JUDGMENT OF THE COURT (Second Chamber)

8 November 2007 *

In Case C-374/05,

REFERENCE for a preliminary ruling under Article 234 EC, from the Bundesgerichtshof (Germany), made by decision of 21 July 2005, received at the Court on 12 October 2005, in the proceedings

Gintec International Import-Export GmbH

v

Verband Sozialer Wettbewerb eV,

THE COURT (Second Chamber),

composed of C.W.A. Timmermans, President of the Chamber, L. Bay Larsen, K. Schiemann (Rapporteur), P. Kūris and J.-C. Bonichot, Judges,

* Language of the case: German.

Advocate General: D. Ruiz-Jarabo Colomer,
Registrar: B. Fülöp, Administrator,

having regard to the written procedure and further to the hearing on 7 December 2006,

after considering the observations submitted on behalf of:

— Gintec International Import-Export GmbH, by R. Nirk, Rechtsanwalt,

— Verband Sozialer Wettbewerb eV, by M. Burchert, Rechtsanwalt,

— the German Government, by M. Lumma and C. Schulze-Bahr, acting as Agents,

— the Polish Government, by J. Pietras, T. Kozek, M. Wiśniewski and P. Dąbrowski, acting as Agents,

— the Slovenian Government, by M. Remic, acting as Agent,

— the Commission of the European Communities, by B. Stromsky and B. Schima, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 13 February 2007,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation 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'), and of 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Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use (OJ 1992 L 113, p. 13), repealed by Directive 2001/83.

2 The reference was made in the context of proceedings between Gintec International Import-Export GmbH ('Gintec') and Verband Sozialer Wettbewerb eV ('Verband Sozialer Wettbewerb'), the German association for the defence of free competition, concerning advertising distributed by Gintec of medicinal products based on ginseng which it markets in Germany.

Legal context

Community legislation

3 Recitals 2 to 5, 42, 43, 45 and 46 in the preamble to Directive 2001/83 are worded as follows:

'(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) Trade in medicinal products within the Community is hindered by disparities between certain national provisions, in particular between provisions relating to medicinal products (excluding substances or combinations of substances which are foods, animal feeding-stuffs or toilet preparations), and such disparities directly affect the functioning of the internal market.

(5) Such hindrances must accordingly be removed; ... this entails approximation of the relevant provisions.

...

(42) This Directive is without prejudice to the application of measures adopted pursuant to 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].

(43) All Member States have adopted further specific measures concerning the advertising of medicinal products. There are disparities between these measures. These disparities are likely to have an impact on the functioning of the internal market, since advertising disseminated in one Member State is likely to have effects in other Member States.

...

(45) 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.

(46) Furthermore, distribution of samples free of charge to the general public for promotional ends must be prohibited.

...'

4 The provisions of Directive 2001/83 concerning advertising of medicinal products are contained in Titles VIII and VIIIa thereof, entitled 'Advertising' (Articles 86 to 88) and 'Information and Advertising' (Articles 88a to 100) respectively.

5 Article 87 of that directive provides:

'...

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.'

6 Under Article 88(6) of the directive:

'Member States shall prohibit the direct distribution of medicinal products to the public by the industry for promotional purposes.'

7 Article 90 of Directive 2001/83 states:

'The advertising of a medicinal product to the general public shall not contain any material which:

(a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail;

(b) suggests that the effects of taking the medicine are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product;

(c) suggests that the health of the subject can be enhanced by taking the medicine;

(d) suggests that the health of the subject could be affected by not taking the medicine; this prohibition shall not apply to the vaccination campaigns referred to in Article 88(4);

(e) is directed exclusively or principally at children;

(f) 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;

(g) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;

(h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;

(i) could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;

(j) refers, in improper, alarming or misleading terms, to claims of recovery;

(k) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof.'

8 Article 96 of Directive 2001/83 provides:

'1. Free samples shall be provided on an exceptional basis only to persons qualified to prescribe them and on the following conditions:

...

