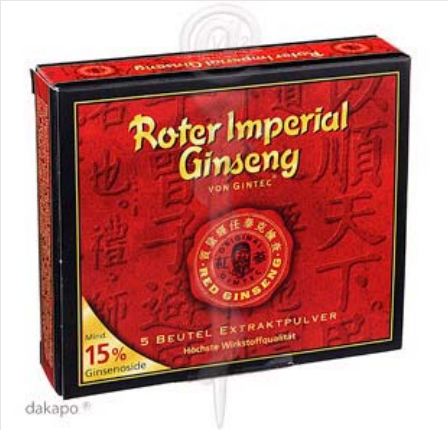
European Court of Justice, 8 November 2007, Gintec



ADVERTISING – FREE MOVEMENT

Complete harmonisation advertising of medicinal products

- **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 Mem-ber State may not provide, in its national legislation, for an absolute and unconditional prohibition, in the adver-tising 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 rea-son of their specific content or the type of person making the statement.

Claims of recovery

- **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.**

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.

Prize draw

- **That Articles 87(3), 88(6) and 96(1) of Directive 2001/83 prohibit the advertising of a medici-nal 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 distribu-tion to the general public and to the presentation of free samples.**

Source: **curia.europa.eu**

European Court of Justice, 8 November 2007
(C.W.A. Timmermans, L. Bay Larsen, K. Schiemann, P. Kūris and J.-C. Bonichot)
JUDGMENT OF THE COURT (Second Chamber)
8 November 2007 (*)
(Directives 2001/83/EC and 92/28/EEC – National legislation prohibiting advertising of medicinal products by way of statements of third parties or prize draws – Use of generally positive results of a consumer survey and a monthly prize draw to win a pack of the product)
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,
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 feedingstuffs 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-0000**, 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.

OPINION OF ADVOCATE GENERAL UIZ-JARABO COLOMER

delivered on 13 February 2007 (1)
Case C-374/05
Gintec International Import-Export GmbH
v
Verband Sozialer Wettbewerb eV
(Reference for a preliminary ruling from the Bundesgerichtshof, (Germany))
(Directive 2001/83/EC– Medicinal products for human use – Advertising – Complete harmonisation – Advertising to the general public – Prohibitions and restrictions – Advertising with a prize draw and claims of recovery – Interpretation of Articles 87(3) and 90(j))

– Introduction

1. The various ingredients which go into the recipe for a preliminary ruling are clearly enough set out in the European Union cookbook, but theory comes up against the varying circumstances which apply each time the dish is prepared, as the chosen heat source, the pans, the condition and origin of the ingredients and even the state of mind of whoever is cooking are always different. While the national courts take primary responsibility for the dish, the Court of Justice merely provides them with the all-important Community seasoning, without interfering in matters which do not concern it. Nevertheless, the European and national elements frequently become mixed up and, to allow them to perform their functions, each must absorb and refine the flavours of the other.

2. The present reference has more dimensions than are first apparent. It puts forward three questions, but between the first and the second questions further queries arise to which, the Court of Justice must give an answer that will determine the outcome of the case.

3. The First Civil Chamber of the Bundesgerichtshof (Federal Court of Justice) would like to know whether the rules on advertising contained in 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, (2) rather than setting out to harmonise by setting minimum standards, devises a complete system so that the Member States have no room for manoeuvre and cannot add further restrictions to those indicated by the directive (first question). However, as German legislation includes prohibitions which do not feature in the European rules, in reality what is sought to be established is whether and to what extent Community law rejects these national prohibitions.

4. If the first question is answered in the affirmative, the German court entertains two further doubts (the second question): first, whether surveys about the overall evaluation of a medicinal product carried out among non-professionals constitute an improper and misleading reference to a 'claim of recovery' within the meaning of Article 90(j) of Directive 2001/83; the second doubt relates to Article 87(3) and whether it can be characterised as a 'catch-all' provision which would prohibit a monthly Internet draw for a small prize. The German court is therefore taking it for granted that these provisions have direct effect, which is questionable, and consequently it may be desirable to address the first question in a manner which allows us to marry in the national legislation applicable in the main proceedings, thereby filling a vacuum which would be to nobody's advantage.

5. It falls to the Court of Justice, like a reliable kitchen hand who is unable to create a whole meal but acts as the chef's adviser, to provide the Bundesgerichtshof with some guidelines on the interpretation of its own national law by offering it a valuable tool for resolving the dispute.

6. Finally, the referring court seeks guidance on whether Directive 92/28/EEC, (3) Article 2(3) and Article 5(j) of which are repeated in Article 87(3) and Article 90(j) of Directive 2001/83, should be treated in the same way (the third question).

II – The legal framework

A – Directive 2001/83

7. The aim of this Directive, which was adopted under Article 95 EC (formerly Article 100a of the EC Treaty), is 'to safeguard public health' (recital 2) without hindering the development of the pharmaceutical industry or trade in medicinal products within the Community (recital 3).

