OPINION OF ADVOCATE GENERAL TRSTENJAK
delivered on 24 November 2010[1]

I — Introduction

1. The present proceedings are based on a reference for a preliminary ruling from the Bundesgerichtshof (Federal Court of Justice, Germany; 'the referring court') in accordance with Article 234 EC[2] seeking the Court's interpretation of Article 88(1)(a) 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,[3] which prohibits in the European Union the advertising to the general public of prescription-only medicinal products.

2. The reference for a preliminary ruling arises from a legal dispute between two manufacturers of medicinal products, MSD Sharp & Dohme GmbH (defendant and appellant, 'MSD') and Merckle GmbH (plaintiff and respondent, 'Merckle') in which the latter seeks to obtain a court order prohibiting MSD from disseminating advertising information on the internet in relation to prescription-only medicinal products which it manufactures. The success of that claim depends on whether the actions of the defendant in the main proceedings must be categorised in legal terms as impermissible advertising to the general public of prescription-only medicinal products.

3. The problems raised in the present case are directly linked to the difficult balance to be struck by the European Union legislature between the safeguarding of public health and the public's right to information. One of the sources of that information is the internet — having advanced as a result of technological developments to become one of today's most important communication media — which allows increasing numbers of people quickly and easily to obtain information and to share this with others. As is well-known, information is precious and undoubtedly the internet has contributed significantly to the dissemination of information and, thus, decisively to the development of today's information society. However, for information to operate as a positive force, it must be ensured that the information made available meets certain qualitative standards without in so doing causing excessive disruption to the free flow

1 — Original language: German.

2 — In accordance with the Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community (OJ 2007 C 306, p. 1), the preliminary ruling procedure is now governed by Article 267 of the Treaty on the Functioning of the European Union.

3 — OJ 2001 L 311, p. 67.

of such. In the area of healthcare — at issue here and of paramount importance — patients need to be safeguarded against information lacking objectivity and apt to mislead stemming from unreliable sources without at the same time depriving them of autonomy. At the same time, those who disseminate information should be required to observe high standards in relation to quality. In that way, that is, specifically in addressing how to deal with modern sources of information such as the internet, a patient's right to information may evolve to become an additional instrument of healthcare provision.

II — Legal framework

A — *Law of the European Union*

4. The subject-matter of the present reference for a preliminary ruling is Directive 2001/83 as amended by Directive 2004/27/EC of the European Parliament and Council of 31 March 2004. [4]

4 — OJ 2004 L 136, p. 34.

5. Recital 2 in the preamble to Directive 2001/83 is worded:

'The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health.'

Recital 40 in the preamble to the Directive states:

'The provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information.'

Recital 45 is worded:

'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.'

6. Article 86 of Directive 2001/83, with which Title VIII ('Advertising') commences, provides:

'1. For the purposes of this Title, "advertising of medicinal products" shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular:

— the advertising of medicinal products to the general public,

— advertising of medicinal products to persons qualified to prescribe or supply them,

— visits by medical sales representatives to persons qualified to prescribe medicinal products,

— the supply of samples,

— the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal,

— sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products,

— sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith.

2. The following are not covered by this Title:

— the labelling and the accompanying package leaflets, which are subject to the provisions of Title V,

— correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product,

— factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims,

— statements relating to human health or diseases, provided there is no reference, even indirect, to medicinal products."

7. Article 87 of the Directive provides:

'1. Member States shall prohibit any advertising of a medicinal product in respect of which a marketing authorisation has not been granted in accordance with Community law.

2. All parts of the advertising of a medicinal product must comply with the particulars listed in the summary of product characteristics.

3. The advertising of a medicinal product:

— shall encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties,

— shall not be misleading.'

8. Article 88 of the Directive states:

'1. Member States shall prohibit the advertising to the general public of medicinal products which:

(a) are available on medical prescription only, in accordance with Title VI;

...'

B — *National law*

9. The relevant provisions of German law are included in the Gesetz über die Werbung auf dem Gebiet des Heilwesens (Law on the advertising of medicines; 'HWG') as published on 19 October 1994, [5] last amended by Article 2 of the Law of 26 April 2006. [6]

'*Paragraph 10*

(1) As regards prescription-only medicines, advertising may be sent only to doctors, dentists, veterinarians, pharmacists or persons authorised to trade in medicinal products.

(2) Medicinal products intended to treat, in humans, insomnia or psychological problems, or which are psychotropic, may not be advertised otherwise than in professional circles.'

5 — BGBl. I p. 3068.
6 — BGBl. I p. 984.

III — Facts, main proceedings and question referred

10. The parties are pharmaceutical undertakings and are in competition with one another. MSD presented its 'Vioxx', 'Fosamax' and 'Singulair' medicinal products, which were available only on prescription, on a website which in each case was available by way of a link which was not password-protected and accordingly was freely accessible. The website contained a reproduction of the packaging of the product, a description of the indication and instructions for the use of the product.

11. Merckle takes the view that such conduct amounts to an infringement of the prohibition laid down in Paragraph 10(1) of the HWG on advertising to the general public medicinal products which are available only on prescription and, at the same time, conduct by MSD contrary to the rules on competition. In proceedings before the Landgericht (Regional Court), Merckle sought an order requiring MSD, on penalty of measures to be specified, to desist from the dissemination in the course of trade for competitive purposes of promotional material on prescription-only medicinal products via the internet in such a way that information contained in that advertising material is freely accessible to those outside the medical profession. The Landgericht granted the application. MSD's appeal to the Oberlandesgericht (Higher Regional Court) against the decision of the Landgericht was dismissed.

12. The success of the appeal brought by MSD before the national court depends on whether Article 88(1)(a) of Directive 2001/83/EC applies also to advertising to the general public of the kind at issue in this case, which contains only information which was made available to the authorising authority in the course of the marketing authorisation procedure and which is accessible in any event to every person acquiring the product, and where that information is not made available to an interested party who has not asked for it but can be accessed through the internet only by a person who takes steps to do so.

13. The referring court concedes that it follows from Article 86(2) of Directive 2001/83/EC that the provisions of Title VIII do not extend to the labelling and the accompanying package leaflets (to which Articles 54 to 69 apply). Accordingly, information set out on the label and in the accompanying package leaflet does not constitute advertising within the meaning of Article 86(1) of the Directive provided that such information is used only in its function as a label or accompanying package leaflet, that is to say, is displayed on the container and — if present — the outer packaging of the medicinal product or accompanies the product and is provided to patients at the same time as they receive the product. Conversely, according to the case-law of the Bundesgerichtshof, what is involved amounts to an advertisement where that mandatory information ceases to be a form of labelling covered by the law relating to medicinal products and is used instead as an independent communication, for example, in a newspaper advertisement.

14. In that connection, the national court questions whether a teleological interpretation of the prohibition on advertising ought not to result in a more restrictive interpretation of the prohibition on advertising laid down by Article 88(1)(a) of Directive 2001/83,

with the consequence that it does not extend to an advertisement directed to the public of the kind at issue in the present proceedings, where the information is accessible only to those persons who take steps to access it on the internet and which extends only to information which was available to the authorising authority and which is provided in any event to patients when they acquire the product. In that regard, in the view of the national court, particular consideration must be given to the fact, first, that publication is effected by the manufacturer and, second, that such information may be apt to avoid or reduce the dangers of 'uninformed self-medication'.

15. In view of the concerns which the Bundesgerichtshof has whether the prohibition on advertising to the general public at issue in the case at hand is compatible with Community fundamental rights and the principle of proportionality, it ordered proceedings to be stayed and made a reference to the Court for a preliminary ruling on the following question:

'Does the scope of application of Article 88(1)(a) of Directive 2001/83 on the Community code relating to medicinal products for human use extend to advertising to the general public of medicinal products which are available only on prescription where that advertising contains only information which was placed before the authorising authority in the course of the marketing authorisation procedure and which is accessible in any event to every person acquiring the product, and where that information is not made available to an interested party on an unsolicited basis but can be accessed through the internet when the party concerned takes steps to do so?'

IV — Procedure before the Court

16. The reference for a preliminary ruling of 16 July 2009 was received at the Registry of the Court on 10 August 2009.

17. Within the period established by Article 23 of the Statute of the Court, written observations were lodged by MSD, by the Governments of the Portuguese Republic, the Czech Republic, the Kingdom of Denmark, the Republic of Hungary, the Republic of Poland and the United Kingdom and by the Commission.

18. At the hearing on 23 September 2010, the representatives of MSD, of the Governments of the Portuguese Republic, the Kingdom of Denmark and the Kingdom of Sweden and of the Commission presented their observations.

V — Main arguments of the parties

19. The arguments of the parties can essentially be distinguished depending on whether or not they categorise a practice such as that mentioned in the question referred as 'advertising to the general public' within the meaning of Article 88(1)(a) of Directive 2001/83. The *Polish*, *Hungarian* and *Portuguese Governments* tend towards categorisation as advertising to the general public whereas the *Czech Government* tends towards an intermediate approach. The *Government of the United Kingdom*, the *Danish* and *Swedish*

Governments and the Commission argue against a categorisation as advertising to the general public.

A — *In favour of categorisation as advertising to the general public*

20. The *Polish Government* takes the view that the publication on a website of photographs of the packaging of a specific medicinal product, a description of its indication and the conditions of use satisfies the criteria defining the concept of advertising established in Article 86(1) of Directive 2001/83. It argues that at the present time the internet constitutes a mass medium which allows consumers to obtain information on certain medicinal products without difficulty in particular when, as in the present case, the website is wholly unprotected. In its view, it is not relevant to the categorisation of such a measure that the advertising for the medicinal products at issue was not actively presented to consumers but simply published on a website because that information was accessible to all.

21. According to the Polish Government, it is irrelevant also for the purposes of a ruling in the present case that the advertising in question contains only information from the documentation on which the marketing authorisation was based as, in that regard, Article 86 of Directive 2001/83 does not provide for exemptions depending on the kind of information made available. In that connection, it refers to Article 89 of Directive 2001/83 according to which all advertising must include as a minimum the name of the medicinal product and the information necessary for correct use of the medicinal product. Thus, it argues, a specific presentation can be regarded as the advertising to the general public of medicinal products simply where that information alone is provided.

22. The Polish Government concludes that Article 88(1)(a) of Directive 2001/83 establishes an absolute prohibition on the advertising of the categories of medicinal products mentioned therein.

23. The *Hungarian Government* points out that the definition of the concept of advertising for medicinal products expressly emphasises the objective pursued by the message, that is, for the purposes of determining whether or not an information communication must be regarded as advertising what is crucial is whether or not it is designed to promote the prescription, supply, sale or consumption of medicinal products.

24. According to the Hungarian Government, in examining that objective, in relation to the present case particular weight must be attached to the fact that the defendant published on its website information concerning

its own products which indicates that such information was designed to promote the prescription, supply, sale or consumption of medicinal products. In its view, that justifies the conclusion that the action in question — having regard to its objective — must be categorised as advertising for the purposes of Directive 2001/83. For the purposes of determining whether this constitutes advertising it is irrelevant that the information published on the website corresponds quite simply to the information which must be supplied in the course of the marketing authorisation procedure and which purchasers of the medicinal product in any event may note. Also irrelevant is the fact that the information in question is not made available on an unsolicited basis but that one must actively search the internet.

25. The *Portuguese Government* states that there are no exemptions from the rule establishing a prohibition on the advertising to the general public of prescription-only medicinal products and that to that extent no distinction is made with reference to the medium, content or form of the advertising.

26. It takes the view that the question is composed of two parts: (i) whether advertising to the general public of prescription-only medicinal products is permitted where that advertising contains only information which was placed before the authorising authority in the course of the marketing authorisation procedure and which is accessible to every person acquiring the product and (ii) whether advertising to the general public of prescription-only medicinal products is permitted where that information is not made available to an interested party on an unsolicited basis but can be accessed through the internet when the party concerned takes steps to do so.