2. Member States may also place further restrictions on the distribution of samples of certain medicinal products.'

9 Directive 2004/27, which amended Directive 2001/83, states in recital 2 in its preamble:

'The Community legislation so far adopted has made a major contribution to the achievement of the objective of the free and safe movement of medicinal products

for human use and the elimination of obstacles to trade in such products. However, in the light of the experience acquired, it has become clear that new measures are necessary to eliminate the remaining obstacles to free movement.'

10 Directive 84/450, as amended by Directive 97/55/EC of the European Parliament and of the Council of 6 October 1997 (OJ 1997 L 290, p. 18) ('Directive 84/450'), provides, in Article 7:

'1. This Directive shall not preclude Member States from retaining or adopting provisions with a view to ensuring more extensive protection, with regard to misleading advertising, for consumers, persons carrying on a trade, business, craft or profession, and the general public.

...

3. The provisions of this Directive shall apply without prejudice to Community provisions on advertising for specific products and/or services or to restrictions or prohibitions on advertising in particular media.

...'

National legislation

11 Paragraph 11 of the Law on the advertising of medicines (Heilmittelwerbegesetz, 'the HWG'), in the version of 19 October 1994 (BGBl. 1994 I, p. 3068), states:

'(1) Outside professional circles medicinal products, procedures, treatments, items or other remedies may not be advertised

...

11. using statements made by third parties, in particular using statements of gratitude, recognition or recommendation, or by reference to such statements,

...

13. using competitions, prize draws or other procedures, the outcome of which is dependent on chance,

...'

The main proceedings and the questions referred for a preliminary ruling

12 The main proceedings arose from Gintec's advertising in May 2000 for various ginseng preparations which it markets and which are registered in Germany as over-the-counter medicinal products. The advertising was accompanied by the following 'Consumer survey evaluation':

'Gintec's Roter Ginseng ®

High intensity of use of Gintec's Roter Ginseng

41% of customers have used Gintec's Roter Ginseng regularly for five years or longer. Another third have been using Gintec's Roter Ginseng for three to four years and around a quarter decided to use it for one to two years.

...

Long-term use of the medication and customer loyalty to Gintec's Roter Ginseng

Almost half of all users decided on long-term use of the medication because the product did them good and they still take Gintec's Roter Ginseng, i.e. daily. Approximately a third take a course of ginseng for 12 months. Only 10% opt for a

shorter course of three to six months and 6% for one of one to three months and repeat their courses of ginseng at certain intervals.

...

Reasons for taking Gintec's Roter Ginseng

Two thirds of those questioned use Gintec's Roter Ginseng to reinforce general well-being. In addition, individual complaints such as heart and circulatory problems were mentioned by half of all those questioned. In each case, a third mentioned that they took Gintec's Roter Ginseng to increase concentration, decrease stress, strengthen the immune system or prevent age-related complaints such as, for example, hardening of the arteries. Around a quarter use Gintec's Roter Ginseng to help with physical stress and 10% use it in convalescence. Another 9% find taking the product to be a useful support during the menopause.

...

Overall evaluation of Gintec's Roter Ginseng

Half of all customers are "very satisfied" with the product and another third consider the product to be "good". Only 2% stated that they noticed no improvement and 17% had to stop taking the product for financial reasons. Over 90% were still using the product at the time of the survey and almost all are always very interested in

receiving further information. 85% choose long-term to buy the 100 capsule pack of Roter Ginseng and only 15% buy the 30 capsule pack of Gintec's Roter Ginseng.'

13 In addition, on 28 May 2000 Gintec announced on its internet site a monthly prize draw with the chance of winning a pack of 'Roter Imperial Ginseng von Gintec Extraktpulver' ('Gintec's Red Imperial Ginseng extract powder') on completion of a form.

