptual clarity to those used in Directive 2001/83. A productive approach

would be, in my view, to take into account the purpose and content of the summary when interpreting the notion of compliance within the meaning of Article 87 (2).

59. The summary contains essential therapeutic, pharmacological and pharmaceutical information concerning the medicinal products. (27) That information is monitored and verified by the competent authority (28) and the holder of the marketing authorisation is required to update the summary on his own initiative. (29) An essential aspect of monitoring is the assessment of the validity, relevance and quality of the scientific information contained in the summary. It follows that the interpretation of Article 87(2) must not permit avoidance of the authorisation holder's obligation to update the summary or to submit information for review by the authorities.

60. As a general rule, it should be unlawful to refer in an advertisement to new scientific developments and results which go beyond the information included in the summary, since there is a procedure expressly laid down for regularly updating the summary. In such a case, I think there is no reason to allow such information to be included in advertising directed at professionals without the competent authorities having given their authorisation. A contrary interpretation would undermine the procedure laid down in Article 23 of Directive 2001/83.

61. Similarly, information which ought to be included in the summary, but which is not, should not be used in advertisements. By that, I mean the particulars which are referred to in Article 11 of Directive 2001/83, but which are not included in the summary because the information was not known at the time the summary was approved by the authorities. That may be the case, for example, of the omission of the fact that the consumption of grapefruit may reduce the effectiveness of a medicinal product although, however, according to Article 11, the summary must include the major incompatibilities. In the light of new information of this kind, it is for the pharmaceutical undertaking to initiate the appropriate procedure to amend the summary, as laid down by Directive 2001/83, and not merely to disseminate that new information in the form of warnings included in advertisements directed at professionals.

62. However, in my view, there are situations in which information which ought to be included in the summary because it is mentioned in Article 11, but is not included, may be included in advertisements. This applies to data which confirm or clarify information given in the summary. For example, new scientific trials which confirm the data given in the summary or which reduce a range of parameters in relation to those set out in the summary ought to be allowed in advertisements for medicinal products directed at professionals. Clearly, that must be verified in each individual case. To give an example: if the summary says that the consumption of grapefruit may reduce the effectiveness of a medicinal product, I think it is lawful to mention in the advertisement a new survey which concluded that the consumption of two grapefruit per day had reduced the

effectiveness of the medicinal product by 15% in the group of patients examined.

63. Nevertheless, it is possible to envisage information or research which is not required by Article 11 of Directive 2001/83, but which is none the less useful for doctors when they are looking for the most appropriate treatment for their patients.

64. Such research and trials may concern, for example, the level of patient satisfaction with the medicinal product in question or alternative methods of administering it or the degree to which patients comply with the recommendations relating to the medicine. By that I mean information on the methods of administration (for example, subcutaneous injection). In the context of insulin treatment, for example, the additional information may concern patient preferences for certain ways of injecting, such as the traditional syringe or an insulin pen provided by the laboratory concerned. The same type of investigation may be envisaged for medicinal products against asthma, which may be ingested or inhaled through a tube.

65. The use of such information in advertisements should be allowed, in so far as they are not incompatible with the information in the summary or if they do not contravene the other requirements of Directive 2001/83, such as the prohibition of misleading advertising.

66. Consequently, additional information which would not have to be included in the summary, but which is not incompatible with the summary, may be included in advertising directed to professionals, provided that it is faithfully reproduced, that its precise source is indicated, that it is not misleading and that it does not contravene the other requirements of Directive 2001/83.

IV – Conclusion

67. In the light of the foregoing considerations, I propose that the Court give the following reply to the Tartu Ringkonnakohus:

‘1. Article 87(2) 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, lays down a general rule which extends to advertisements for medicinal products designed to inform the public and also to advertisements to persons qualified to prescribe or supply medicines, even where the latter include quotations taken from medical journals and other scientific works.

2. Article 87(2) of Directive 2001/83, as amended by Directive 2004/27, is to be interpreted as precluding the publication, in an advertisement for a medicinal product, of claims which are incompatible with the summary of product characteristics.

However, it is not necessary for all the claims made in an advertisement for a medicinal product to be included in the summary of product characteristics or to be derivable from it.