8. It seeks to remove hindrances to such trade caused by disparities between national provisions by approximating national provisions (recitals 4 and 5), and the advertising of medicinal products is no exception to this, since Member States have adopted specific measures in this area, leading to disparities which are likely to have an impact on the functioning of the internal market (recital 43).

9. Title VIII (4) defines 'advertising of medicinal products' (Article 86) and, having prohibited advertis-

ing of medicinal products which do not have a marketing authorisation (Article 87(1)), provides that such advertising should encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties, and should not be 'misleading' (Article 87(3)).

10. Advertising of medicinal products which are only available on medical prescription is prohibited (Article 88(1)(a)), (5) while advertising of those which, by virtue of their composition and purpose, can be obtained without a prescription (Article 88(2)) is permitted.

11. Even so, the legislature shows great concern for the harmful effect that such advertising might have on public health if it were excessive or ill-considered and, consequently, undertakes to define certain essential criteria (recital 45).

12. To this end, the Directive prohibits the direct distribution of medicinal products for promotional purposes (recital 46 and Article 88(6)). (6)

13. More specifically, Article 89 deals with the form and minimum content of advertising to consumers and Article 90 prohibits the inclusion of any material which:

'…

(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;

…

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

…'

B – The German legislation

14. The Gesetz gegen den unlauteren Wettbewerb (7) (Law against unfair competition (former version) ('UWG')) provides that acts which prejudice competitors, consumers or other parties active in the market are illegal (Paragraph 4); thus, a party acts unfairly when it infringes legal provisions which regulate market conduct in the interest of parties active in the market (Paragraph 4(11)).

15. One such piece of legislation is the Gesetz über die Werbung auf dem Gebiete des Heilwesens (8) (the Heilmittelwerbegesetz or Law on advertising medicines ('HWG')), Paragraph 11(1) of which prohibits advertising outside professional circles:

'…

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, lotteries or other procedures, the outcome of which is dependent on chance;

…'.

III – The facts, the main proceedings and the questions referred for a preliminary ruling

16. Gintec International Import-Export GmbH ('Gintec') markets various ginseng preparations (9) registered in the Federal Republic of Germany as over-the-counter medicinal products.

17. In May 2000 it published leaflets on a 'consumer survey evaluation', which set out information using various different headlines:

– 'High intensity of use … 41% of customers have used Gintec's Roter Ginseng regularly for five years or longer …'.

– 'Long-term use of the medication and customer loyalty … 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 …'.

– 'Reasons for taking Gintec's Roter Ginseng. Two thirds of those questioned use Gintec's Roter Ginseng to reinforce general good health. In addition, individual complaints such as heart and circulatory problems were mentioned by half of all those questioned …'.

– '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 …'.

18. On 28 May 2000 Gintec announced on its website a monthly draw for a pack of 'Roter Imperial Ginseng von Gintec Extraktpulver' (Red Imperial Ginseng extract powder), the participant needing only to complete and send off a questionnaire.

19. Verband Sozialer Wettbewerb (Association for the Defence of Free Competition) brought legal proceedings against Gintec on the basis that the two advertising campaigns infringed Paragraph 11(1)(11) and 11(1)(13) of the HWG respectively and, on appeal, it obtained a judgment from the Oberlandesgericht (Higher Regional Court) Frankfurt am Main prohibiting them.

20. Gintec appealed on a point of law to the Bundesgerichtshof, which has stayed proceedings in order to refer the following questions to the Court of Justice for a preliminary ruling:

'1. Do the provisions of Directive 2001/83, 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, 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 mean that this is basically permitted, or does Article 87(3) of Directive 2001/83 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?'

IV – The proceedings before the Court of Justice

21. The order of the Bundesgerichtshof was lodged at the Registry of the Court of Justice on 12 October 2005. The parties to the main proceedings, the Commission and the German, Slovenian and Polish Governments have submitted written observations and, with the exception of the representative of the Slovenian Government, their representatives appeared at the hearing on 7 December 2006.

V – Analysis of the questions referred for preliminary ruling

A – The first question: full harmonisation

22. The essence of this referral is the nature of the harmonisation sought by the rules on the advertising of medicinal products contained in Directive 2001/83. It is not clear whether these rules are exhaustive, with no leeway at all for the national legislature, or whether they lay out a minimum programme, leaving the Member States free to adopt other rules and tighter restrictions.

23. The Commission, the Slovenian Government and Gintec opt for the first of these alternatives, while Verband Sozialer Wettbewerb and the German (10) and Polish Governments advocate the second, paradoxically using the same criteria of interpretation to point to opposing outcomes.

24. If the Directive is interpreted in the light of its objectives, its overall system and the general sense of its provisions and with regard to the legal basis which underpins it, support is found for the view that it establishes a system which allows no room for innovation beyond what is expressly provided for.