14 The Verband Sozialer Wettbewerb, the principal task of which is to combat unfair competition and which is made up of a large number of undertakings in the pharmaceutical sector, criticised Gintec's two advertisements, arguing that they were incompatible with German legislation. First, the advertising including the 'Consumer survey evaluation' contained prohibited references to statements from third parties within the meaning of Paragraph 11(1)(11) of the HWG. Secondly, the prize draw announced on Gintec's internet site is contrary to Article 11(1)(13) of the HWG.

15 The Verband Sozialer Wettbewerb's claim for the withdrawal of the two advertisements at issue was upheld by the Oberlandesgericht (Higher Regional Court) Frankfurt am Main (Germany). Gintec lodged an appeal for 'Revision' of that decision before the referring court.

16 Against that background, the Bundesgerichtshof (Federal Court of Justice) (Germany) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Do the provisions of Directive 2001/83/EC, concerning a reference to statements of third parties who lack professional knowledge of the subject

and advertising with a prize draw, set not only a minimum standard for the prohibition on advertising of a medicinal product to the general public, but also a definitive maximum standard?

(2) If the answer to the first question is in the affirmative:

(a) Is there an improper or misleading reference to a "claim of recovery" within the meaning of Article 90(j) of Directive 2001/83/EC, where the advertiser reports the result of a survey of third parties who lack professional knowledge of the subject with a positive overall evaluation of the medicinal product advertised, without attributing the evaluation to individual fields of application?

(b) Does the lack of an express prohibition on advertising with a prize draw in Directive 2001/83/EC mean that this is basically permitted, or does Article 87(3) of Directive 2001/83/EC contain a catch-all provision on which the prohibition of internet advertising with a monthly low-value prize draw may be based?

(3) Are the above questions to be answered analogously in respect of Directive 92/28/EEC?'

The questions referred for a preliminary ruling

Question 1

17 By its first question, the national court essentially seeks clarification as to the degree of harmonisation brought about by Directive 2001/83 in the area of medicinal products advertising in order to assess a system such as that established by Paragraph 11(1)(11) and (13) of the HWG which prohibits the use, in an advertisement, of all references to statements from third parties and advertising by means of prize draws.

18 It is clear from the order for reference that the national court favours an interpretation to the effect that the provisions of Directive 2001/83 concerning advertising of medicinal products bring about complete harmonisation, subject to any special provisions expressly laying down minimum standards. Whilst Gintec, the Slovenian Government and the Commission of the European Communities essentially share that position, the defendant in the main proceedings and the German and Polish Governments for their part favour the minimum harmonisation argument, considering that the Member States are entitled to provide for stricter rules than those laid down by that directive.

19 In that regard, it is necessary to point out that Directive 2001/83 was adopted on the basis of Article 95 EC, which, in paragraph 1, permits, by way of derogation from Article 94 EC and save where otherwise provided in the EC Treaty, the adoption of measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market. Accordingly, recitals 4 and 5 in the preamble to that directive state that the directive aims to remove the hindrances to trade in

medicinal products that are created by disparities between national provisions relating to medicinal products thus directly affecting the functioning of the internal market. Recital 43 in the preamble to the directive specifically concerns the medicinal products' advertising sector and states that the disparities between the measures adopted by the Member States in that field are likely to have an impact on the functioning of the internal market.

20 On examination, Titles VIII and VIIIa of Directive 2001/83, which bring together the common rules on advertising medicinal products, lend support to the view that that directive brought about a complete harmonisation in that field, since it lists expressly the cases in which Member States are authorised to adopt provisions departing from the rules laid down by that directive.

21 Reference should be made, by way of example, first, to Article 88(3) of Directive 2001/83, which permits Member States to ban, on their territory, advertising of medicinal products the cost of which may be reimbursed.