27. In relation to the first part, it argues that advertising to the general public of prescription-only medicinal products cannot be effected simply through the reproduction of the packaging of the medicinal product and a description of the indication and instructions for use as such advertising will always contravene some of the requirements for advertising which is permitted to the general public.

28. In relation to the second part, it states that the question's emphasis reflects an inaccurate view on advertising. According to the Portuguese Government, a distinction should be made between advertising which an individual receives without having to take any steps to obtain such and advertising which he obtains only as a result of certain efforts. However, the efforts which an advertising recipient expends to access via the internet the advertising for the medicinal products at issue in the main proceedings are considerably less onerous than those he has to expend, for example, in acquiring and paying at a kiosk for a magazine in which he has access to

advertising for such medicinal products, assuming, that is, that the inclusion of such advertising in magazines available to the public is permitted.

29. The Portuguese Government submits further that advertising such as that at issue in the main proceedings, if it were permitted, to that extent would be misleading as the public has been convinced for many years that advertising aimed at the general public may be effected only in respect of medicinal products which are available without prescription. In its view, in establishing that belief, radio and television advertising has played a crucial role.

30. The *Czech Government* takes a more nuanced view. It submits that the fundamental defining characteristic of advertising is its intended purpose, that is, the objective of the advertising which must be determined in all cases without reference to the substance of the information communicated or the character of the activity exercised; that is particularly so, as those factors do not constitute defining characteristics of advertising but are simply helpful in reaching an assessment.

31. According to the Czech Government, the information mentioned in Article 86(2) of the Directive cannot be excluded a priori from the scope of application of the concept of advertising for medicinal products or from the requirements to be satisfied by advertising for medicinal products as such an exclusion would imply jeopardising the primary objective of the Directive, that is, to safeguard public health. Such an approach would allow the requirements which advertising for medicinal products must satisfy to be easily circumvented through the publication (or making available) of the relevant kinds of information for advertising purposes, that is, in a way which promotes the prescription, supply, sale or consumption of medicinal products. Accordingly, it must be possible that those kinds of information included in Article 86(2) satisfy the concept of advertising for medicinal products as defined in Article 86(1) of the Directive. It is for the national court to determine, having regard to the circumstances of the individual case, whether a specific communication pursues a promotional purpose and, thus, constitutes advertising or whether it pursues a different purpose and does not constitute advertising.

B — *Against categorisation as advertising to the general public*

32. *MSD* takes the view that the question referred concerns not only the interpretation but also the validity of Article 88(1)(a) of Directive 2001/83. A legal provision which prohibits the placing on the internet of information — officially approved and for the benefit of patients — concerning medicinal products cannot be compatible with

Community fundamental rights, in particular, freedom of information, the right to autonomy in health matters, freedom of expression and the right to conduct a business. It argues that the Court is not precluded from examining the validity of a Community provision even if the questions referred expressly address only its interpretation.

33. MSD argues that a strict interpretation of Article 88(1)(a) of Directive 2001/83 restricts the opportunities for consumers — in particular, patients — to obtain objective information on prescription-only medicinal products and, as a result, affects both the fundamental right to information and the fundamental right to autonomy in health. However, that is directly linked to an even more serious interference with a fundamental right, that is, a restriction on a patient's right to bodily integrity.

34. Moreover, according to MSD, the prohibition on advertising to the general public prescription-only medicinal products constitutes an interference with freedom of expression, guaranteed as a fundamental right, which protects also 'commercial communications'. In particular, in the area of healthcare, the European Court of Human Rights (ECHR) has delivered judgment on several occasions on disproportionate prohibitions on advertising. Moreover, this prohibition constitutes an interference with the protection established by the fundamental right to conduct a business, guaranteed under the Charter of Fundamental Rights and recognised by the Court as part of the freedom of occupation.

35. In addition, according to MSD, the prohibition on advertising to the general public of prescription-only medicinal products established by Article 88(1)(a) of Directive 2001/83 is incompatible with the principle of proportionality as a general prohibition on information is clearly neither apt nor necessary for the purposes of safeguarding public health. In that connection, it must be noted that the Community legislature did not state its reasons for that prohibition on advertising to the general public.

36. Moreover, MSD argues that in *Stambuk* v *Germany*[7] the ECHR emphasised the fact that prohibitions on advertising in the area of healthcare need always to be examined in the circumstances of the individual case taking account of the public's legitimate interest in information and of the substance of the prohibition and, as a result, may never be applied in a blanket manner. In relation to the

7 — Judgment of the European Court of Human Rights in *Stambuk* v *Germany*, No 37928/97, 17 October 2002.

implementing provision under German law, Paragraph 10(1) of the HWG, the Bundesverfassungsgericht (Federal Constitutional Court) has required an equally differentiated assessment. [8]

37. MSD argues further that to the extent that the validity of Article 88(1)(a) of Directive 2001/83 is not questioned a restrictive interpretation of the concept of advertising must be presumed. Moreover, respect for fundamental rights and the principle of proportionality must result in the question being answered in the negative. In support of that view, it points to the flexibility of interpretation inherent in the Directive's wording which precludes a uniform interpretation of the terms 'advertising' and 'information'. It is misguided to presume that every publication of information by a manufacturer is made with a view to increasing sales as there are many conceivable rationales on which the publication of information by a manufacturer may be based. For example, the publication of information may be connected to the general public relations activities of an undertaking without any specific aim of increasing sales.

38. Moreover, according to MSD, a schematic interpretation demonstrates that in relation to medicinal products a category of 'non-promotional information' exists which as a matter of existing law may be disseminated via the internet. However, in the view of the defendant to the main proceedings, also the spirit and purpose of the prohibition on advertising do not preclude according a strict interpretation to the concept of advertising to the general public.

39. The *Danish Government* contends that for the purposes of determining whether or not material constitutes advertising for medicinal products it is, in principle, irrelevant that the material concerned includes information which was available to the authorising authority in the course of the marketing authorisation procedure. Instead, crucial in reaching that determination is a specific assessment of the objective pursued by way of the information, taking account, too, of the material's form and substance.

40. According to the Danish Government, it does not constitute advertising if the website of an undertaking merely reproduces unedited and in full the officially approved information on a medicinal product in the form of the package leaflet, a summary of the product's characteristics or a publicly accessible evaluation report of a medicines authority. Neither in terms of form or substance has that kind of information a promotional nature. If, on the other hand, edited information on the medicinal product is at issue, it may be presumed that this constitutes advertising designed to promote the prescription, supply, sale or consumption of medicinal products unless, that

8 — Judgment of the Bundesverfassungsgericht of 30 April 2004 (1 BvR 2334/03).

is, the information is necessary for safety (and not advertising) purposes.

41. Further, the Danish Government argues that in the case of prescription-only medicinal products the risk of self-medication is much lower than in the case of products which are available without a prescription as the former cannot be obtained — at least through lawful channels — without the involvement of a doctor or pharmacist and counselling and examination in that connection. On the other hand, advertising for prescription-only medicinal products may result in mail-order or internet purchases of prescription-only medicinal products in the absence of a prescription. In that context, both lawful and unlawful traders in original or counterfeit medicinal products may be involved.

42. The *Government of the United Kingdom* takes the view that publication of the information at issue in the present case which is taken from the basic information on the product characteristics approved by the authorising authority does not constitute 'advertising' for the purposes of Article 88(1)(a) of the Directive. The publication is not promotional in nature but provides essential information on the products.

43. According to the Government of the United Kingdom, under Article 86(2), the labelling of a medicinal product and the accompanying package leaflets do not constitute advertising for medicinal products and are subject to the provisions of Title V of the Directive. The only reason for that must be the fact that the packaging and package leaflet are designed to provide patients with essential information and not, however, to promote the sale, etc. of the medicine. In governing the substance of the packaging and the package leaflet Title V of the Directive ensures that those particulars are restricted to the provision of information and do not appear as advertising. In any event, that is also confirmed by Article 62 which states, in wholly unambiguous terms, that the inclusion of 'any element of a promotional nature' on the packaging or in the package leaflet is not permitted.

44. The fact that approved information on packaging and package leaflets does not constitute advertising is unaffected where that information is duly placed on an undertaking's website such that it can be accessed only by those who take active steps to do so. In that case, the same information is presented in a similarly neutral manner and for the same purpose, that is, to provide patients with relevant information on the medicine concerned, and not for promotional or advertising purposes. Publication of information in that way is perfectly common practice in certain Member States including the United Kingdom and is considered lawful in those countries; in addition, it corresponds to the practice of the European Medicines Agency.

45. According to the Government of the United Kingdom, provision of information in that manner does not endanger public health, the protection of which is the objective of the provisions of Title VIII of the Directive. Self-evidently, in the course of the authorisation procedure, the informational content has been approved and all advertising claims removed therefrom. The information is accessible only to those who take steps to do so. Moreover, patients can get hold of the products in question only with the consent of and on prescription from a doctor. They obtain such only when a doctor considers that to be of benefit to their health.

46. The *Commission* notes that the prohibition on advertising constitutes a restriction on the freedom of expression which can be justified for the purposes of safeguarding human health (see on that point *Damgaard*,[9] paragraph 26 et seq.) subject to the proviso that due consideration must given, inter alia, to the principle of proportionality. In the Commission's view, there are many factors in support of the presumption that the measure in question does not correspond to the concept of 'advertising'.

47. In order to qualify as 'advertising' in that sense, the overriding consideration is the purpose of the communication, that is, whether or not it is intended to promote sales. The fact that the manufacturer is also the author of the material can be only one of many different criteria which must be taken into account. In addition to the question of authorship, the substance, intended audience and technical design of the communication and any previous availability of information capable of achieving the prohibited purpose must be taken into account.

48. As regards the substance of the communication, the Commission argues that in the present case the information on the prescription-only medicinal products was verified and approved by the competent authorities and, as a result, it may be presumed that the substance of the communication does not pose any immediate risk to consumers.

49. With reference to the intended audience of the communication, the Commission contends that the risk of uncontrolled consumption of medicines appears in the present case to be at the most extremely limited as the medicines in question are available only on prescription. Moreover, even if a patient or another person comes across prescription-only medicine in its primary packaging, that is, without the outer packaging and the information for patients contained therein, the publication in question neither restricts the protection of public health nor is detrimental to the high level of consumer protection required by the Directive, given the fact that as a result of the publication 'uninformed self-medication' may be avoided. As regards the possibility that after reading the information the individual concerned may be inclined not to consult a doctor, that situation can be easily avoided by stating very clearly in the

9 — Case C-421/07 *Damgaard* [2009] ECR I-2629.

publication that visiting the relevant website cannot in any way substitute for consulting a doctor.

50. As regards the technical design of the communication, the Commission argues that where the information concerned is merely made available on the internet ('pull services') a user must actively search this out and, as a result, anyone who is not interested in the medicinal products concerned is not unwillingly confronted with that information. It is different in the case of push services where internet users, for example, by means of 'pop-ups', that is, windows which appear unsolicited on the screen, are confronted with such content without having searched for this of their own accord.

51. Finally, the Commission observes that it has proposed an amendment to the Directive in order to ensure the uniform application of the basic prohibition on advertising established by the Directive and a high level of consumer protection. The Commission concludes that having regard to the legitimate aim pursued, that is, to safeguard public health, the contested prohibition cannot be regarded — contrary to the position reached in *Damgaard*[10] — as an appropriate and proportionate restriction on the freedom of expression.

52. At the hearing, in response to questioning by the Court, the Commission clarified its argument, stating that when it refers to the information mentioned in the question referred for a preliminary ruling it means the information included in the package leaflet.

