OPINION OF ADVOCATE GENERAL RUIZ-JARABO COLOMER delivered on 13 February 2007 [1]

I — 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

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).

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

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

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 advertising 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

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.

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;

...'.

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.

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)

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

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*

1. The legal basis of Directive 2001/83

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.

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

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.

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

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).

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.

19 — Article 95(4) to (10) EC.

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

21 — [2005] ECR I-5141.

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

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.

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]

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.

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]

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.

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]

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.

(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

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.

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

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 *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.

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.

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.

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.

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 *El Licenciado 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.

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.