22 Further, Article 89(1)(b) of that directive does not give an exhaustive list of the information which any advertising to the general public of medicinal products is to contain, thus leaving the Member States some leeway in that regard. In addition, Article 89(2) authorises derogations from Article 89(1) by stating that Member States may decide that the advertising of a medicinal product may include only the name of the medicinal product or its international non-proprietary name, where this exists, or the trade mark if it is intended solely as a reminder.

23 An analogous possibility of derogating from the requirements of Directive 2001/83 in the context of advertising to persons qualified to prescribe medicinal products appears in Article 91 thereof.

24 Finally, Article 96 of Directive 2001/83, which, according to paragraph 1 thereof, permits the distribution of free samples of medicinal products, on specific conditions and on an exceptional basis, only to persons qualified to prescribe them, provides, in paragraph 2, that the Member States may place further restrictions on the distribution of samples of certain medicinal products.

25 Where the option of laying down different rules is not given to Member States expressly, the only conditions which they can place on advertising for medicinal products are those laid down by Directive 2001/83, as Gintec, the Slovenian Government and the Commission rightly maintain. Complete harmonisation of the rules regarding advertising contributes to the removal of hindrances to trade in medicinal products between the Member States, in accordance with Article 95 EC.

26 In Case C-322/01 *Deutscher Apothekerverband* [2003] ECR I-14887, paragraph 144, the Court held that Article 88(1) of Directive 2001/83, which prohibits the advertising of medicinal products which are subject to medical prescription, precludes a national prohibition on advertising the sale by mail order of medicinal products which may be supplied only by pharmacists, in so far as that prohibition also covers medicinal products which are not subject to medical prescription. Thus, in the absence, in Article 88(1) of the directive, of express reference to the possibility of laying down more restrictive or simply different rules, the Court interpreted that provision as an exhaustive rule.

27 It is also necessary to respond to certain arguments submitted to the Court seeking to call into question the contention that Directive 2001/83 brings about a complete harmonisation in the area of advertising for medicinal products except where the possibility of adopting derogating rules is expressly provided for.

28 The defendant in the main proceedings relied in particular on recital 2 in the preamble to Directive 2004/27, according to which the Community legislation so far adopted has made a major contribution to the achievement of the objectives of the free movement of medicinal products for human use and the elimination of obstacles to trade in such products, but, to eliminate the remaining obstacles to free movement, new measures are necessary. According to the defendant in the main proceedings, the fact that the Community legislature wishes to adopt new legislative measures demonstrates that complete harmonisation in that area has not yet been brought about.

29 That argument is based on the erroneous premiss that complete harmonisation in a particular field is incompatible with the fact that such harmonisation is in a state of continuing evolution. The fact that Directive 2001/83 lays down a complete system of rules for the advertising of medicinal products in no way means that the Community legislature cannot amend or adapt those rules or, if necessary, introduce new ones so as better to attain the objectives of removing barriers to intra-Community trade and the protection of public health (see, to that effect, Case C-84/06 *Antroposana and Others* [2007] ECR I-7609, paragraphs 40 and 41).

30 Another argument seeking to demonstrate the alleged incomplete harmonisation brought about by Directive 2001/83 in the field of advertising of medicinal products is based on recital 42 in the preamble to Directive 2001/83, according to which that directive is without prejudice to the application of measures adopted pursuant to Directive 84/450 concerning misleading and comparative advertising. It is submitted that the fact that Article 7 of that directive permits Member States to retain or adopt

provisions with a view to ensuring more extensive protection for consumers than that provided for by Directive 84/450 is indicative of the degree of harmonisation brought about by Directive 2001/83.

31 That argument cannot be accepted. It is clear from the wording of Article 7(3) of Directive 84/450 that the provisions of that directive apply without prejudice to Community provisions on advertising for specific products or services. Since Directive 2001/83 contains specific rules on the advertising of medicinal products, it constitutes, as the Slovenian Government maintained in its written observations, a special rule as compared with the general rules concerning protection against misleading advertising provided for by Directive 84/450. The minimal nature of the harmonisation brought about by Directive 84/450 is therefore irrelevant for the assessment of the degree of harmonisation effected by Directive 2001/83.