53. The *Swedish Government*, which participated at the hearing, submitted argument to the effect that a situation such as that at issue in the main proceedings is not covered by the prohibition on advertising to the general public. It follows much the same line of reasoning as the Government of the United Kingdom. On the question of how to differentiate advertising from other forms of information, in its view, an individual examination of various factors, for example, the substance of the information is required. In that connection, the Swedish Government argues that there are most certainly categories of information not disseminated for promotional purposes as is demonstrated, in particular, by Article 86(2) of Directive 2001/83. At issue in that provision is information which has been verified by the competent authorities. In addition, the Swedish Government refers to the public right to information. In relation to the fact that the information in question in the main proceedings was disseminated by the manufacturer itself, the Swedish Government states that although authorship by the manufacturer may hint at an advertising purpose that factor alone cannot be decisive. If it had been intended as a criterion of assessment, the legislature of the European Union would have expressly incorporated such in the Directive.

10 — Ibid., paragraph 28.

VI — Legal appraisal

A — *Introductory observations*

1. Relevance of the boundary

54. The present proceedings raise once again the difficult question of how to differentiate between 'advertising' and 'information' in the area of the law on medicinal products.

55. The need for as precise as possible a boundary between both categories based on clear criteria rests not least on the fact — as held by the Court in *Gintec* [11] — that Directive 2001/83, as amended by Directive 2004/27, provides for complete harmonisation in the field of advertising of medicinal products, [12] since it lists expressly the cases in which Member States are authorised to adopt provisions departing from the rules laid down by that directive. The prohibition on advertising of medicinal products — regarded by the Court to that extent as exhaustive [13] — established in Article 88(1) of Directive 2001/83 demands, thus, a uniform interpretation throughout the European Union on which national courts can rely in their application of European Union law.

56. The distinction between 'advertising' and 'information' is evident simply from the heading to Title VIIIa of Directive 2001/83. In that connection, it must be observed that legal harmonisation is restricted simply to the field of advertising whereas the rules relating to information on medicinal products are a matter for the Member States provided that they do not infringe the European Union rules on advertising laid down in Directive 2001/83. [14] That explains why at present there is considerable divergence between national legal orders on the provision of information to patients on medicinal products. As the Commission noted in its Communication on the Report to the European Parliament and Council of 20 December 2007, [15] certain

11 — Case C-374/05 *Gintec* [2007] ECR I-9517.

12 — Ibid., paragraphs 20 and 39. See also Meyer, F., 'Das strenge deutsche Heilmittelrecht — ein Fall für den Europäischen Gerichtshof', *Pharma Recht*, 2007, p. 231, who argues that the advertising rules in the directive constitute a comprehensive and complete system which, in principle, does not allow any scope for derogations.

13 — *Gintec*, cited above in footnote 11, paragraph 26.

14 — See the Opinion of Advocate General Ruiz-Jarabo Colomer in *Damgaard*, cited above in footnote 9, point 34. To the same effect, see also De Grove-Valdeyron, N., 'Vers un marché unique des médicaments: acquis et nouvelles orientations communautaires', *Cahiers de droit européen*, Volume 45 (2009), No 3-4, p. 357.

15 — Communication from the Commission to the European Parliament and the Council concerning the Report on current practice with regard to provision of information to patients on medicinal products, COM(2007) 862 final, pp. 3 and 10.

Member States are very restrictive in that regard whereas others allow the publication of non-promotional information. Therefore, the boundary between both categories is relevant also to the division of competences between the Union and its Member States.

2. The prohibition on advertising as the outcome of a legislative process in search of a balance

57. In terms of regulatory policy, the basic prohibition on advertising medicinal products to the general public can be explained by the need to safeguard public health against the risks to patients resulting from 'excessive and ill-considered advertising'.[16] That follows expressly from Recital 45 in the preamble to Directive 2001/83 which indicates that, by way of exception, advertising for non-prescription medicinal products is permitted provided, however, that certain legal requirements are satisfied. However, for prescription-only medicinal products that derogation from the prohibition on advertising does not apply and, as a result, it must be presumed that for this category of medicinal products there is an absolute prohibition on advertising. Such a comprehensive prohibition on advertising is intended to prevent advertising-induced self-medication by patients in the light of the health risks generally associated with the use of prescription-only medicinal products. In *Deutscher Apothekerverband*,[17] citing Article 71(1) of Directive 2001/83 in support,[18] the Court emphasised the health risks which those medicinal products present.

58. However, at the same time, in Article 88a of Directive 2001/83 inserted later by Directive 2004/27, the European Union legislature stresses the need for 'good-quality, objective, reliable and non-promotional information on medicinal products and other treatments'. That provision must be read in conjunction with Recital 40 in the preamble to Directive 2001/83 from which it follows that 'the provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information'.

16 — See the Opinion of Advocate General Ruiz-Jarabo Colomer in *Gintec*, cited above in footnote 11, point 60, in which he stated that he had no doubts 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)). See, in addition, *Damgaard*, cited above in footnote 9, paragraphs 22 and 29 and Case C-62/09 *Association of the British Pharmaceutical Industry* [2010] ECR I-3603, paragraph 30.

17 — Case C-322/01 *Deutscher Apothekerverband* [2003] ECR I-14887, paragraph 117.

18 — That provision states that medicinal products must be subject to medicinal prescription where they are likely to present a danger either directly or indirectly, even when used correctly, if utilised without medical supervision.

59. From that it must be concluded that the European Union legislature seeks to reconcile, on the one hand, the safeguarding of public health with, on the other hand, the right of consumers to information and the freedom of expression of pharmaceutical manufacturers, by reason of the fact that it prohibits only the product-related information which, on account of specific features, is harmful to the public. Thus, ultimately, the advertising prohibition appears to be the outcome of a legislative process seeking to balance fundamental rights which must be taken into account in the interpretation of Article 88(1) of the Directive.

of the reference for a preliminary ruling in which the referring court states:

'In the circumstances described above, the referring court is uncertain whether the prohibition on advertising, otherwise than to the medical profession, medicinal products that are available only on prescription is proportionate having regard to Community fundamental rights, where only mandatory information is involved and where that information is available only on the internet, with the result that they are not "imposed" on a wider public which is unprepared to receive it...'

B — *The subject-matter of the reference for a preliminary ruling*

60. That leads us to the question of what is the subject-matter of the reference for a preliminary ruling in the present case. In the light of the restrictions on fundamental rights resulting from the prohibition on advertising medicinal products, MSD argues that the question referred concerns not only the interpretation but also the validity of Article 88(1)(a) of Directive 2001/83. It bases its understanding of the question on paragraph 15

61. That must be countered by reference to the actual question referred which clearly seeks an interpretation of Article 88(1)(a) of Directive 2001/83. Even taking account of the passage at issue in the reference for a preliminary ruling, on an objective appraisal the question must be interpreted as meaning that, in essence, the referring court seeks to establish whether the EU law concept of advertising of medicinal products covers a specific set of facts described in detail in the question referred. The Court is requested to confirm a certain interpretation of that concept and, in that regard, in the light of primary law requirements the referring court raises the possibility of a more restrictive interpretation. However, that does not mean that the validity itself of the relevant EU provision

is questioned. The referring court neither hints at uncertainties concerning the validity of that provision nor states that such a question has been raised in the proceedings which are pending before that court. Instead, it seeks to understand in the light of a specific case where the boundary lies between prohibited 'advertising' and permissible 'information'.

62. To the extent that this argument advanced by MSD goes beyond the actual question referred, as a matter of procedural law, it must be regarded as a request by a party to extend the original subject-matter of the preliminary ruling procedure.

63. In that connection, first, it must be observed that the system established by Article 234 EC with a view to ensuring that Community law is interpreted uniformly in the Member States instituted direct cooperation between the Court of Justice and the national courts by means of a procedure which is completely independent of any initiative by the parties. [19] Thus, in the framework of the preliminary ruling procedure, the parties to the main proceedings do not have rights of initiative but simply are invited to be heard. [20] Accordingly, in my view, the Court was correct to hold that as Article 234 EC does not constitute a means of redress available to the parties to a case pending before a national court, the Court cannot be compelled to evaluate the validity of an act of Community law on the sole ground that that question has been put before it by one of the parties in its written pleadings. [21] From that case-law, it must be concluded that MSD does not have the right in procedural law terms to seek an amendment to the subject-matter of the reference for a preliminary ruling, for example, in questioning the validity of a particular provision of secondary law. Accordingly, its request must be rejected.

64. Given the fact that with the exception of MSD no other party raised the question of validity, for the sake of completeness, it would appear prudent to mention the case-law of the Court according to which to answer additional questions raised by the parties to the main proceedings in their observations would be incompatible with the Court's function under Article 234 EC and with its duty to ensure that the Governments of the Member States and the parties concerned are given the opportunity to submit observations under

19 — To that effect, see Joined Cases 28/62 to 30/62 *Da Costa and Others* [1963] ECR 31, at 38; Case 62/72 *Bollmann* [1973] ECR 269, paragraph 4; Case C-261/95 *Palmisani* [1997] ECR I-4025, paragraph 31; and Case C-2/06 *Kempter* [2008] ECR I-411, paragraph 41 et seq.

20 — See the Opinion of Advocate General Kokott in Case C-404/07 *Katz* [2008] ECR I-7607, point 28. On the role of the parties in preliminary ruling proceedings see further my Opinion of 6 July 2010 in the pending Case C-137/08 *Pénzügyi Lízing*, point 80.

21 — See Case 283/81 *Cilfit* [1982] ECR 3415, paragraph 9; Case C-402/98 *ATB and Others* [2000] ECR I-5501, paragraphs 30 and 31; Case C-344/04 *IATA and ELFAA* [2006] ECR I-403, paragraph 28; and Joined Cases C-376/05 and C-377/05 *Brünsteiner* and *Autohaus* [2006] ECR I-11383, paragraphs 27 and 28.

Article 23 of the Statute of the Court, bearing in mind that, under that provision, only the order of the referring court is notified to the interested parties. [22]

65. Regardless of those procedural considerations, for reasons of substantive law, examination by the Court of the validity of such a provision may simply be unnecessary, if the relevant provision of secondary law is susceptible of an interpretation consistent with primary law. It is settled case-law that when a provision of secondary Community law is open to more than one interpretation, preference should be given to the interpretation which renders the provision consistent with the Treaty. [23] In doctrinal terms, that rule of interpretation follows from the principle of the coherence of the legal order of the European Union. [24] In that connection, it is open to the Court to examine whether a question of validity that has been raised is based on a correct interpretation of the relevant provision of secondary law. Correspondingly, where an interpretation consistent with primary law is possible, the Court declined to examine the validity of a particular provision of secondary law in the light of primary law. [25]

66. In my view, such an approach appears appropriate in the present case as, on my analysis, the question of whether a comprehensive prohibition on advertising is compatible with primary law only arises if the making available of information on medicinal products on the internet, in the manner described in the question referred, can be included within the concept of advertising of medicinal products. In that connection, from the point of view of legal method, it must be noted that in the process of interpretation itself — for example, in the framework of a schematic

22 — Case C-352/95 *Phyteron* [1997] ECR I-1729, paragraph 14, and Case C-412/96 *Kainuun Liikenne and Pohjolan Liikenne* [1998] ECR I-5141, paragraph 24.

23 — Case 218/82 *Commission* v *Council* [1983] ECR 4063, paragraph 15, Case 205/84 *Commission* v *Germany* [1986] ECR 3755, paragraph 62, and Joined Cases 201/85 and 202/85 *Klensch and Others* v *Secrétaire d'État* [1986] ECR 3477, paragraph 21.

24 — To that effect, see Leible, S. and Domröse, R., 'Die primärrechtskonforme Auslegung', in *Europäische Methodenlehre* (edited by Karl Riesenhuber), Berlin 2006, p. 187 et seq. who refer to Case C-499/04 *Werhof* [2006] ECR I-2397, paragraph 32. In that paragraph, the Court stated that 'in accordance with the Court's settled case-law, when interpreting the provisions of a directive account must be taken of the principle of the coherence of the Community legal order which requires secondary Community legislation to be interpreted in accordance with the general principles of Community law'.