1. The legal basis of Directive 2001/83

25. Article 95 EC, which constitutes the legal basis for Directive 2001/83, provides an initial indicator in support of that view: Article 95(1) enables the Council, acting in accordance with the procedure referred to in Article 251 EC (formerly Article 189b of the EC Treaty) and after consulting the Economic and Social Committee, to adopt the 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.

26. It has been held that that provision (11) is intended to improve that market (12) and to eliminate barriers to trade arising from differences between national rules, (13) albeit that a mere abstract risk that such barriers may emerge is not sufficient to justify such Community intervention; the emergence of such barriers must be likely and the measure in question must be designed to prevent them. (14)

27. The Slovenian and German Governments are correct in noting that Article 95 EC gives no guidance as to what type of harmonisation it is advocating, (15) but it seems contradictory that, in an attempt to overcome differences it should open the door to local disparities. (16) The fact that one of the aims of Directive 2001/83 is to safeguard public health (17) does not per se justify stricter national rules since Article 95(3) EC itself requires that harmonisation take as a base a high level of health protection, while Article 152(1) EC (formerly Article 129(1) of the EC Treaty) regards health protection requirements as part of EU policies. (18)

28. I am obliged to concede, however, that, unlike Article 94 EC (formerly Article 100 of the EC Treaty), Article 95 EC does permit exceptions by allowing Member States to depart from the Community common denominator, although these special situations are subject to a strict procedure, (19) which was not observed in this case.

29. Article 153 EC (formerly Article 129a of the EC Treaty) significantly supports the approach I am advocating. Under that article consumer protection is to be attained through approximation measures based on Article 95 EC, as well as through other measures which support, supplement and monitor the policies of the Member States (Article 153(3)), adopted by the Council in accordance with Article 251 EC (Article 153(4)). Thus, national initiatives giving a higher level of protection are authorised only under the second limb, from which it can be concluded that the harmonisation under Article 95 EC is maximum harmonisation apart from the exceptions provided for by that provision. In other words, as the Court emphasised in Case C-52/00 Commission v France, (20) harmonisation under Article 95 EC must be equated with harmonisation under Article 94 EC for these purposes.

2. Teleological interpretation

30. Directive 2001/83 seeks to remove barriers to the free movement of medicinal products caused by disparities between national regulations while safeguarding public health (recitals 2 to 4). However, there is nothing to support the argument that, in fulfilling their commitment under Articles 95 and 152 EC to safeguard that collective interest, the Community institutions can adjust downwards and accommodate each Member State's particular requirements, which, as the EU legislature points out, hinders the achievement of the project. In Joined Cases C-211/03, C-299/03 and C-316/03 to C-318/03 HLH Warenvertriebs and Orthica (21) the Court stated that, in so far as Directive 2001/83 harmonises the procedures for the production, distribution and use of medicinal products, it is no longer possible for Member States to adopt national measures which restrict the free movement of these goods on the basis of Article 30 EC, in particular on grounds of the protection of health of humans (paragraph 58).

31. The German Government correctly argues that minimum harmonisation does not always hinder this freedom of movement and does not necessarily entail the fragmentation of the single market. However, if the hindrances to this freedom arise from disparities in national provisions and the aim is to get rid of them by bringing the relevant national rules into line with each other (Recital 5 of Directive 2001/83), there is absolutely no room for national differences and complete

harmonisation is essential, particularly if the other objective (the protection of health) is met through common rules.

32. This approach fits in very well with drugs advertising as, here too, local disparities also have an impact on the functioning of the internal market (Recital 43 of Directive 2001/83). (22)

33. The exception contained in Recital 42 of Directive 2001/83, which exempts 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, (23) is not inconsistent with the approach I am putting forward. I accept that the first paragraph of Article 7 of Directive 84/450 (24) allows stricter national rules, but this conduit for national divergence in relation to a general rule (Directive 84/450) cannot be used in respect of a special rule (Directive 2001/83) which attempts to impose uniformity in order to overcome national differences which hinder the market. In other words, the countries of the European Union are permitted to protect their citizens from misleading advertising by constructing higher defences than those provided by the Community, which constitute the lowest common denominator; moreover, when it comes to medicinal products, advertising, whether honest or misleading, must comply with the exhaustive harmonisation provisions contained in Directive 2001/83. Article 7(3) of Directive 84/450 (25) bears out this interpretation by providing that the Directive shall apply without prejudice to Community provisions on specific products or services.

34. Thus, both the legal basis and the objectives of Directive 2001/83 lend weight to the point of view that the legislative harmonisation that it brings about is comprehensive in its nature. The text and overall scheme of the Directive are also in line with this approach.