32 Finally, it is necessary to deal with the argument of the Polish Government, which referred in its written observations to recital 45 in the preamble to Directive 2001/83, which highlights the fact that the Community legislature intended to lay down minimum criteria of a fundamental nature.

33 Such an interpretation cannot be upheld. The wording of the provisions of Directive 2001/83 concerning the advertising of medicinal products, and their general scheme and purpose, show that that directive seeks to lay down substantive, mandatory criteria for the regulation of the sector in question.

34 It remains to examine what the consequences of the exhaustive harmonisation established by Directive 2001/83 in the field of advertising of medicinal products are for a national provision such as Paragraph 11(1)(11) and (13) of the HWG which

prohibits the use, in an advertisement, of all references to statements from third parties and advertising by means of prize draws.

35 Since the question as to whether advertising for medicinal products in the form of prize draws is lawful is the subject of Question 2(b), it is appropriate in the answer to Question 1 to consider only the question of the interpretation of the provisions of Directive 2001/83 in connection with the prohibition in Paragraph 11(1)(11) of the HWG.

36 In that regard, it must be stated immediately that Directive 2001/83 does not prohibit the use, in an advertising message, of statements by third parties in such a general and unconditional way as Paragraph 11(1)(11) of the HWG. The limits on the use of such statements are specified, in particular, by Articles 87(3) and 90 of that directive. Article 87(3) of Directive 2001/83 requires that advertising should encourage the rational use of the medicinal product by presenting it objectively and without exaggerating its properties and that it should not be misleading. Article 90 of that same directive contains, for its part, specific directions regarding the content of advertising for medicinal products, prohibiting the use of various specific types of material.

37 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.

38 It is for the national court, in applying the provisions of domestic law, to interpret them, so far as possible, in the light of the wording and the purpose of the directive concerned in order to achieve the result sought by it (see, to that effect, Joined Cases C-397/01 to C-403/01 *Pfeiffer and Others* [2004] ECR I-8835, paragraph 113).

39 In those circumstances, the answer to Question 1 must be that Directive 2001/83 brought about complete harmonisation in the field of advertising of medicinal products and lists expressly the cases in which Member States are authorised to adopt provisions departing from the rules laid down by that directive. The directive must therefore be interpreted to the effect that a Member State may not provide, in its national legislation, for an absolute and unconditional prohibition, in the advertising of medicinal products to the general public, on the use of statements from third parties, whilst their use can be limited, under that same directive, only by reason of their specific content or the type of person making the statement.

Question 2(a)

40 By this question, the national court seeks an interpretation from the Court of the term 'claims of recovery' in Article 90(j) of Directive 2001/83, in order to determine whether an advertisement for a medicinal product, containing a positive overall evaluation of that medicinal product without indicating individual therapeutic effects, must be considered to be referring in improper or misleading terms to such a claim.

41 Gintec submits in its written observations that the term 'claim of recovery' presupposes the existence of a certificate issued by a person, whether qualified or not, stating that the use of the medicinal product in question contributed to relieving a specific illness.

42 That argument cannot succeed. Directive 2001/83 does not specify the nature, the form or the possible origin of such a claim.

43 In fact, any form of door-to-door information, however it is presented and whoever its author, the content of which states that the use of the medicinal product will lead to recovery, in other words to the restoration to health of the person suffering from an illness or from particular health problems, is in the nature of a 'claim of recovery'.

44 However, positive overall evaluation of the medicinal product which includes only references to the reinforcing of the person's general well-being does not correspond, generally, to those criteria. For such references to be classified as claims of recovery, it is necessary, as the Advocate General pointed out at point 68 of his Opinion, for there to be a reference to therapeutic efficacy in terms of alleviating or curing illnesses or injuries.