25 — See Case C-334/95 *Krüger* [1997] ECR I-4517, paragraphs 23 and 35. To that effect, see Lenaerts, K., Arts, D. and Maselis, I., *Procedural Law of the European Union*, 2nd edition, London 2006, paragraph 2-021, p. 50, who state that the Court may determine whether a question of validity is based on a correct interpretation of the relevant provision of secondary law. As a rule, following interpretation, the Court holds that an examination of a provision's compatibility with higher-ranking law has been rendered unnecessary as the argument alleging incompatibility with the Treaty is based on a different interpretation.

and teleological interpretation of that concept — regard may be had to considerations reflecting the requirements of primary law. [26] If, on the other hand, the manufacturer's actions are categorised as permissible information to patients, the question of compatibility no longer arises. On those grounds, it is appropriate to begin the legal analysis with an interpretation of Directive 2001/83.

C — *Examination of the question referred*

1. The definition of advertising of medicinal products and the distinction from information

67. At the outset, it must be noted that EU law neither expressly permits nor prohibits the publication on the internet of information about a particular medicinal product. The question of whether or not that action is permissible depends primarily on whether it is included in the concept of advertising provided for in the Community code. Article 86(1) of Directive 2001/83 contains a definition consisting of two limbs requiring as an objective element the provision of a 'form of door-to-door information' and which, in subjective terms, is designed 'to promote the prescription, supply, sale or consumption of medicinal products'. The provision lists in an indicative manner several examples of advertising of medicinal products.

68. That definition expressly includes 'advertising to the general public' and, as a consequence, the prohibition on advertising to the general public applies also to publication on the internet. [27] Further, it follows from the wording and the context of that provision that advertising constitutes only one element of the total information available. [28] Thus, the term 'information' is all-encompassing and acquires a legal relevance only where the information has the specific characteristics — defined in EU law — of advertising. [29] Consequently, in the light of the definition established in Article 86(1) of Directive 2001/83, the notion of advertising does not in principle preclude the possibility

26 — According to Leible, S. and Domröse, R., cited above in footnote 24, p. 186 et seq., interpretation in conformity with primary law does not imply that primary law requirements cannot be considered in the process of interpretation itself — in the framework of a schematic and teleological interpretation — or that possible interpretations contrary to primary law may not be excluded and, instead, that only the outcome of the interpretation may be measured against primary law.

27 — To the same effect, Gellissen, G., *Arzneimittelwerbung im Internet*, Hamburg 2008, p. 149.

28 — See González Vaqué, L., 'Publicidad e información sobre los medicamentos: dos conceptos difíciles de delimitar en el ámbito del Derecho comunitario', *Revista electrónica de Derecho del Consumo y de la Alimentación*, No 21 (2009), p. 34, who argues that information without a promotional purpose is clearly possible.

29 — Michaux, G., 'La publicité et l'information relative aux médicaments en droit européen', *European Journal of Consumer Law*, 2-3/2009, p. 349, is correct to point out that there is neither a definition of 'other information' nor criteria to distinguish such from 'advertising'. In my view, it is for the Court by means of interpretation to develop distinguishing criteria with a view to ensuring the application of Directive 2001/83 in conformity with the principle of legal certainty.

that the publications in question consist simply in objective information. Unlike the predominant characterisation of advertising, for the purposes of the Directive the concept of advertising does not presume sensational form, exaggeration or even puffery. [30] Instead, the fundamental criterion separating advertising from mere information is the purpose of the message. If the intention is to promote the prescription, supply, sale or consumption of medicinal products, there will be advertising for the purposes of the Directive; if, on the other hand, purely informative material is being disseminated without promotional intent, it will not come within the rules of European Union law on advertising of medicinal products. The crucial element is thus the deliberate and direct intention of the party who issues the message. [31]

2. Assessment criteria

69. Whether or not such promotional intent exists is primarily — as the Court held most recently in *Damgaard* — for the national court to determine in the light of the specific circumstances of the case before it. [32] However, that does not preclude the Court in the exercise of its interpretative authority from furnishing national courts with suitable criteria with which — when applying European Union law and national implementing provisions [33] — they may determine the factual existence of such a promotional intent.

(a) Giving due account to fundamental rights in the interpretation

70. In formulating assessment criteria, consideration should be given also to the adoption of a strict interpretation, having regard to the fact, in particular, that in terms of its wording the concept of advertising established in Directive 2001/83 is relatively undefined and hence depending on the interpretation given could be accorded a very broad meaning such that potentially it might include actions which in the light of both the

30 — To that effect, see Lorz, A., 'Internetwerbung für verschreibungspflichtige Arzneimittel aus gemeinschaftsrechtlicher Perspektive', *Gewerblicher Rechtsschutz und Urheberrecht - Internationaler Teil*, 2005, p. 895.

31 — See the Opinion of Advocate General Ruiz-Jarabo Colomer in *Damgaard*, cited above in footnote 9, point 38.

32 — *Damgaard*, cited above in footnote 9, paragraph 23. In the view of González Vaqué, L., cited above in footnote 28, p. 41, determination of a promotional intent can constitute only a starting point for distinguishing advertising from other information. He argues that the Court has given over to national authorities and courts the task of determining in an individual case whether a specific communication is intended to promote the prescription, supply, sale or consumption of medicinal products.

33 — According to the case-law of the Court, when applying domestic law, the national court is bound to interpret national law, 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 the directive (see *Gintec*, cited above in footnote 11, paragraph 38, and Joined Cases C-397/01 to C-403/01 *Pfeiffer and Others* [2004] ECR I-8835, paragraph 113).

circumstances of the individual case and the relevant legal framework do not appear to require prohibition.

71. The objective of the prohibition on the advertising to the general public of medicinal products is, as I stated earlier, [34] to safeguard patients against improper or unreasonable influence and hence, ultimately, to safeguard public health. That prohibition under the law on the advertising of medicinal products extends the protection established by the requirement for a prescription. However, due consideration must be given to that protective purpose in the interpretation of the concept of advertising. If the information concerned does not jeopardise the health of consumers or the suppression of information appears even to be counterproductive, there is no objective justification for a comprehensive prohibition.

72. The necessity for a strict interpretation — at the level of secondary law — of the concept of advertising results not least from the balance required to be struck between the legal interest that the provision is intended to protect and the primary law rights of consumers and manufacturers of medicinal products which are characterised by a different protective purpose. [35] In addition, that balance is subject to the principle of proportionality as a function of the requirement to act in accordance with the rule of law. To that extent, fundamental rights and the principle of proportionality, which are included in the general principles of the law of the European Union, constitute a substantial element of the legal framework in which the interpretation of secondary law must fit. [36]

73. As the Court has stated on many occasions, [37] the Community cannot accept measures which are incompatible with observance of the human rights thus recognised

34 — See point 57 of this Opinion.

35 — For a similar view in connection with the German implementing provisions see Stoll, V., 'Das Publikumswerbeverbot für verschreibungspflichtige Arzneimittel — erste Anzeichen einer Auflockerung', *Pharma Recht*, 2004, p. 101 et seq., who argues that in order to establish a fundamental rights justification for the prohibition on the advertising to the general public of medicinal products a balancing process is needed. The author considers that such prohibition constitutes a restriction on the fundamental rights of manufacturers and patients.

36 — In point 74 of his Opinion in *Damgaard*, cited above in footnote 9, Advocate General Ruiz-Jarabo Colomer reached a similar conclusion, stating that the intention to safeguard public health must allow some margin for the specific features of freedom of expression, since the protection afforded by that right also extends to statements which the health authorities may consider a threat to that objective of safeguarding health. In that connection, W. Schroeder, in his article 'Die Auslegung des EU-Rechts', *Juristische Schulung*, 2004, No 3, p. 182, refers to the requirement for interpretation in conformity with the constitution. In his view, that principle implies in particular that every interpretation of the law of the European Union must observe the fundamental rights of the European Union and the principle of proportionality.

37 — See, in particular, Case C-260/89 *ERT* [1991] ECR I-2925, paragraph 41, Case C-299/95 *Kremzow* [1997] ECR I-2629, paragraph 14, and Joined Cases C-402/05 P and C-415/05 P *Kadi and Al Barakaat International Foundation* v *Council and Commission* [2008] ECR I-6351, paragraph 284.

and guaranteed. It is settled case-law that fundamental rights form an integral part of the general principles of law the observance of which the Court ensures. For that purpose, the Court draws inspiration from the constitutional traditions common to the Member States and from the guidelines supplied by international instruments for the protection of human rights on which the Member States have collaborated or to which they are signatories. The European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 ('the ECHR') has special significance in that respect. [38] The principles established by that case-law were reaffirmed in Article 6(2) TEU. That provision states that 'the Union shall respect fundamental rights, as guaranteed by the [ECHR] and as they result from the constitutional traditions common to the Member States, as general principles of Community law'. Furthermore, on several occasions, the Court has relied on the Charter of Fundamental Rights of the European Union proclaimed in Nice on 7 December 2000 [39] in order to confirm the existence of certain general principles of law, [40] an instrument which, following the entry into force of the amending Treaty of Lisbon, in accordance with the first subparagraph of Article 6(1) TEU, has the same legal value as the Treaties. [41]

74. According to the Court, the European Union's commitment to fundamental rights binds also the authorities and courts of the Member States which are responsible for the interpretation and application of the law by which a directive is implemented. The Court held in *Lindqvist* [42] that it is for such bodies not only to interpret their national law in a manner consistent with a particular directive but also to make sure they do not rely on an interpretation of it which would be in conflict with the fundamental rights protected by the Community legal order or with the other general principles of Community law, such as inter alia the principle of proportionality.

75. Moreover, according to settled case-law, where national legislation falls within the scope of application of Community law the Court, in a reference for a preliminary ruling, must give the national court all the guidance as to interpretation necessary to enable it to

38 — See, in particular, *ERT*, cited above in footnote 37, paragraph 41; Case C-274/99 P *Connolly* v *Commission* [2001] ECR I-1611, paragraph 37; Case C-94/00 *Roquette Frères* [2002] ECR I-9011, paragraph 25; Case C-112/00 *Schmidberger* [2003] ECR I-5659, paragraph 71; Case C-540/03 *Parliament* v *Council* [2006] ECR I-5769, paragraph 35; Case C-229/05 P *PKK and KNK* v *Council* [2007] ECR I-439, paragraph 76; and Case C-71/02 *Karner* [2004] ECR I-3025, paragraph 48.

39 — OJ 2000 C 364, p. 1.

40 — See Case C-244/06 *Dynamic Medien* [2008] ECR I-505, paragraph 42, Case C-438/05 *International Transport Workers' Federation and Finnish Seamen's Union* [2007] ECR I-10779, paragraph 43, and *Parliament* v *Council*, cited above in footnote 38, paragraph 38.

41 — See Case C-407/08 P *Knauf Gips* v *Commission* [2010] ECR I-6375, paragraph 91, and Case C-555/07 *Kücükdeveci* [2010] ECR I-365, paragraph 22.

42 — Case C-101/01 *Bodil Lindqvist* [2003] ECR I-12971, paragraph 87.

assess the compatibility of that legislation with the fundamental rights the observance of which the Court ensures.[43] Accordingly, the following analysis will address the fundamental rights which are touched upon by the advertising prohibition established by Article 88(1)(a) of Directive 2001/83 and which suggest a restrictive interpretation in conformity with primary law. Subsequently, I will consider in detail other criteria which may be of assistance also in the interpretation of that provision.

(i) The fundamental right to freedom of expression

76. The prohibition on advertising impacts primarily on the fundamental right to freedom of expression, recognised in the case-law of the Court as a general principle of law[44] and laid down in Article 11(1) of the Charter of the Fundamental Rights of the European Union. The Court regards the freedom of expression as one of the fundamental pillars of a democratic society and refers in its case-law in addition to Article 10(1) of the ECHR and the case-law of the European Court of Human Rights.

