OPINION OF ADVOCATE GENERAL STIX-HACKL

delivered on 11 March 2003 [1]

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1 — Original language: German.

I — Introduction

1. The present reference for a preliminary ruling concerns 'internet pharmacies' and the question whether the Member States may restrict the supply of medicinal products by a pharmacy established in another Member State on the basis of individual orders placed by consumers on the internet. In particular, it concerns the interpretation of the principle of free movement of goods and a number of provisions of secondary law.

II — Legal framework

A — *Community law*

1. Authorisation of medicinal products

(a) Previous legal position: Directive 65/65/EEC as amended by Directive 93/39/EEC

2. The central provisions on the authorisation of medicinal products can be found in Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products,[2] as amended by Council Directive 93/39/EEC of 14 June 1993 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products[3] (hereinafter: Directive 65/65). Article 3 of that directive provides:

'No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or an authorisation has been granted in accordance with Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.

The provisions of this Directive shall not affect the powers of the Member States' authorities either as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes, on the basis of health, economic and social conditions.'

(b) Present legal position: Directive 2001/83/EC

3. With effect from 18 December 2001, Directive 65/65 was replaced by 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[4] (hereinafter: Community code). Article 6(1) of the Community code provides:

'No medicinal product may be placed on the market of a Member State unless a

2 — OJ, English Special Edition 1965-1966, p. 24.
3 — OJ 1993 L 214, p. 22.
4 — OJ 2001 L 311, p. 67.

marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or an authorisation has been granted in accordance with Regulation (EEC) No 2309/93.'

2. Advertising of medicinal products

(a) Previous legal position: Directive 92/28/EEC

4. The relevant legislation in this regard is Council Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use [5] (hereinafter: Directive 92/28).

5. Article 1(3) and (4) of that directive provides:

'For the purposes of this Directive, 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,

5 — OJ 1992 L 113, p. 13.

— 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.

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

6. Article 2(1) states:

(4) The following are not covered by this Directive:

'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.'

— the labelling of medicinal products and the accompanying package leaflets, which are subject to the provisions of Directive 92/27/EEC;

7. Article 3 provides inter alia:

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

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

— are available on medical prescription only, in accordance with Directive 92/26/EEC,

— 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;

— contain psychotropic or narcotic substances, within the meaning of the international conventions,

— may not be advertised to the general public in accordance with paragraph 2.

2. Medicinal products may be advertised to the general public which, by virtue of their composition and purpose, are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary.'

(b) Present legal position: Community code

8. With effect from 18 December 2001, Directive 92/28 was replaced by the Community code.

9. Article 86 of the Community code has essentially the same wording as Article 1(3) and (4) of Directive 92/28.

10. Article 87 of the Community code, which replaces Article 2 of Directive 92/28, 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.'

11. Article 88 contains a similar provision to Article 3 of Directive 92/28.

3. Distance sales

12. The provisions applicable to distance sales can be found in Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts (hereinafter: Directive 97/7). [6]

13. Article 14 of Directive 97/7 provides:

'Member States may introduce or maintain, in the area covered by this Directive, more stringent provisions compatible with the Treaty, to ensure a higher level of consumer protection. Such provisions shall, where appropriate, include a ban, in the general interest, on the marketing of certain goods or services, particularly medicinal products, within their territory by means of distance contracts, with due regard for the Treaty.'

4. Electronic commerce

14. The relevant legislation for electronic commerce is Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce', [7] hereinafter: E-commerce directive).

15. The 11th recital of the E-commerce directive provides:

'This Directive is without prejudice to the level of protection for, in particular, public health and consumer interests, as established by Community acts.... that same Community acquis, which is fully applicable to information society services, also embraces in particular Council Directive... and Council Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products'.

16. Article 1 of that directive includes the following provisions:

'1. This Directive seeks to contribute to the proper functioning of the internal market by ensuring the free movement of information society services between the Member States.

6 — OJ 1997 L 144, p. 19.

7 — OJ 2000 L 178, p. 1.

2. This Directive approximates, to the extent necessary for the achievement of the objective set out in paragraph 1, certain national provisions on information society services relating to the internal market, the establishment of service providers, commercial communications, electronic contracts, the liability of intermediaries, codes of conduct, out-of-court dispute settlements, court actions and cooperation between Member States.

3. This Directive complements Community law applicable to information society services without prejudice to the level of protection for, in particular, public health and consumer interests, as established by Community acts and national legislation implementing them in so far as this does not restrict the freedom to provide information society services.'

17. Article 3 provides inter alia as follows:

'2. Member States may not, for reasons falling within the coordinated field, restrict the freedom to provide information society services from another Member State.