45 It is for the national court, which alone has direct knowledge of the facts of the main proceedings, to assess the extent to which Gintec's advertising, taken as a whole, referred to the therapeutic efficacy of ginseng-based medicinal products marketed by that company in the context of a specific illness or health problems. However, its attention should be drawn to the fact that, as is clear from the file submitted to the Court, the 'Consumer survey evaluation' in question refers, under the heading 'Reasons for taking Gintec's Roter Ginseng', the text of which is set out at paragraph 12 of this judgment, to heart and circulatory problems, as well as hardening of the arteries and the menopause.

46 In any event, if the national court should actually find, in the advertising in question, a reference to the therapeutic efficacy of the medicinal products at issue in the main proceedings, in terms of the alleviation or cure of illnesses and health problems, thus

enabling that advertisement to be classified as one including claims of recovery, it is still necessary for such a reference to be made in improper, alarming or misleading terms for it to constitute advertising such as that defined in Article 90(j) of Directive 2001/83.

47 That would, in particular, be the case if the curative effects of those medicinal products were presented in exaggerated terms which could encourage their consumption or in terms liable to provoke fear of the possible consequences of not taking them, or, again, if properties they do not possess were attributed to the same medicinal products, thus misleading the consumer as to how they work and what their therapeutic effects are. It must be pointed out, in that regard, that there is an obligation under Article 87(2) of Directive 2001/83 to ensure that all parts of the advertising of a medicinal product comply with the particulars listed in the summary of product characteristics.

48 Finally, in order to provide the national court with an answer which will be of use to it and enable it to determine the case before it, its attention should be drawn to Article 90(c) of Directive 2001/83, the potential relevance of which was referred to by the Commission in its written observations. It should be borne in mind that the Court may find it necessary to consider provisions of Community law to which the national court has not referred in its question (see Case C-421/04 *Matratzen Concord* [2006] ECR I-2303, paragraph 18).

49 Article 90(c) of Directive 2001/83 provides that the advertising of a medicinal product to the general public is not to contain any material which suggests that the health of the subject can be enhanced by taking the medicine, the objective being to prevent consumers from being encouraged to obtain medicine the use of which is not objectively necessary, in the absence of a specific health problem.

50 That appears to be the case of the 'Consumer survey evaluation' at issue which, under the heading 'Reasons for taking Gintec's Roter Ginseng', the text of which is set out at paragraph 12 of this judgment, gives the impression that the use of the ginseng-based medicines in question contributes to reinforcing 'general well-being'. It is for the national court to investigate that possibility.

51 It must be recalled that recital 45 in the preamble to Directive 2001/83 emphasises the need to prevent any excessive and ill-considered advertising which could affect public health. That imperative is reflected in Article 87(3) of the directive, under which advertising of medicinal products must encourage their rational use.

52 In the light of the foregoing, the answer to Question 2(a) must be that Directive 2001/83 requires Member States to provide, in their national legislation, for a prohibition on the use, in the advertising of medicinal products to the general public, of statements from third parties where those refer, in improper, alarming or misleading terms, to claims of recovery within the meaning of Article 90(j) of Directive 2001/83, the term 'claims of recovery' having thus to be interpreted as not including references to the reinforcement of a person's well-being where the therapeutic efficacy of the medicinal product in terms of the elimination of a particular illness is not referred to. Article 90(c) of Directive 2001/83 also requires Member States to provide, in their national legislation, for a prohibition on the use, in the advertising of medicinal products to the general public, of statements from third parties where they give the impression that the use of the medicinal product contributes to the reinforcement of general well-being.

Question 2(b)

53 By this question, the national court asks, essentially, whether, in the absence of an express prohibition in Directive 2001/83 on the advertising of medicinal products by

means of prize draws, the latter is permitted or prohibited by Article 87(3) of that directive.

54 It is clear from the order for reference that Gintec announced on its internet site that it was introducing a monthly prize draw offering participants the chance of winning a pack of Red Imperial Ginseng extract powder.