77. As regards the question whether the provision on the internet of information on medicinal products is included within the scope of the protection established by that fundamental right, it must be observed that the common European concept of fundamental rights relies on a broad notion of opinion which may be expressed. In accordance with that notion, any view, conviction, appraisal, assessment, statement of fact or value judgment regardless of its quality or subject-matter is deemed an opinion.[45] Even advertising effected purely on commercial grounds is included within the scope of the protection

43 — See *ERT*, cited above in footnote 37, paragraph 42; Case C-159/90 *Grogan* [1991] ECR I-4685, paragraph 31; *Kremzow*, cited above in footnote 37, paragraph 15; and *Karner*, cited above in footnote 38, paragraph 49.

44 — See Joined Cases 43/82 and 63/82 *VBVB and VBBB* v *Commission* [1984] ECR 19, paragraph 34; Joined Cases 60/84 and 61/84 *Cinéthèque and Others* [1985] ECR 2605; Case 352/85 *Bond van Adverteerders and Others* [1988] ECR 2085, paragraph 40; Case 100/88 *Oyowe and Traore* v *Commission* [1989] ECR 4285, paragraph 16; *ERT*, cited above in footnote 37, paragraph 44; Case C-288/89 *Collectieve Antennevoorziening Gouda* [1991] ECR I-4007, paragraph 23; Case C-353/89 *Commission* v *Netherlands* [1991] ECR I-4069, paragraph 30; Case C-23/93 *TV10* [1994] ECR I-4795, paragraph 23 et seq.; Case C-368/95 *Familiapress* [1997] ECR I-3689, paragraph 26; Case C-60/00 *Carpenter* [2002] ECR I-6279, paragraph 42; and *Karner*, cited above in footnote 38, paragraph 50.

45 — See Streinz, R., *EUV/EGV-Kommentar*, Munich 2003, Article 11 of the Charter of Fundamental Rights, point 11, p. 2597; Calliess, C., *EUV/EGV-Kommentar* (edited by Christian Calliess and Matthias Ruffert), 3rd edition, Munich 2007, Article 11 of the Charter of Fundamental Rights, points 5 and 6, p. 2578. Sporn, S., 'Das Grundrecht der Meinungs- und Informationsfreiheit in einer Europäischen Grundrechtscharta', *Zeitschrift für Urheber- und Medienrecht*, 2000, p. 540, argues that the fundamental right to freedom of expression must be given broad scope in order to ensure that its protection applies not only to opinions but also to statements of fact. A similar view is taken by Knecht, M., *EU-Kommentar* (edited by Jürgen Schwarze), 2nd edition, Baden-Baden 2009, Article 11 of the Charter of Fundamental Rights, point 6, p. 2229, according to whom the concept of opinion must be interpreted very widely with a view to ensuring that both correct and incorrect statements of fact and expressions of value judgments are protected.

established by the freedom of expression.[46] It constitutes part of the protected sphere of 'commercial communication' which includes the provision of opinions, information and ideas for commercial purposes regardless of whether its emphasis is informational or promotional.[47] Accordingly, publication of the package leaflet accompanying a medicinal product, an image of the packaging and supplementary information are included within the fundamental right to freedom of expression.[48] Moreover, in *Damgaard*, the Court held the dissemination of information on medicinal products to be covered, in principle, by the fundamental right to freedom of expression.[49]

78. However, that fundamental right does not apply without limitation but, as the Court has repeatedly held by reference to Article 10(2) of the ECHR,[50] may be subject to certain limitations justified by objectives in the public interest, in so far as those derogations are in accordance with the law, motivated by one or more of the legitimate aims under that provision and necessary in a democratic society, that is to say justified by a pressing social need and, in particular, proportionate to the legitimate aim pursued.

79. Pursuant to Article 10(2) of the ECHR in conjunction with the first sentence of Article 53(1) of the Charter of Fundamental Rights, the safeguarding of public health constitutes, in principle, a legitimate aim for the purposes of limiting the freedom of expression.[51] However, determination of an objective in the public interest is linked to the division of powers and, as a consequence, for the purposes of legitimating an interference with a fundamental right, the European Union may rely only on those legal interests which as a matter of European Union law it is required to protect. Regardless of the prohibition on harmonisation in the area of health policy pursuant to Article 152(4)(c) EC, on grounds of its transversal character, the safeguarding of health is recognised — at any rate for these purposes — as a legitimate objective of European Union policy, as reflected in particular in Article 95(3) EC and Article 152(1) EC. It follows from those provisions that in the

46 — See *Karner*, cited above in footnote 38, paragraph 51, Case C-245/01 *RTL Television* [2003] ECR I-12489, paragraph 73, and Opinion of Advocate General Fennelly in Case C-376/98 *Germany* v *Parliament and Council* [2000] ECR I-8423, point 154 et seq. See the European Court of Human Rights in *Markt intern Verlag GmbH and Klaus Beermann*, judgment of 20 November 1989, Series A No 165, and *VGT Verein gegen Tierfabriken* v *Switzerland*, judgment of 28 June 2001, *Reports of judgments and decisions* 2001-VI. See also Streinz, R., cited above in footnote 45, point 11, p. 2597; Calliess, C., cited above in footnote 45, points 6 and 10, pp. 2578 and 2579; Reid, K., *A Practitioner's Guide to the European Convention on Human Rights*, 2nd edition, London 2004, paragraph IIB-1765, p. 318.

47 — See *Casado Coca* v *Spain*, judgment of the European Court of Human Rights of 24 February 1994, Series A No 285, paragraph 35 et seq.

48 — See also Lorz, A., cited above in footnote 30, p. 902.

49 — *Damgaard*, cited above in footnote 9, paragraph 23.

50 — Ibid., paragraph 26 and *Karner*, cited above in footnote 38, paragraph 50.

51 — See Case C-491/01 *British American Tobacco* [2002] ECR I-11453, paragraph 150.

definition and implementation of all Community policies and activities a high level of health protection must be ensured. The same is provided in the second sentence of Article 35 of the Charter of Fundamental Rights.

80. According to the case-law of the Court, the interests involved must always be weighed having regard to all the circumstances of the case in order to determine whether a fair balance was struck between those interests. The same requirement for a balancing of interests is established in the case-law of the European Court of Human Rights. [52] However, in that regard, it must be noted that absolute prohibitions on advertising, as Advocate General Fennelly observed correctly in his Opinion in Case C-376/98 *Germany* v *Parliament and Council* [53] in connection with a prohibition on the advertising of tobacco products in magazines and newspapers, constitute a particularly serious interference especially with the freedom of expression and, as a consequence, for this to be justified specific reasons are needed to demonstrate that a less burdensome measure would not have sufficed. Consequently, the requirements to be shown in establishing the legality of an advertising prohibition must be regarded as particularly stringent.

(ii) Freedom to impart information

81. At a subsidiary level, if a manufacturer publishes on its website information not expressing a value judgment and for non-commercial purposes, consideration should be given to the applicability of the specific fundamental freedom to impart information. It grants an independent right to provide information to others regardless of whether the communication is effected orally or in written, printed or electronic form. [54] As a rule, the freedom to impart information is included within the scope of protection established by the general fundamental right to freedom of expression. [55] Correspondingly, Article 10(1) of the ECHR provides initially for the freedom of expression in general terms and specifies this in the second sentence to include the communication of information. [56] Pursuant also to the second sentence of Article 11(1) of the Charter of Fundamental Rights, the right to freedom of expression includes the freedom to communicate information without interference by public authority. In that regard, not only is the communication of one's own ideas but also the transmission of third-party ideas and information protected.

52 — See *Stambuk* v *Germany*, judgment of the European Court of Human Rights of 17 October 2002, (Application no 37928/97), paragraphs 39 and 41.

53 — Opinion of Advocate General Fennelly in *Germany* v *Parliament and Council*, cited above in footnote 46, point 164.

54 — See Grabenwarter, C., *Europäische Menschenrechtskonvention*, 4th edition, Munich 2009, point 5, p. 269.

55 — See Calliess, C., cited above in footnote 43, point 8, p. 2579.

56 — See Frowein, J., *Europäische Menschenrechtskonvention*, Kehl, Strasbourg and Arlington 1985, point 2, p. 225.

82. In relation to this fundamental right, the same limiting provisions apply as govern freedom of expression within the narrower meaning of that term and, consequently, I refer to my observations above. [57]

(iii) Freedom to conduct a business

83. The prohibition on the advertising of medicinal products impacts also on the freedom to conduct a business recognised in Article 16 of the Charter of Fundamental Rights and the case-law of the Court. The freedom to conduct a business constitutes a particular expression of the freedom to pursue a trade or profession which, in itself, has the status of a general principle of Community law. [58] Commercial communication is closely linked to the freedom to conduct a business. As essential preconditions for product sales, advertising and information constitute a typical expression of the fundamental freedom to conduct a business.

84. However, as held by the Court in settled case-law, [59] that principle is not absolute, but must be viewed in relation to its social function. Consequently, restrictions may be imposed on the exercise of the freedom to pursue a trade or profession provided that such restrictions in fact correspond to objectives of general interest pursued by the European Union and do not constitute in relation to the aim pursued a disproportionate and intolerable interference, impairing the very substance of the rights guaranteed.

(iv) The freedom of consumers to receive information

85. Finally, the prohibition on the advertising of medicinal products restricts also the freedom of consumers to receive information, as provided for also in Article 11(1) of the Charter of Fundamental Rights. The substantive scope of the protection established by the freedom of information encompasses the whole process from the mere receipt of

57 — See points 78 to 80 of this Opinion.

58 — See Streinz, R., cited above in footnote 45, point 4, p. 2607, who argues that, in the light of the cases reaching it hitherto, the Court has developed the freedom to pursue a trade or activity as a fundamental principle of Community law simply as the freedom to conduct a business. A similar view is taken by Knecht, M., cited above in footnote 45, point 1, p. 2237.

59 — See Case 4/73 *Nold* v *Commission* [1974] ECR 491, paragraph 14; Case C-44/94 *Fishermen's Organisations and Others* [1995] ECR I-3115, paragraph 55; Case C-200/96 *Metronome Musik* [1998] ECR I-1953, paragraph 21; Joined Cases C-20/00 and C-64/00 *Booker Aquaculture and Hydro Seafood* [2003] ECR I-7411, paragraph 68; and Joined Cases C-37/02 and C-38/02 *Di Lenardo and Dilexport* [2004] ECR I-6911, paragraph 82.

information to its preparation and storage. [60] The freedom to receive information, that is, as a right to access and acquire information, may not be regarded as simply limited to conduct which is passive but protects also the steps taken by an individual to obtain information. [61]

86. In the area of medicinal products, the right of patients to information is particularly important in connection with the new model of 'informed patients' who are to be given the greatest possible opportunity to decide on their own treatment and medication and hence require objective and comprehensive information. [62] In a similar vein, in the above-mentioned communication to the European Parliament and Council, [63] the Commission presumes that patients have a right to information and, accordingly, should be able to access information about their health, medical conditions and the availability of treatments. According to the Commission, [64] that right to information reflects the fact that patients are no longer simply taking what is prescribed for them, but are increasingly involved as managers of their health. It is said that they become intensely involved with their illness, show great interest in health issues and have a constantly growing need for information. The Commission interprets the new model of 'informed patients', implying an increasingly active role for patients in health care provision, as empowering citizens, as follows also from its White Paper on Health. [65]

87. In accordance with that new model, the responsible authorities in several Member States are at present increasingly providing the public with information on medicinal products and illnesses whether on the internet or in magazines, brochures, information campaigns, workshops or symposia. In addition, information is disseminated also via pharmacies and the media. [66] In examining the individual criteria for assessing whether or not publication by the manufacturer on the internet of information on medicinal products must be categorised as advertising, I will consider in detail the consequences of

60 — See Streinz, R., cited above in footnote 45, point 11, p. 2597.

61 — See Grabenwarter, C., cited above in footnote 54, point 6, p. 269.

