JUDGMENT OF THE COURT (Third Chamber)

5 May 2011 *

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 the Chamber, D. Šváby (Rapporteur), R. Silva de Lapuerta, E. Juhász and J. Malenovský, Judges,

* Language of the case: Estonian.

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. Linntam, acting as Agents,

— the Belgian Government, by A. Wespes and T. Materne, 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 47, 48 and 52 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, contra-indications, 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) (Estonia), 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 authorisation 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) (Estonia). 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-3603, 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 that the precise sources are 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 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.**

[Signatures]