3. Systematic and textual criteria

35. Having defined 'advertising of medicinal products' in Article 86, Directive 2001/83 goes on to set its boundaries by directing the Member States to prohibit advertising of unauthorised products (Article 87(1)). As far as licensed products are concerned, the directive distinguishes between advertising directed at patients, which is absolutely prohibited ('Member States shall prohibit') when it is in respect of preparations which are available only on medical prescription (26) or which contain psychotropic or narcotic substances (Article 88(1) and (2)) (27) and, on the other hand, advertising to persons qualified to prescribe such products, which is not, in principle, subject to restrictions of any kind. Direct distribution to consumers for promotional purposes is also prohibited (Article 88(6)). (28)

36. Having thus delimited advertising in the sector, Directive 2001/83 goes on to restrict it severely by providing that, irrespective of the intended addressee of the advertising, it must encourage the rational use of the medicinal product, by presenting it objectively, without exaggerating its properties or being misleading (Article 87(3)).

37. When the advertising is directed at potential patients, Directive 2001/83 prescribes the minimum content (name, information for use and an invitation to read the instructions) and the way in which this is to be done (Article 89(1)), as well as setting out excluded material (Article 90). Similar provisions apply to advertising directed at medical professionals (Articles 91, 92 and 96).

38. Within this well-defined framework, the Member States enjoy a degree of discretion in certain respects. They can ban advertising of medicinal products the cost of which may be reimbursed, even if the directive itself does not impose such a ban (Article 88(3)), and show more flexibility in respect of the minimum information required by reducing it to the name of the product only (Article 89(2)) and Article 91(2)), or more rigour by requiring additional information (second paragraph of Article 91(1)). Finally, regarding the distribution of free samples, Member States are permitted to impose restrictions on such distribution beyond those imposed by Directive 2001/83 (Article 96(2)).

39. Thus, a careful analysis of Title VIII of Directive 2001/83 reveals an exhaustive system, leaving no autonomy to the Member States except where this is expressly allowed.

40. This can also be inferred from Case C-322/01 Deutscher Apothekerverband, (29) which concerned three other provisions of German law relating to medicinal products. The first prohibited advertising of unauthorised medicines, the second prohibited commercial advertising of medicines only available under medical prescription and the third precluded advertising for sale by mail order because the medicines could only be sold in pharmacies. The Court found that the first two were consistent with Community law, as they were contemplated by the provisions of Directive 2001/83, but it rejected the third in so far as it related to substances whose supply did not require a prescription because Article 88(1) does not prohibit such advertising and Article 88(2) cannot be interpreted as precluding advertising for sale by mail order. (30) Hence, according to this judgment, the Member States must not restrict activities which are not prohibited by Directive 2001/83.

4. The reply to the first question: a link to the second

(a) Inapplicability of Paragraph 11(1)(11) and Paragraph 11(1)(13) of the HWG, as drafted

41. Directive 2001/83 on the advertising of medicinal products to the general public therefore sets out a maximum standard which the Member States cannot exceed, unless expressly permitted to do so by the directive itself.

42. Consequently, the point which must be settled is whether Paragraph 11(1)(11) and Paragraph 11(1)(13) of the HWG are consistent with those requirements

when they impose an absolute prohibition on advertising using statements of third parties and methods which are dependent on chance, such as lotteries and prize draws.

43. A literal reading of Title VIII of Directive 2001/83 would indicate an answer in the negative, as it does not contain a prohibition of the type in question; neither does the advertising fall within the exceptions to the general rule described at point 38 above, which authorise the national authorities to impose greater restrictions. (31)

44. It might be possible to offer the Bundesgerichtshof a broad interpretation of the Directive which would leave these national rules intact, but this would be mistaken on two counts.

45. First of all, it would mean resorting to extravagant criteria of interpretation by way of analogy, when the general approach of the directive is prohibitive and co-ordinating, which would seem to require a restrictive interpretation. If Directive 2001/83, which offers a high level of protection of human health, is directed at eliminating disparities in national provisions relating to the advertising of medicinal products by introducing a common regime which guarantees their free movement within the single market, it would be inconsistent to interpret the exceptions broadly.

46. Moreover it would be contrary to the principle of 'consistent interpretation' and, instead of requiring the referring court to try to interpret national law in a way which is compatible with Community law, (32) it would be shifting the burden onto the Court of Justice and asking it to go against the terms of a directive by giving its blessing to a national provision which is inconsistent with it.

47. In short, Directive 2001/83 does not contain an outright abstract ban on advertising using prize draws and statements of non-professional third parties. The reply to the German court should therefore be that this directive seeks maximum harmonisation and is inconsistent with Paragraph 11(1)(11) and Paragraph 11(1)(13) of the HWG because they ban this type of advertising of medicinal products outright.

48. This being the case, the Bundesgerichtshof is required by virtue of the primacy of Community law (33) to decide the case by setting aside the provisions of the HWG, since that primacy dictates that the courts of the Member States are obliged to give full effect to Community law by disapplying contrary provisions of national law, even if adopted subsequently, without waiting for them to be repealed or removed from the statute book by constitutional means. (34)

(b) In search of a useful answer

49. For reasons which I will go on to explain, if the Court confines itself to replying that the directive precludes provisions such as those in dispute in this case, it should stop there, thus sidestepping the complexities of the second question.