62 — See, for example, in connection with the prohibition under German law on the advertising of medicinal products Stebner, F., 'Einschränkende Auslegung einzelner Normen des HWG am Beispiel des BGH-Urteils vom 1. März 2007 (I ZR 51/04) sowie anderer Urteile und rechtspolitische Überlegungen', *Pharma Recht*, 2008, p. 25, who argues that the HWG of 11 July 1965 contains numerous restrictions on advertising in particular in relation to advertising to the general public. However, so he argues, circumstances have changed considerably since the Law entered into force. For example, patients now have greater autonomy and a greater need for information which they may satisfy by resorting to a multiplicity of sources such as the internet.

63 — See footnote 15 of this Opinion.

64 — See Section 3 (The patient needs on the provision of information and its benefits and risks) of the Commission's Communication.

65 — See Commission White Paper 'Together for Health: A Strategic Approach for the EU 2008-2013' of 23 October 2007, COM(2007) 630 final, Section 2, Principle 1 (A strategy based on shared health values).

66 — See Section 2.1 (Practices in the Member States) of the Commission's Communication.

that development in the area of medicinal products.

Instead, a precise teleological interpretation of that provision is required.

(b) The individual assessment criteria

88. As I mentioned in point 69 of this Opinion, in the following analysis I intend to identify certain objective criteria intended to assist national courts in determining whether having regard to all the circumstances of the individual case a particular internet publication relating to medicinal products discloses a promotional intent.

90. Admittedly, the fact that in the main proceedings a manufacturer provides information on its own medicinal products and, in addition, that it places this on the internet, accessible to a broad population, constitutes strong evidence in favour of categorising that action as advertising within the meaning of the abovementioned definition, particularly as a manufacturer is generally likely to have a commercial interest in the product's marketing. That conclusion, as the following analysis will demonstrate, can be supported also by the existing case-law of the Court on European Union law on medicinal products.

(i) Limited evidential value attaching to authorship

89. First, the importance attaching to the authorship of product-related information must be examined. The wording of Article 86 of Directive 2001/83 does not allow a distinction to be drawn a priori between statements which are advertising and which are merely informational solely on the basis of who the author is. [67]

91. In *Ter Voort*, [68] in connection with the categorisation of a product as a medicinal product within the definition of medicinal products established in the first subparagraph of Article 1(2) of Directive 65/65 [69] 'by virtue of its presentation', the Court held that 'the conduct, action and approaches of the *manufacturer* or the seller which disclose his intention to make the product he markets appear to be a medicinal product in the

67 — This point was made by Advocate General Ruiz-Jarabo Colomer in his Opinion in *Damgaard*, cited above in footnote 9, point 56. To the same effect, see also De Grove-Valdeyron, N., cited above in footnote 14, p. 356.

68 — Case C-219/91 *Ter Voort* [1992] ECR I-5485.

69 — Council Directive 65/65 of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition 1965-66, p. 20)

eyes of an averagely well-informed consumer may therefore be conclusive for the purposes of deciding whether a product should be regarded as a medicinal product by virtue of its presentation'.[70] In the Court's view, 'in particular, the fact that the *manufacturer* or the seller sends the purchaser of the product a publication describing or recommending it as having therapeutic effects constitutes conclusive evidence of the manufacturer's or the seller's intention to market it as a medicinal product'.[71] In other words, in certain circumstances, a manufacturer is presumed, in principle, to be disposed to advertising its own products, to which consideration must be given.

92. In *Damgaard*, too, the Court emphasised 'that the situation of the author of a communication about a medicinal product and, in particular, *his relationship with the company which manufactures* or distributes it, are a factor which... may help to determine whether the communication constitutes advertising'.[72] Evidently, the Court implicitly presumes that the proximity of a third party to the manufacturer may influence the assessment whether in its reporting on a particular medicinal product the third party is in fact objective or has adopted the interests of the manufacturer. *A fortiori*, therefore, the conclusion cannot, in principle, be precluded that where a manufacturer of its own accord publishes information on its own medicinal products, it pursues, as a rule, a promotional purpose.

93. In my view, although such conclusion may be legitimate, it is by no means always compelling, as there are indeed many conceivable motives on which the publication of information by a manufacturer may be based. The presumption that every publication of information by a manufacturer is made with a view to increasing sales presupposes too wide a concept of the advertising of medicinal products.

94. As MSD convincingly argues, the publication of information may be connected to the general public relations activities of an undertaking without any specific aim of increasing sales. For example, one reason for such publication may be to counter third-party internet publications of unverified and therefore unsafe information on the undertaking's medicinal products with objectively correct information. Self-evidently, a manufacturer possesses first-hand knowledge and, accordingly, is likely to be in the best position to recognise false information and require the withdrawal thereof. The aim of such an action would not be, for the sake of argument, to increase the sales of a particular product but to protect the reputation of the undertaking and its staff. Moreover, by such an action a manufacturer may seek also to inform patients who already purchased the medicinal product but have lost the accompanying package leaflet. Prevention of potentially health-threatening

70 — *Ter Voort*, cited above in footnote 68, paragraph 26 (emphasis added).

71 — Ibid., paragraph 27 (emphasis added).

72 — *Damgaard*, cited above in footnote 9, paragraph 24. In that respect, the Court followed the view expressed by Advocate General Ruiz-Jarabo Colomer who in point 56 of his Opinion argued that the existence of a link between the author of the dissemination and the pharmaceutical company was particularly important. More specifically, the Advocate General pointed out that such link, although not a determining factor, constitutes a particularly important indication, because a third party does not often provide information about a medicinal product for a promotional purpose.

self-medication by a consumer not consulting the package leaflet is likely also to be in the interests of the undertaking, for example, to avert a loss of image or even liability claims. [73] Finally, it cannot be denied that a manufacturer of medicinal products may seek simply to satisfy the public's desire for and right to information with a view, for example, to advertising the transparency of the undertaking.

95. This demonstrates that the publication of information by the manufacturer itself cannot be regarded as a measure designed to promote the prescription, supply, sale or consumption of medicinal products. Instead, there must be additional factors to justify such an assessment. In accordance with the approach proposed by the Commission, [74] consideration must given, inter alia, to the subject-matter and substance of the contested information, the intended audience and the design of the medium by which the information is made accessible to the public.

96. However, before I consider those assessment criteria in detail, in that connection I should like to make a few remarks concerning the role of the State in the dissemination of information on medicinal products which was raised as an issue at the hearing. Given that the mere fact of authorship — as has already been seen — provides, in itself, little insight on the intention of a manufacturer when it makes information on medicinal products accessible to the public, I fail to be convinced by the argument of the Portuguese Government that publication of such information must be effected necessarily by public bodies. Instead, other models for the communication of information are perfectly conceivable in which, for example, all manufacturers are equally permitted — subject to official supervision and compliance with a strict framework of rules which takes account of the EU law on the prohibition of advertising of prescription-only medicinal products — to publish at their own initiative information on medicinal products on the internet. The objectives laid down in the Directive and which such a public system is intended to achieve are in my

73 — To that effect, see also von Hoff, K., 'Zulässigkeit des Einstellens von Beiträgen über Arzneimittel bei Wikipedia und diesbezügliche Überwachungspflichten und Löschungsansprüche pharmazeutischer Unternehmen', *Pharma Recht*, 2010, p. 49, who argues that for pharmaceutical undertakings information on medicinal products on the internet in general and on Wikipedia in particular constitutes a different balancing act between both the provision of patient information and the pursuit of marketing interests and the legal limits on advertising for medicinal products and the risks of product liability. At the same time, the author continues, a substantively incorrect and negative Wikipedia entry on a medicinal product may constitute a serious risk to patients and present major economic repercussions for the pharmaceutical manufacturer and, as a result, the undertaking concerned may have an interest in the rectification or deletion of such entries.

74 — See paragraph 14 of the observations of the Commission.

view attainable even where the information is communicated by manufacturers. The advantage of such an approach is not least the fact that the best use is made of first-hand expertise. I concede that the design of health information system is primarily a matter for the Member States. However, that does not imply that on implementing into domestic law the EU rules on the advertising to the general public of medicinal products, Member States are not required to give due consideration to the information rights of patients and to the rights of manufacturers and, if necessary, to re-examine existing schemes.

(ii) Subject-matter of the information

97. According to the reference for a preliminary ruling, the subject-matter of the information at issue in the main proceedings was a series of prescription-only medicinal products manufactured by MSD. At an initial glance, a prohibition on the advertising to the general public of prescription-only medicinal products appears justified as the incorrect use of those products can have sufficiently grave repercussions for the health of the consumer that a strict requirement for supply only on prescription and through a pharmacy appears necessary. On the other hand, specifically in relation to this category of medicinal products the risk of self-medication is likely to be considerably lower than in the case of medicinal products available without prescription, especially given the fact that they cannot be obtained — at least through lawful channels — without prior consultation of a doctor and pharmacist and due counselling and examination. As a consequence, any inducement resulting from advertising cannot be transposed immediately into a decision to purchase.

98. Admittedly, the possibility cannot be entirely precluded that publication of information on medicinal products on the website of a pharmaceutical undertaking may, ultimately, have an influence on the sales of such products. However, the mere communication of information is in principle suited only in a very marginal way to increasing the sales of a medicinal product as the requirement for a prescription means that is for a doctor alone to decide whether to prescribe a medicinal product, and if so, which product. As a rule, he will obtain the information necessary for that purpose from professional publications and pharmaceutical undertakings.

99. The additional information obtained by a patient may have two effects on his behaviour as a consumer. First, the fact that a patient has already read the package leaflet on the internet may result in his objection to the prescription of a particular medicinal product having regard to its possible risks and side-effects. To that extent, publication would have a negative impact on sales. On the other hand, informational materials obtained through the internet may result in a patient drawing his doctor's attention to a particular medicinal

product relevant to his condition and, as a consequence, facilitates its very prescription. However, regardless of such fact, it must, in principle, be presumed that a doctor is better informed than his patient on potential medicinal products. In addition, it is extremely unlikely that as a result of internet search a layman would come across a suitable product given the fact, in particular, that access to the product information, in principle, presupposes knowledge of the product name. And, ultimately, the final decision on prescription rests always with the doctor. Consequently, informational material obtained from the internet may influence only indirectly purchasing behaviour and, in particular, only through the conduit of a doctor who must analyse the product critically and is also capable of doing so on the basis of his training.

100. Accordingly, the information is not even conducive to increasing sales. The contrary view, which presumes that a doctor cannot escape his patients' wishes to be prescribed a particular medicinal product and, accordingly, reduces a doctor to a mere intermediary between patient and pharmaceutical undertaking, fails adequately to recognise his central role in the healthcare system. Regardless of that fact, in all Member States it is prohibited for doctors to prescribe medicinal products which are inappropriate or to abet the misuse of medicinal products. In that respect, as the Court held most recently in *Association of the British Pharmaceutical Industry*, [75] they are subject to the constraints of criminal law, the law on civil liability, the law on professional conduct and social security law which are intended to ensure their correct behaviour. [76]

101. In the case of prescription-only products, the risk of incorrect use is limited to the specific package which has been prescribed. To that extent, use of the product for incorrect purposes or in the incorrect dose may result in harm to the health of the patient. However, such risks do not result, in fact, from the effects of advertising and, as a consequence, from that perspective a comprehensive

75 — Most recently, in *Association of the British Pharmaceutical Industry*, cited above in footnote 16, paragraphs 40 and 41, the Court recognised the professional conduct constraints which operate on a prescribing doctor. In that case, it held that prescribing doctor is required, from the point of view of professional conduct, not to prescribe a given medicinal product if it is not fitting for the therapeutic treatment of his patient, despite the existence of public financial inducements for its prescription. At the same time, the Court pointed out that all doctors are authorised to practise only under the supervision of the public health authorities, which the latter carry out either directly or indirectly by appointing professional organisations to that effect.