An advertisement may include:

– claims supplementing the information referred to in Article 11 of the aforementioned directive and already

included in the summary of product characteristics, provided that such additional information clarifies or confirms the information given in the summary and does not distort it, and

– claims which supplement the summary of product characteristics, even if they are not mentioned in Article 11 of the aforementioned directive, provided that the additional information is faithfully reproduced, that its precise source is indicated, that it is not misleading and that it does not contravene the other requirements of that directive.’

1 – Original language: French.

2 – 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, ‘Directive 2001/83’). Directive 2001/83 codified several directives in this domain by assembling them in a single text (see the first recital of Directive 2001/83).

3 – Since the reference for a preliminary ruling was made before the entry into force of the Treaty on the Functioning of the European Union (OJ 2008 C 115, p. 47), this document refers to the articles of the Treaty establishing the European Community (OJ 2002 C 325, p. 33).

4 – The Estonian Government pointed out at the hearing that the wording of this provision has recently been amended to bring it into line with the wording of Article 87(2) of Directive 2001/83.

5 – Case C-374/05 Gintec [2007] ECR I-9517, paragraph 36.

6 – Article 92(3) of Directive 2001/83.

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

8 – COM (90) 212 final, paragraph 12.

9 – The second recital in the preamble to Directive 2001/83. Judgments in Case C-421/07 Damgaard [2009] ECR I-2629, paragraph 22, and Case C-62/09 Association of the British Pharmaceutical Industry [2010] ECR I-0000, paragraph 34.

10 – Recitals 47 and 52.

11 – Recital 48.

12 – With regard to the so-called Ross paradox, see José Juan Moreso: Legal Indeterminacy and Constitutional Interpretation, Dordrecht 1998, p. 39.

13 – Opinion of Advocate General Geelhoed in Case C-301/04 P Commission v SGLCarbon [2006] ECR I-5915, point 64.

14 – Signed in Rome on 4 November 1950 (‘the ECHR’).

15 – See the opinion of Advocate General Alber in Case C-71/02 Karner [2004] ECR I-3025, paragraph 75. See also the judgments of 20 November 1989 of the European Court of Human Rights in Markt intern Verlag GmbH and Klaus Beermann, series A. No 165, paragraph 25 et seq., and of 24 February 1994 in Casado Coca v Spain, series A No 285-A, paragraph 35 et seq.

16 – Opinion in *Commission v SGL Carbon*, cited above, point 64.

17 – See the judgments of the European Court of Human Rights of 5 March 2009 in *Hachette Filipacchi Presse automobile and Dupuy v France*, paragraph 56, and *Société de conception de presse et d’édition and Ponson v France*, paragraph 46.

18 – For example, see the second and third recitals of Directive 2001/83.

19 – As regards the second aspect, see the Protocol on the application of the principles of subsidiarity and proportionality (Protocol No 2 annexed to the Treaty on European Union) and Article 5(4) of that Treaty.

20 – See Article 11 of the revised European Social Charter and Article 12 of the International Covenant on Economic, Social and Cultural Rights (<http://www2.ohchr.org/english/law/cescr.htm>). In the judgment of 9 June 1998 in *LCB v United Kingdom* (Reports of Judgments and Decisions 1998-III), the Court of Human Rights also acknowledged the existence of a right to health, linked to the right to life.

21 – The fundamental right to health protection, provided for in Article 35 of the Charter, is not the only relevant fundamental right in this case. In my view, the obligation of the States to adopt positive measures, recognised in the case-law of the European Court of Human Rights (judgment of 23 September 1998 in *A v United Kingdom*, Reports of Judgments and Decisions 1998-VI), also justifies measures to combat threats to human health arising from the activities of private individuals.

22 – See Robert Alexy: ‘On Balancing and Subsumption. A Structural Comparison’, *Ratio Juris* Vol.14 No 4. 2003 (433-449), p. 440.

23 – Recitals 47 and 52 of Directive 2001/83.

24 – The second recital of Directive 2001/83.

25 – Recitals 47 and 48 of Directive 2001/83.

26 – Recital 52 of Directive 2001/83.

27 – Article 11 of Directive 2001/83.

28 – Article 21 of Directive 2001/83.

29 – Article 23 of Directive 2001/83.