50. With this question the Bundesgerichtshof is seeking to ascertain whether Article 87(3) of Directive 2001/83 applies to Internet advertising with a monthly draw for a small prize and whether advertising citing a survey of persons having no professional knowledge which gives a positive overall evaluation constitutes an improper reference to a claim of recovery within the meaning of Article 90(j) of the Directive.

51. The manner of enquiry, making no reference to national law, indicates that the German court expects to decide the case by looking to Directive 2001/83 and that, therefore, it assumes, in my opinion wrongly, that these two articles have direct effect.

52. In reality, the primacy of Community law means that the national authorities are obliged to apply Community rules, even of their own motion, notwithstanding the existence of national rules which conflict with them. (35) This duty presupposes direct effect, which directives do not inherently have.

53. For a directive to have direct effect, in addition to a failure to adopt implementing measures within the prescribed period or an incorrect adoption of such measures, its provisions must be, as far as their subject-matter is concerned, precise and unconditional. (36)

54. Case-law establishes the direct effect of directives as an automatic 'penalty' for failure by Member States to fulfil their obligations. Member States which have not implemented a directive or have not done so correctly cannot plead, as against individuals, their own failure to do so and then apply an incompatible national provision or deny such individuals rights which are clearly and unconditionally accorded to them under the directive. (37)

55. However, it is a different story when the obligations created under a directive fall on another individual, in which case the provision which has not been transposed does not have the same immediate effect and does not of itself bind that other individual, who bears no responsibility for the failure of national law to incorporate the provision. (38) A directive that has not been transposed cannot, then, be relied on against another individual; (39) this criterion laid down by the Court of Justice has so far remained unchanged. (40)

56. Consequently, in the absence of a new approach, the second question would be founded on a false assumption: the horizontal direct effect of Directive 2001/83, as it is being relied on in proceedings between private parties to prevent Gintec from carrying out an advertising campaign. (41)

57. These considerations support an interpretative approach to the problem; this would give the Bundesgerichtshof's second question substance as, by integrating the German provision with the directive, the way is opened for the Court of Justice to provide some guidance to the court in the main proceedings.

(c) The interpretative solution

58. The above-mentioned principle of consistent interpretation dictates that, before adopting an extreme solution such as disapplying a provision of national law, we should consider whether, despite their tenor, it is possible to attribute to the provisions of the HWG a meaning which is compatible with Directive 2001/83. In this respect, two of the directive's provisions – those

referred to in the second question – provide some helpful indicators.

59. I am aware that what follows risks turning into something of a balancing act between the separate areas of competence in the two-way process of preliminary rulings, since it could encourage the Court of Justice to interfere in matters which are beyond its powers and supplant the role of the national court. It should be recalled that on numerous occasions the Court has not only stated the principle of consistent interpretation but has even suggested a suitable outcome. (42) Some commentators, especially German writers, take the view that the primacy of Community law also extends to its interpretation, which implies that the solution provided by the judges in Luxembourg prevails over any other attributable to national implementation measures. (43)

60. There is no doubt that Directive 2001/83, mindful of the regard shown by the EC Treaty for public health, seeks to encourage the correct and rational use of medicinal products (recital 40, Article 87(3), first indent, and Article 89(1)(b), second and third indents) by the avoidance of excessive and ill-considered advertising (recital 45) and advertising which could be misleading in relation to the product's properties (Article 87(3), second indent, and Article 90 (j)).

61. In view of the above and to avoid a legal vacuum which, as pointed out at the beginning of this Opinion, benefits nobody and jeopardises the attainment of the objectives of Directive 2001/83, my advice to the Bundesgerichtshof would be to construe Paragraph 11(1)(11) of the HWG as meaning that it prohibits the advertising of medicinal products 'using statements made by third parties, in particular using statements of gratitude, recognition or recommendation' whenever this involves improper, alarming or misleading references to claims of recovery, within the terms of Article 90(j) of the Directive.

62. Similarly, Paragraph 11(1)(13) of the HWG could be interpreted as prohibiting advertising 'using prize draws, lotteries or other procedures' dependent on chance, if it results in irrational use of the product, thereby rejecting the type of advertising prohibited by Article 87(3) of Directive 2001/83.

B – The second question: claims of recovery and responsible use of medicinal products

63. Having made these observations, in order to resolve the issue in the main proceedings it is important for the Court to analyse Article 87(3) and Article 90(j) of Directive 2001/83.

1. Claims of recovery

64. First of all, the factual situation contained in the referring order must be respected, although the Slovenian Government (see point 4.11 of its statement in intervention) sets out a different factual framework. Accordingly, the German court wishes to know whether the prohibition contained in Article 90(j) of Directive 2001/83 on improper, alarming or misleading references to claims of recovery in advertising of medicinal products precludes an advertising campaign which publicises a survey of third parties without professional medical knowledge with a positive overall evaluation of the product advertised, without specifying whether the evaluation relates to individual fields of application.

65. First of all, it is worth pointing out that subparagraph (j) relates to statements by people who have no specialist knowledge of drugs and health, as recommendations by scientists, health professionals or persons with particular influence are covered by subparagraph (f) of Article 90.