76 — On that point, see, in addition, Hondius, E., 'General Introduction' in *The development of medical liability* (edited by Ewould Hondius), Volume 3, 2009, p. 7, who argues that the behaviour of doctors is constrained not only by liability rules but also by rules of professional and ethical conduct. As an example of such a constraint, the author refers to the French 'Ordre des médecins' (Professional association of doctors) established in 1940 which in 1941 published the first ethical code for doctors. According to the author, in the course of the 19th century professional associations were established in several Member States with a view to certifying the professional competence of doctors. Their activities contributed to endowing the conduct of doctors with a certain professionality regardless of whether the treatment was effected by a recognised member of the profession or a beginner.

prohibition on advertising cannot be justified. On the contrary, in drawing attention once again to the risks, the continued availability on the internet of the package leaflet and other objective information on prescription-only medicinal products may even avert such incorrect treatment. That is particularly relevant specifically in the case — which cannot be excluded — of a patient who loses the package leaflet. Numerous not implausible situations are imaginable in which renewed consultation of the product information on the medicinal product administered is required. A patient may lose the package leaflet, go on holiday and simply forget the leaflet at home or even dispose of it in error with the result that important information on the treatment of his illness is inevitably lost. To that extent, I agree with the finding of the referring court, namely, that factual information made available on the internet concerning dosage, risks, side effects and possible reactions if complications occur after taking the product is perfectly suited to avoid or reduce the dangers of 'uninformed self-medication.' [77]

(iii) Substance of the information

102. Specifically in a case in which the action in question is limited to the communication of objective information, categorisation as advertising within the meaning of the definition established in Article 86(1) of Directive 2001/83 appears difficult, as it cannot be said unambiguously to be of a promotional nature. In determining whether there is a promotional intent, the specific content of the information is particularly important. It follows from the reference for a preliminary ruling that the website in question contains only information which was placed before the authorising authority in the course of the marketing authorisation procedure and which is accessible in any event to every person acquiring the product. It may be concluded from that statement that the information in question evidently does not exceed what in any event is included in the labelling and package leaflet. Consequently, at issue are the particulars listed in Article 54 of Directive 2001/83. These include, inter alia, qualitative and quantitative particulars of all the constituents of the medicinal product, therapeutic indications, contra-indications and side-effects, posology, pharmaceutical form, method and route of administration, expected shelf life, particulars on overdose (symptoms, emergency procedures, antidotes) and effects on ability to drive and to use machines.

103. In that regard, it must be observed, first, that Article 86(2) of Directive 2001/83 expressly excludes the labelling and the accompanying package leaflet from the scope

77 — See paragraph 14 of the reference for a preliminary ruling.

of the advertising prohibition. [78] From that it follows that, in principle, neither the accompanying leaflet nor the particulars printed on the external packaging are relevant for the purposes of the law on medicinal products. As the Government of the United Kingdom argues, [79] in my view correctly, that can only be explained by the fact that the purpose of the packaging and accompanying package leaflet is to provide patients with essential information not, however, to promote the sale of a medicinal product.

104. Leaving that on one side, the fact cannot be ignored that contra-indications and information on side-effects and interactions not infrequently dominate the package leaflet and, as a result, this is more likely to discourage than to motivate a patient to purchase and use the product.

105. However, it must be questioned whether this assessment can be applied to the publication on the internet of the accompanying package leaflet. Admittedly, the fact that certain information constitutes mandatory particulars does not, in principle, preclude in a different context its categorisation as advertising. If, however, no additional elements are present which suggest a categorisation as advertising, the word-for-word reproduction of mandatory particulars on the internet is incapable of justifying such categorisation. In the light of the protective purpose — mentioned above — of the advertising prohibition, that conclusion is appropriate, if one takes account of the fact that pursuant to Article 61 of Directive 2001/83 the medicinal product at issue together with the related information have already been examined and approved by the competent authorities. In accordance with Article 62 of the Directive, that examination expressly includes information which might be of a promotional nature. Consequently, I agree with the Commission in its assessment that in the circumstances at issue the substance of the communication does not in itself constitute a threat. [80] It is doubtful, therefore, whether such a restriction on the communication of information as applies in the main proceedings is necessary for the purposes of safeguarding public health.

106. It must be concluded, therefore, that no promotional intent may be presumed, if a manufacturer's website only reproduces unedited and in full the official information on a medicinal product in the form of the package leaflet, a summary of its characteristics or a publicly accessible evaluation report of a medicines authority. I agree with the Danish Government in its assessment [81] that this

78 — To the same effect, see Marwitz, P., 'Internetapotheken zwischen Gerichten und Gesetzgebern', *Multimedia und Recht*, 2004, p. 218.

79 — See paragraph 12 of the observations of the Government of the United Kingdom.

80 — See paragraph 17 of the observations of the Commission.

81 — See paragraph 10 of the observations of the Danish Government.

kind of information neither in terms of form or substance has a promotional nature. A different assessment may be appropriate in the case of information on a medicinal product which has been edited by its manufacturer, unless, that is, the information is necessary for safety purposes.

107. Finally, a further schematic argument may be advanced in support of the view taken here. Pursuant to Article 86(2) of the Directive, correspondence needed to answer a specific question about a particular medicinal product and factual, informative announcements and reference material must be categorised as the provision of information and not as promotional or advertising measures. If the provision of basic approved information of an undertaking to answer a specific question of a patient does not constitute advertising, there is hardly a reason why publication of the very same information on the internet where it is accessible to interested parties should result in a different conclusion. Publication on the internet constitutes simply a more comfortable and more effective means of communication for the purposes of answering basic factual questions.

108. These arguments support an interpretation of the concept of advertising which excludes objective, substantively correct product information — corresponding to the instructions for use and technical information approved by the authorities — provided by a manufacturer to consumers, in particular when that information is communicated via the internet.

(iv) Intended audience and design

109. Further criteria to be considered for the purposes of distinguishing advertising and other information are the intended audience and design of the medium used to disseminate the information and crucial in that regard is whether the information is aimed, for example, at professional circles for consulting purposes or at potential patients. That must be determined by an individual examination of the website concerned.

110. First, it must be noted, as the Polish Government argues, in my view, correctly, that in today's world the internet constitutes a mass medium which is accessible to a wide

audience.[82] The internet has long since become a major factor for the purposes of obtaining and communicating information of all kinds. In that connection, in addition, the significance of the internet as a virtual marketplace for many products ('e-commerce') — including also medicinal products — across State borders should not go unmentioned, resulting in new challenges for health protection. However, not all areas of the internet are open to everyone. As a rule, it is technically possible for a website administrator, by establishing a password protection, to deny unauthorised persons access to certain pages and, thus, from the outset to restrict access to certain interest groups, for example, professionals.[83] However, there is nothing in the main proceedings to suggest that access to the information on the medicinal products is restricted and, as a result, in principle, the information in question relating to the medicinal products is accessible to everyone. Accordingly, the manufacturer evidently accepts that potential patients may view the information. Moreover, the kind of information concerned does not suggest that the website content was aimed at a particular professional circle.

111. On the other hand, a categorisation as advertising may be countered by the argument that the manufacturer in the main proceedings did not publish the information at issue concerning medicinal products in a manner which forces it on potential purchasers. A different assessment might apply in the case of push services, that is, where, as the Commission mentions,[84] internet users, for example, as a result of pop-ups, that is, windows which appear unsolicited on screen, are confronted with such content, without having searched for this of their own accord. That kind of website design might be evidence of a promotional intent on the part of a manufacturer. However, in the main proceedings that situation does not in any way apply. Instead, it must be presumed that an internet search is required in order to access the information at issue concerning the medicinal products. As a general rule, the internet constitutes a medium which is characterised by the search behaviour of users.[85] A potential purchaser must probably already be aware of the medicinal product and know that the manufacturer provides product information on its website. Anyone who is not interested in the medicinal product concerned will not be

82 — Michaux, G., cited above in footnote 29, p. 369, is correct to observe that the internet raises particular problems as, in theory, it allows pharmaceutical manufacturers to establish advertising portals which are accessible to everyone (that is, patients and specialists).

83 — See Marwitz, P., 'Heilmittel im Internet', *Multimedia und Recht*, 1999, pp. 84 and 87, who argues that the internet, by way of contrast to other means of communication aimed at the general public, allows information to be communicated to a limited category of users by protecting content with a password. In the author's view a password system would prevent the circumvention of the legislative purpose. See also Dieners, P., Reese, U., Gutmans, A., and Vonzun, R., *Handbuch des Pharmarechts*, 1st edition, Munich 2010, §23, point 123, and Eggenberger Stöckli, U., 'Praxis der schweizerischen Behörde Swissmedic zur Arzneimittelwerbung im Internet', *Pharma Recht*, 2007, No 3, p. 130, who mention the possibility to restrict access to specialist advertising as advocated by Swissmedic in August 2006 in guidelines on the advertising of medicinal products on the internet and as applied by that body since 1 January 2007.

84 — See paragraph 23 of the observations of the Commission.

85 — To the same effect, see Stoll, V., cited above in footnote 35, p. 104.

confronted unwillingly with that information. Contrary to the view advanced by the Portuguese Government, [86] it in no way suffices that a relevant internet user simply enters a certain internet address, as such action specifically presupposes knowledge of the information provided by the manufacturer. For that reason, I endorse the Commission's argument that this mode of communicating information by means of passive presentational platform as a rule is not intrusive and does not force itself upon a broad public which is unprepared. [87] Given that in circumstances such as those which apply in the main proceedings the design of the information medium does not demonstrate any grounds for presuming a promotional intent on the part of the manufacturer, it is sensible to interpret the concept of advertising more restrictively.

112. Leaving that to one side, in the light of the abovementioned considerations, it is doubtful whether simply the fact that potential patients are also targeted as an audience for such information may justify a prohibition on the making available of information on medicinal products, in particular, given the fact, as I argued earlier, [88] that patients have a legitimate interest in technically correct and objective information.

113. In addition, in the light of their capacity as consumers in a specific market sector, it appears to me conceivable in principle to apply the model of an average consumer [89] developed in the case-law to the area of medicinal products. [90] A further argument in favour of applying the information model of the law

86 — See paragraph 31 of the observations of the Portuguese Government.

87 — According also to Gellissen, G., cited above in footnote 27, p. 167, it must be presumed that advertising for which a user has searched does not constitute as great a threat as which is forced upon him.

88 — See points 85 to 87 of this Opinion.

89 — On the model of the consumer in the Court's case-law, see Case C-373/90 *X* [1992] ECR I-131, paragraphs 15 and 16; Case C-210/96 *Gut Springenheide and Tusky* [1998] ECR I-4657, paragraph 31; Joined Cases C-108/97 and C-109/97 *Windsurfing Chiemsee* [1999] ECR I-2779, paragraph 29; Case C-220/98 *Estée Lauder* [2000] ECR I-117, paragraph 27; Case C-30/99 *Commission* v *Ireland* [2001] ECR I-4619, paragraph 32; Case C-99/01 *Linhart and Biffl* [2002] ECR I-9375, paragraph 31; Case C-44/01 *Pippig Augenoptik* [2003] ECR I-3095, paragraph 55; Case C-363/99 *Koninklijke KPN Nederland* [2004] ECR I-1619, paragraph 77; Case C-218/01 *Henkel* [2004] ECR I-1725, paragraph 50; Case C-421/04 *Matratzen Concord* [2006] ECR I-2303, paragraph 24; and Case C-356/04 *Lidl Belgium* [2006] ECR I-8501, paragraph 78. On that issue, see additionally point 101 et seq. of my Opinion of 24 March 2010 in the pending Case C-540/08 *Mediaprint*.