55 Although Directive 2001/83 does not lay down specific rules on the advertising of medicinal products by means of prize draws, such advertising is difficult to accept in the light of the need, expressed in recital 45 in the preamble to that directive, to prevent any excessive and ill-considered advertising which could affect public health. Article 87(3) of that directive reiterates that need, by requiring that advertising of medicinal products must encourage their rational use.

56 As the German and Slovenian Governments rightly submitted, the advertising of a medicinal product by means of prize draws encourages the irrational and excessive use of that medicinal product, by presenting it as a gift or a prize, thus distracting the consumer from an objective evaluation of whether he needs to take such medicine.

57 Gintec submits that the purpose of such a 'low value' prize is to encourage the consumer to participate in a survey. That argument cannot be upheld, since such a survey could be organised just as well without resorting to measures encouraging the irrational use of a medicinal product, a phenomenon which Directive 2001/83 seeks to combat.

58 Moreover, the possibility of winning a medicinal product in a prize draw can be equated with free distribution. It should be noted in this regard that Article 88(6) of Directive 2001/83 prohibits the direct distribution of medicinal products to the public by the pharmaceutical industry for promotional purposes. In addition, under Article 96(1) of that directive, free samples are to be provided on an exceptional basis only to persons qualified to prescribe medicinal products and on the conditions listed in the provision.

59 In the light of the foregoing, the answer to Question 2(b) must be that Articles 87(3), 88(6) and 96(1) of Directive 2001/83 prohibit the advertising of a medicinal product by means of a prize draw announced on the internet, inasmuch as it encourages the irrational use of that medicinal product and leads to its direct distribution to the general public and to the presentation of free samples.

Question 3

60 By its third question, the national court asks whether the first and second questions referred would be answered in the same way if Directive 92/28 applied.

61 Since Directive 2001/83 repeats the provisions of Directive 92/28 without changing their content and Directive 2004/27 does not introduce significant changes to the provisions applicable to the present case, that question must be answered in the affirmative.

62 Accordingly, the first and second questions submitted for a preliminary ruling would be answered in the same way if the provisions of Directive 92/28 applied.

Costs

63 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:

1. **Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, brought about complete harmonisation in the field of advertising of medicinal products and lists expressly the cases in which Member States are authorised to adopt provisions departing from the rules laid down by that directive. The directive must therefore be interpreted to the effect that a Member State may not provide, in its national legislation, for an absolute and unconditional prohibition, in the advertising of medicinal products to the general public, on the use of statements from third parties, whilst their use can be limited, under that same directive, only by reason of their specific content or the type of person making the statement.**

2. **(a) Directive 2001/83, as amended by Directive 2004/27, requires Member States to provide, in their national legislation, for a prohibition on the use, in the advertising of medicinal products to the general public, of statements from third parties where those refer, in improper, alarming**

or misleading terms, to claims of recovery within the meaning of Article 90(j) of Directive 2001/83, as amended by Directive 2004/27, the term 'claims of recovery' having thus to be interpreted as not including references to the reinforcement of a person's well-being where the therapeutic efficacy of the medicinal product in terms of the elimination of a particular illness is not referred to. Article 90(c) of Directive 2001/83, as amended by Directive 2004/27, also requires Member States to provide, in their national legislation, for a prohibition on the use, in the advertising of medicinal products to the general public, of statements from third parties where they give the impression that the use of the medicinal product contributes to the reinforcement of general well-being.

(b) **Articles 87(3), 88(6) and 96(1) of Directive 2001/83, as amended by Directive 2004/27, prohibit the advertising of a medicinal product by means of a prize draw announced on the internet, inasmuch as it encourages the irrational use of that medicinal product and leads to its direct distribution to the general public and to the presentation of free samples.**

3. **The first and second questions submitted for a preliminary ruling would be answered in the same way if the provisions of Council Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use applied.**

[Signatures]