66. The expression 'claim of recovery' and the three adjectives applied to it ('improper', 'alarming', 'misleading') are not defined legal terms, but this uncertainty can be reduced by looking to one of the objectives of Directive 2001/83, that is the protection of health through rational and responsible use of medicinal products.

67. Approached from this angle, the provision covers not only 'claims' in the strict sense of a reliable assertion of, or testimonial to, a fact, which can be proved and backed up, but, in a looser sense, can also cover statements of an opinion or expressions of a state of mind. Taking this broader view, and in the interests of not frustrating the objectives of the directive, the term includes not only assertions of total recovery but also those which attribute health benefits to the product.

68. On the other hand, vague references to the well-being, vigour or vitality bestowed by a medicinal product are not sufficient; it is necessary to refer to its therapeutic potential to alleviate or cure pain or injury.

69. Using this admittedly wide definition, the article does not prohibit all favourable statements, since medicines can prevent as well as cure, (44) but it does prohibit statements which are in some way unusual and, because they are inappropriate, exaggerated or excessive ('improper'), worrying or perturbing ('alarming') or potentially deceptive (45) ('misleading'), (46) encourage uncontrolled consumption.

70. In these circumstances I do not think that a 'positive overall evaluation' of red ginseng which does not attribute improvements in specific complaints or ailments to the product can be considered a 'claim of recovery' or merits the descriptions referred to in Article 90(j) of Directive 2001/83, given that, as the Bundesgerichtshof emphasises, the survey carried out by Gintec does no more than show that a high proportion of customers are satisfied and say that the product has done them good, even if a significant number recommend it as a remedy for minor ailments.

71. Consequently, the first part of the second question would be answered in the negative, in that advertising that publicises a survey of persons with no professional knowledge with an 'overall positive evaluation' of the medicinal product does not in principle constitute an improper or misleading reference to a claim of recovery within the meaning of Article 90(j) of Directive 2001/83.

2. Advertising using prize draws

72. Prize draws, lotteries and tombolas are all ways of using chance or fate to obtain an outcome by luck.

(47) In addition to being a breeding ground for addiction, (48) the negative effects of games of chance are magnified when the gambling is connected to health, an area which is also associated with other psychological conditions such as hypochondria, (49) and certain obsessions such as self-medication.

73. The prudent and responsible use of medicinal products, which, as I have mentioned, informs the whole directive but particularly Article 87(3), does not sit well with advertising which stimulates the interest of consumers in a manner unrelated to its medicinal properties and purpose.

74. Two scenarios are possible here: either that the purchase of the remedy entitles the purchaser to enter the draw or that there is no requirement to buy the substance and the reward is the medicinal product itself.

75. Under the first scenario, there is no certainty that the medicine has been selected for its properties, as the chance to try one's luck and win something of value also enters into the decision. The size of the prize and whether it is really appealing or of little interest is not decisive because there is always some doubt as to the reason for participating: the size of the prize or the simple pleasure of playing the game.

76. This use of a prize draw, which is legitimate in other sectors, is hard to accept when there are underlying public health considerations. Consequently, Article 87(3), first indent, of Directive 2001/83, which steers advertising of medicinal products in the direction of encouraging rational use and objective presentation, does not endorse a practice which, using the cover of the prize draw, fails to explain the nature of the product and seduces the consumer with snares which have nothing to do with its known properties.

77. The second scenario is the one which corresponds to the main proceedings and this too is open to criticism, although for different reasons. Recital 46 and Article 88(6) of Directive 2001/83 reject direct distribution and free samples of medicinal products for promotional purposes because it encourages people to take them for reasons other than for their therapeutic value.

78. If it is the case, as Gintec claims, that the aim of the advertising is to encourage participation in a survey on red ginseng, the requirements of Directive 2001/83 could be met by simply offering a prize other than the medicinal product.

C – The third question: Directive 92/28

79. In its third question the Bundesgerichtshof asks whether the explanations provided in relation to the previous questions apply also to Directive 92/28, which is the precursor of Title VIII of Directive 2001/83. The reply can only be in the affirmative, given that the latter incorporates the 1992 directive and reproduces its provisions.

80. The foregoing observations provide the ingredients with which to compose a recipe which will furnish the referring court with the seasoning it needs to offer the parties in the main proceedings a meal which is to their taste and which reconciles their different aspirations.

VI – Conclusion

81. In conclusion, I propose that the Court of Justice should inform the Bundesgerichtshof that:

(1) The rules on advertising contained in Title VIII 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, require maximum harmonisation, such that the Member States may not legislate for stricter prohibitions or restrictions unless the directive itself so permits.

(2) Directive 2001/83 precludes national rules of a general and abstract nature which prohibit the advertising of medicinal products to the general public using:

(a) statements made by third parties, unless such prohibition applies only where the statements suggest, in an improper, alarming or misleading manner, claims of recovery, within the meaning of Article 90(j) of Directive 2001/83, which is not, in principle, the case with advertising which uses a survey of non-professionals with a positive overall evaluation of the medicinal product, without referring to individual fields of application.