90 — A similar view is also taken by Reese, U., 'Zur Bedeutung des Verbraucherleitbilds für das nationale und europäische Heilmittelwerberecht', *Pharma Recht*, 2002, p. 242, who argues that the informational model on which the European consumer model is based must be realised also in the area of advertising of medicinal products. According to that author, the rules on medicinal products must be designed and interpreted appropriately to ensure that both professional circles and medical laymen can be provided with objective and correct information. In his view, derogations from that principle must be of an exceptional nature. They must be justified on objective grounds and satisfy the requirements of proportionality. He argues that specifically in the area of healthcare consumers have an interest in obtaining as unrestricted an access as possible to information which they are capable of correctly understanding and assessing.

on consumer protection is the fact that the case-law of the Court in the area of the law on medicinal products has long since adopted the perspective of the average consumer when determining, for example, whether a product falls within the definition of a medicinal product by function for the purposes of Directive 2001/83. According to settled case-law, the national authorities, acting under the supervision of the courts, are obliged to determine that question on a case-by-case basis, in particular, taking account also of *the familiarity of that product to consumers*. [91] Accordingly, also in determining the effects on the general public of product-related information, in principle, normally informed, reasonably attentive and critical patients must be presumed.

114. Admittedly, on the other hand, the field of medicine is characterised by a particular technical complexity as a result of which it would appear unreasonable to transfer to an individual patient sole responsibility for his own health. [92] Moreover, that is neither realistic nor, having regard to the public health protection required, does it appear in policy terms desirable. Protection of human health is a requirement pursuant to Article 152 EC and Article 168 TFEU. [93] However, appropriate respect for the right of patients to information would be achieved simply if access to objective information were not comprehensively denied to patients but permitted under certain conditions. That would be a less intrusive measure than a comprehensive prohibition on information concerning medicinal products.

115. In addition, it should not be forgotten that specifically in the case of prescription-only medicinal products a patient will always be reliant on the counsel of the prescribing doctor. [94] His key role in the area of health

91 — According to settled case-law, for the purpose of determining whether a product falls within the definition of a medicinal product by function within the meaning of Directive 2001/83, the national authorities, acting under the supervision of the courts, are required to decide on a case-by-case basis, taking account of all the characteristics of the product, in particular its composition, its pharmacological properties to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail. See Case C-140/07 *Hecht-Pharma* [2009] ECR I-41, paragraph 32; Case C-319/05 *Commission* v *Germany* [2007] ECR I-9811, paragraph 55; Case C-387/99 *Commission* v *Germany* [2004] ECR I-3751, paragraph 57; Case C-112/89 *Upjohn* [1991] ECR I-1703, paragraph 23; Case C-290/90 *Commission* v *Germany* [1992] ECR I-3317, paragraph 17; Case C-60/89 *Monteil and Samanni* [1991] ECR I-1547, paragraph 2; and Case 227/82 *Van Bennekom* [1983] ECR 3883, paragraph 29.

92 — To the same effect, see also Stebner, F., cited above in footnote 62, p. 25, who regards it as uncontested that outside professional circles regulations are needed to counter the threat to consumer health which results from inappropriate self-medication. In his view, given their lack of expertise concerning the advertised services and products, consumers have to be protected against specific threats. That is particularly so — he continues — as patients on account of their illness are often in exceptional situations from a psychological point of view and may be particularly liable to accept advertising claims uncritically.

93 — That is recognised also by the Commission in its White Paper 'Together for Health: A Strategic Approach for the EU 2008-2013' of 23 October 2007, COM(2007) 630 final.

94 — See point 99 of this Opinion.

care provision is in no way undermined by greater information; instead, it is likely to be confirmed. Doctors have an obligation to inform patients extensively prior to prescription on the effects of a medicinal product and the possible risks involved. Where at an early stage prior to a consultation a patient obtains objective information from reliable sources, to that extent this may even contribute to an improvement in health care provision as in such a case a doctor meets with an informed patient and thus is required to discuss in detail with him the advantages and disadvantages of his treatment. That ensures that an appropriate and in certain cases also inexpensive treatment is prescribed. The latter point is all the more important, the more regularly patients are involved in the funding of the health system, for example, where they must bear some of the costs of medicinal products. [95] Ultimately, this consensus-based solution has the advantage that it takes account of a patient's right to self-determination without questioning the authority of the prescribing doctor.

116. Conversely, the effect of maintaining a situation where as a result of a comprehensive prohibition, such as that described in the reference for a preliminary ruling, patients are uninformed is that they are more susceptible to potentially incorrect information from unverifiable sources such as, for example, discussion fora, free encyclopaedias and health portals on the internet. In that regard, self-help, patient support and relative support groups are reliant to a considerable extent on information whose accuracy and objectivity they can trust. Having regard to the fact, that both the internet and print media and television include a multiplicity of reports on health issues and medicinal products, whose seriousness, comprehensiveness of substance and accuracy are not always ensured, it appears all the more important to make information available to consumers stemming from trustworthy and technically knowledgeable sources. [96] Professionally unverified third-party publications may result in confusion and false information amongst the public. Therefore, ultimately, too generous an interpretation of Article 88(1)(a) of Directive 2001/83 would contradict the objective of the prohibition on the advertising of medicinal products, that is, to safeguard public health

95 — Under Article 168(7) TFEU, the law of the European Union does not detract from the power of the Member States to organise their social security systems and to adopt, in particular, provisions intended to govern the consumption of pharmaceutical products in order to promote the financial stability of their health-care insurance schemes (see Joined Cases C-352/07 to C-356/07, C-365/07 to C-367/07 and C-400/07 *A. Menarini and Others* [2009] ECR I-2495, paragraph 19, and *Association of the British Pharmaceutical Industry*, cited above in footnote 16, paragraph 36). Correspondingly, there are considerable differences between the systems of health care provision in the Member States. For example, on the share of public and private health care provision in the United Kingdom, Spain, Austria, France and the Netherlands, see Hondius, E., cited above in footnote 76, p. 4.

96 — To the same effect, Lorz, A., cited above in footnote 30, p. 898.

against the risks to patients resulting from 'excessive and ill-considered advertising'.

117. In order to ensure that the consultation of a doctor is not circumvented, it would suffice, in principle, to oblige manufacturers on their relevant website to draw the attention of potential customers to the fact that consultation of their own information on medicinal products cannot substitute for a visit to a doctor. It is uncertain, therefore, whether a comprehensive prohibition which categorically prohibits a manufacturer from publishing on its website objective information on medicinal products which it has manufactured is at all appropriate to effectively protect public health. Against that background, a more restrictive interpretation of the concept of advertising of medicinal products appears essential.

c) Observations *de lege ferenda*

118. Finally, mention should be made of the Commission Proposal of 10 December 2008 to amend Directive 2001/83 [97] which inserts into the Directive a new Title VIIIa (Information to the general public on medicinal products subject to medical prescription) with the aim of ensuring that on satisfying certain conditions specific information on prescription-only medicinal products is excluded from the scope of the advertising prohibition.

119. The proposed new Article 100a provides that 'Member States shall allow the marketing authorisation holder to disseminate, either directly or indirectly through a third party, information to the general public or members thereof on authorised medicinal products subject to medical prescription provided that it is in accordance with the provisions of this Title'. According to that provision, such information is not to be regarded as advertising. In support of that rule, it is stated in Recital 8 in the preamble to the proposed directive that 'marketing authorisation holders may be a valuable source of non promotional information on their medicinal products'. That assessment coincides also with the view I have taken in the present case. [98] According to Recital 12 in the preamble to the directive proposed by the Commission, dissemination of information on prescription-only medicinal products also through the internet is expressly included.

120. Article 100b lists the kinds of information which the marketing authorisation holder may disseminate. In that regard, it may be

97 — Proposal of the Commission of 10 December 2008 for a Directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use, COM(2008) 663 final.

98 — See point 94 of this Opinion.

observed that these concern product-related particulars — the elements of the summary of product characteristics, labelling and the package leaflet of the medicinal product, and the publicly accessible version of the assessment report drawn up by the competent authorities — the objectivity of which cannot be questioned as they are subject to control by the public authorities. Such a situation corresponds exactly with the set of facts which gave rise to the main proceedings. Therefore, subject to any amendments which the Commission's proposal may experience in the course of the legislative process, the information which MSD has published on the internet would probably not be categorised as advertising and hence not prohibited.

121. This legislative initiative is linked to the development which was set in motion by the amendment to the Community code by means of Directive 2004/27 and which aims to establish a clear distinction between factual information and advertising. Consequently, a new Title VIIIa 'Information and advertising' was inserted in the Community code which in Article 88a provides that within three years of the Directive entering into force the Commission should present a report on current practice with regard to information provision, particularly on the internet. On the basis of that report, the Commission was required to propose an information strategy to ensure good-quality, objective, reliable and non-promotional information on medicinal products.

122. Those projects can be interpreted as a reaction to the threat posed by a concept of advertising in the law on medicinal products which is formulated too widely. They must be understood as reflecting a liberal trend within the legislative organs of the European Union towards the dissemination of factual information on prescription-only medicinal products which aims to establish the ideal balance between the safeguarding of public health and the fundamental rights of consumers and manufacturers. In my view, that basic trend, which coincides in part with the legal assessment I have developed in this Opinion, cannot be ignored in the interpretation of Directive 2001/83.

3. Conclusions

123. In the light of the foregoing, I conclude that the concept of the advertising of medicinal products must be interpreted in conformity with fundamental rights in order to reconcile the safeguarding of public health with the fundamental rights of consumers and manufacturers. On the other hand, as regards the boundary between advertising and mere information, the decisive criterion consists in the purpose of the message concerned. Whether or not a relevant promotional intent exists is primarily for the national court to

determine in the light of the specific circumstances of the case before it. Suitable criteria for the purposes of determining whether information is published for promotional purposes include authorship, subject-matter and substance of the information at issue, the intended audience and the design of the medium by which that information is made available to the public. As the Court is sufficiently apprised of the main factual elements of the proceedings before the national court, in exercising its interpretative jurisdiction, it is entitled to provide its own assessment in relation to the specific question referred. [99]

124. Having regard to the abovementioned principles, the answer which must be given to the question referred is that Article 88(1)(a) of Directive 2001/83 must be interpreted as meaning that the said provision does not extend to advertising to the general public of prescription-only medicinal products such as is at issue in the main proceedings provided that such advertising contains only information which was placed before the authorising authority in the course of the marketing authorisation procedure and which is accessible in any event to every person acquiring the medicinal product concerned, and provided that such information is not made available to an interested party on an unsolicited basis but can be accessed through the internet when the party concerned takes steps to do so.

125. Given that in accordance with a more restrictive interpretation I have proposed here the provision on the internet of information on medicinal products in the manner described in the question referred cannot be included within the concept of advertising of medicinal products, it is unnecessary to determine the validity of Article 88(1)(a) of Directive 2001/83 in the light of primary law. [100]

99 — In the framework of the preliminary ruling procedure a referral back to the referring court for the purposes of determining unresolved facts or details of national law may be permissible. The Court will indicate to the national court the determinations which are necessary to resolve the legal dispute in conformity with its case-law (see Joined Cases 286/82 and 26/83 *Luisi and Carbone* [1984] ECR 377, paragraph 36, and Case 171/88 *Rinner-Kühn* [1989] ECR 2743, paragraphs 14 and 15). However, in so doing, it may not abdicate its responsibility for the interpretation of EU law. If, however, the Court is in possession of uncontested facts or details on national law, it is not precluded from providing national courts with specific guidance to facilitate their application of EU law to the actual case in hand (to the same effect see Lenaerts, K., Arts, D. and Maselis, I., *Procedural Law of the European Union*, 2nd edition, London 2006, paragraph 2-021, p. 191 et seq.).

100 — See point 65 et seq. of this Opinion.

VII — Conclusion

126. In the light of the above considerations, I propose that the Court should answer the question referred by the Bundesgerichtshof as follows:

Article 88(1)(a) of Directive 2001/83/EC on the Community code relating to medicinal products for human use must be interpreted as meaning that it does not extend to advertising to the general public of prescription-only medicinal products at issue in the main proceedings provided that such advertising contains only information which was placed before the authorising authority in the course of the marketing authorisation procedure and which is accessible in any event to every person acquiring the medicinal product concerned, and provided that such information is not made available to an interested party on an unsolicited basis but can be accessed through the internet when the party concerned takes steps to do so.