(b) prize draws, lotteries or other procedures, the outcome of which is dependent on chance, unless such prohibition is conditional on those means encouraging irrational use of the remedy, contrary to Article 87(3) of Directive 2001/83. That article and Article 88(6) of the directive prohibit the advertising of a medicinal product over the Internet using a monthly draw for a low-value prize consisting of a pack of the medicinal product in question.

(3) The foregoing answers apply analogously to Council Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use.

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1 – Original language: Spanish.

2 – OJ 2001 L 311, p. 67, amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 34).

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

4 – This title, which comprises Articles 86 to 100, reproduces, almost verbatim, Articles 1 to 14 of Directive 92/28.

5 – As amended by Directive 2004/27.

6 – The 2004 amendment removed the exemption contained in the original version of this provision relating to distribution for other purposes in special cases.

7 – RGBl. 1909, p. 499, which has been successively amended, most recently on 23 July 2002 (BGBl. I, p. 2850), and has now been replaced by the law of the same name of 3 July 2004 (BGBl. I, p. 1414).

8 – BGBl. 1994 I, p. 3068.

9 – Perhaps the best-known medicinal herb, Ginseng belongs to the panax ('panacea') genus and grows in the northern hemisphere, in Asia and America. The genus is made up of six species of slow-growing, perennial plants with fleshy roots, from which is ex-

tracted the main active ingredient, which is indicated as a stimulant and revitalizer to combat mental and physical fatigue and stress.

10 – In the view of the German Government, the absence of any reference to full harmonisation in the text of Directive 2001/83 shows that the legislature did not intend it, but this overlooks the fact that the same argument could also be used against partial harmonisation and that the challenge in this reference for a preliminary ruling is precisely to discover the legislative intent.

11 – Article 95 EC, read together with Article 3(1)(c) EC and Article 14(2) EC (formerly Article 3(c) and Article 7a(2) of the EC Treaty). According to these articles, the internal market is an area without frontiers in which the free movement of goods, persons, services and capital is ensured.

12 – Case C-376/98 Germany v Parliament and Council [2000] ECR I-8419, paragraph 83.

13 – Case C-41/93 France v Commission [1994] ECR I-1829, paragraph 22, and Case C-359/92 Germany v Council [1994] ECR I-3681, paragraph 22.

14 – Germany v Parliament and Council, paragraphs 84 and 86, and Case C-377/98 Netherlands v Parliament and Council [2001] ECR I-7079, paragraph 15.

15 – The German Government goes on to conclude that the aim of directives based on Article 95 EC is to introduce minimum harmonisation. In support of this it refers to the words of Advocate General Stix-Hackl in Case C-390/99 Canal Satélite Digital [2002] ECR I-607, at point 31 of her Opinion, but it does so tendentiously, adding that although this is the general rule, the tenor and objectives of such directives sometimes require full harmonisation.

16 – The principle of subsidiarity relied upon by the German Government to support a type of harmonisation which allows Member States to depart from the general rule is in my view irrelevant. That principle limits Community intervention in areas which do not fall within its exclusive competence to situations where the objectives can only be achieved by Community action (the second paragraph of Article 5 EC, formerly the second paragraph of Article 3b EC Treaty), and this fits in well with Directive 2001/83, since, as stated in its recitals, the special measures adopted by each Member State hinder trade in medicinal products, making it essential to reduce or even remove them. In Netherlands v Parliament and Council, it was emphasised that the principle was observed where the legislation and practice of the Member States impedes the proper functioning of the internal market, making some kind of co-ordinating action necessary. Joined Cases C-154/04 and C-155/04 Alliance for Natural Health and Nutri-Link [2005] ECR I-6451 confirmed this approach (paragraphs 101 to 107).

17 – This does not prevent reliance on Article 95 EC as a legal basis, provided that the relevant conditions are fulfilled (Germany v Parliament and Council, at paragraph 88).

18 – Germany v Parliament and Council made these points (see paragraph 88) in relation to Directive 98/43/EC of the European Parliament and of the Council of 6 July 1998 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products (OJ 1998 L 213, p. 9).

19 – Article 95(4) to (10) EC.

20 – [2002] ECR I-3827 at paragraph 15.

21 – [2005] ECR I-5141.

22 – In Joined Cases C-281/03 and C-282/03 Cindu Chemicals and others [2005] ECR I-8069, which concerned Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (OJ 1976 L 262, p. 201), as amended by European Parliament and Council Directive 94/60/EC of 20 December 1994 (OJ 1994 L 365, p. 1), the Court found that as the Directive aims to eliminate obstacles to trade within the internal market, its provisions are exhaustive in their scope and are incompatible with the retention or adoption of different measures in the Member States (paragraph 44).

23 – OJ 1984 L 250, p. 17.

24 – As amended by Directive 97/55/EC of European Parliament and of the Council of 6 October 1997 amending Directive 84/450/EEC so as to include comparative advertising (OJ 1997 L 290, p. 18).

25 – Added by Directive 97/55.

26 – On the other hand, advertising of specific products which are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of the patient is permitted (Article 88(2)).

27 – Text as amended by Directive 2004/27.

28 – Also introduced by Directive 2004/27 (as outlined in footnote 6).

29 – [2003] ECR I-14887.

30 – Paragraphs 138 to 144, in conjunction with paragraphs 112 to 116 of the judgment.

31 – That is why it is somewhat confusing that the first question refers to ‘the provisions of Directive 2001/83, concerning a reference to statements of third parties and advertising with a prize draw’, since the whole point of the question is that the Community measure does not cover this type of advertising and the referring court wishes to know what type of harmonisation is involved in order to ascertain whether the route taken by the German legislature is correct or not; consequently the Court’s reply to the question will have to overlook this phrase.

32 – The Member States’ obligation to achieve the result envisaged by a directive and their duty under Article 10 EC to ensure the fulfilment of that obligation is binding on all the authorities of Member States including the courts (Case 14/83 von Colson and Kamann [1984] ECR 1891, paragraph 26), which are required to seek a ‘consistent interpretation’ of national provisions which would allow them to be applied in a manner which would achieve the result pursued by the directive, thereby complying with the third paragraph of

Article 249 EC (Case C-106/89 Marleasing [1990] ECR I-4135, paragraph 8).
33 – Announced in Case 10/61 Commission v Italy [1962] ECR 1 and solemnly proclaimed in Case 6/64 Costa v ENEL [1964] ECR 585.
34 – Case 106/77 Simmenthal [1978] ECR 629.
35 – Case 103/88 Fratelli Costanzo [1989] ECR 1839, paragraph 33.
36 – Case 8/81 Becker [1982] ECR 53, paragraph 25.
37 – Becker, at paragraph 24.
38 – Case 152/84 Marshall [1986] ECR 723, paragraph 48.
39 – This is to be distinguished from the situation where, as in Case C-201/02 Delena Wells [2004] ECR I-723, invoking a directive against the Member State has repercussions on the rights of another individual.
40 – In Joined Cases C-397/01 to C-403/01 Pfeiffer and Others [2004] ECR I-8835, paragraphs 108 and 109, the Court accepted the suggestion made in my Opinion of 27 April 2004 and held that the provisions of a directive which has not been transposed do not have direct effect in proceedings between private parties.
41 – This is based on a misreading of Community case-law which, by giving directives direct effect in the face of a Member State's failure to fulfil its obligations, protects those who would have benefited had their national authorities acted correctly and accords them the rights which the failure of those authorities to act has deprived them of. In the present case, a correct reading of this case-law would indicate that Gintec is entitled to carry out the advertising campaign notwithstanding the provisions of the HWG. However, in its formulation of the second question the Bundesgerichtshof is seeking the opposite result: to prevent Gintec from carrying out the advertising campaign by interpreting Directive 2001/83, contrary to its literal meaning and in proceedings which have nothing to do with the German State, so as to give it the same scope as the national law which has not been harmonised.
42 – See the examples given at point 26 et seq. of my Opinion in Pfeiffer and Others.
43 – Götz, V., 'Europäische Gesetzgebung durch Richtlinien – Zusammenwirken von Gemeinschaft und Staat', Neue Juristische Wochenschrift, 1992, p. 1854.
44 – It is surprising that Article 90(c) of Directive 2001/83 prohibits the inclusion of suggestions that the health of the patient can be enhanced in the advertising of medicinal products. Lema Devesa, C., comments to this effect in 'La Directiva de la CEE sobre la publicidad de los medicamentos', Actas de derecho industrial, volume XIV, 1991-92, Marcial Pons, Madrid, 1993, p. 57. Paragraph 11(1)(11) of the HWG prohibits any statement relating to the positive effects of a medicinal product.
45 – The definition of misleading advertising contained in Article 2(2) of Directive 84/450.
46 – Excess can always be criticised but, in sectors where health is involved it becomes dangerous. When it comes to medicines, the idea of using advertising to aim at the head in the hope of hitting the pocket (Vogt, S., Lexikon des Wettbewerbsrechts, Verlag C.H. Beck, Munich 1994, p. VII) is out of place.
47 – I set out my thoughts on gambling and its legal implications at points 95 to 97 of my Opinion in Joined Cases C-338/04, C-359/04 and C-360/04 Placanica and Others, pending.
48 – In his short story The Queen of Spades Alexander Pushkin (1799-1837) draws a vivid picture of high society in Tzarist Russia where the love of gambling plunges a young and austere army officer into madness.
49 – In ElLicenciado Vidriera, one of his 'exemplary novels', Miguel de Cervantes (1547-1616) tells of the fortunes of Tomás Rodaja, who believes that he is made of glass and lives in fear of being shattered into a thousand pieces.