4. Member States may take measures to derogate from paragraph 2 in respect of a given information society service if the following conditions are fulfilled:

(a) the measures shall be:

(i) necessary for one of the following reasons:

— ...,

— the protection of public health,

— ...,

— the protection of consumers, including investors;

(ii) taken against a given information society service which prejudices the objectives referred to in point (i) or which presents a serious and grave risk of prejudice to those objectives;

(iii) proportionate to those objectives.'

18. Articles 5 and 6 impose a number of information requirements on electronic service providers. Article 10 governs the obligation to make certain information available to consumers.

B — *National law*

1. Trade in medicinal products

19. The main provisions relating to trade in medicinal products can be found in the German Arzneimittelgesetz [8] (Law on Medicinal Products, hereinafter: the AMG).

20. Paragraph 43(1) of the AMG essentially lays down a prohibition on mail order trade in medicinal products that are required to be sold through pharmacies. It provides:

'Medicinal products within the meaning of Paragraph 2(1) or 2(2)(1), which are not freely available for sale other than in pharmacies in accordance with the provisions of Paragraph 44 or regulations adopted under Paragraph 45(1) may, except in the cases provided for in Paragraph 47, be marketed professionally or commercially to the end user only in pharmacies and not by mail order. With the exception of the cases provided for in subparagraph 4 and Paragraph 47(1), medicinal products the sale of which is restricted to pharmacies in accordance with the first sentence of this subparagraph may not be sold other than in pharmacies.'

21. The AMG provides for a number of exceptions that did not, however, apply in the main proceedings. Paragraph 44 of the AMG lays down exceptions to the requirements of sale through pharmacies for various medicinal products. Paragraph 45(1) of the AMG enables the competent Federal Ministry to authorise the release for sale other than in pharmacies of certain preparations. Paragraph 47 of the AMG provides for the supply of medicinal products without recourse to pharmacies, including to hospitals and doctors.

8 — As amended by BGBl. 1998 I, p. 2649.

22. The AMG also lays down a prohibition on importation. The relevant rules are laid down in the section on 'Import and Export', in Paragraph 73. Paragraph 73(1) includes the following provision:

'(1) Medicinal products which are subject to authorisation or registration may be brought into the territory in which this Law applies, with the exception of duty-free areas other than the island of Helgoland, only if they are authorised or registered for being placed on the market in that territory, or if they have been exempted from the obligation to be so authorised or registered, and subject to the following conditions:

where the product has been imported from a Member State of the European Communities or from another State party to the Agreement on the European Economic Area, the recipient must be a pharmaceutical business, a wholesaler or a veterinarian or must run a pharmacy, or

...'

23. Paragraph 73(2), point 6a of the AMG provides for an exception for medicinal products which 'may be marketed in their country of origin and which have been purchased, without a commercial or professional intermediary, in a quantity not exceeding the amount needed for normal personal use in a Member State of the European Community or in another State party to the Agreement on the European Economic Area'.

24. The referring court interprets the national provisions as meaning that the exception laid down in Paragraph 73(2), point 6a of the AMG does not apply to the defendant in the present case. Both a systematic interpretation of that exception and the purpose of the law as revealed by the background legal materials point to a restrictive interpretation of that provision, which is not intended to cover commercial, cross-border volume trade in medicinal products for human use on the basis of orders placed on the internet.

25. In the view of the German Government, the insertion of the terms 'without a commercial or professional intermediary' is intended to prevent the individual import of unauthorised medicines being extended in such a way that the authorisation requirement is circumvented.

2. Advertising of medicinal products

26. Paragraph 3a of the German Gesetz über die Werbung auf dem Gebiete des

Heilwesens (Law on Advertising in the field of Medicine, hereinafter: the HWG)[9] prohibits 'Any advertising of medicinal products which require authorisation and which are not authorised or deemed to be authorised under the law on pharmaceutical products'.

27. Paragraph 8 of the HWG provides:

'(1) Any advertising the aim of which is to sell by mail order medicinal products which may be supplied only by pharmacies is illegal. This prohibition does not apply to advertising relating to the supply of medicinal products in the cases provided for in Paragraph 47 of the AMG.

(2) Any advertising the aim of which is to sell medicinal products by way of teleshopping or particular medicinal products by way of individual importation as described in Paragraph 73(2), point 6a, or Paragraph 73(3) of the AMG is also illegal.'

28. In the view of the German Government, the intention is thus to prevent the individual importation of unauthorised medicinal products being extended by advertising measures in such a way that it amounts to circumvention of the rules on authorisation.

9 — BGBl. 1994 I, p. 3068.

Paragraph 10 of the HWG provides:

'(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 disorders, or which are psychotropic, may not be advertised other than in professional circles.'

III — Facts and main proceedings

29. The duties of the Deutsche Apothekerverband e.V. (hereinafter: the Apothekerverband) in accordance with its constitution include the protection and promotion of the economic and social interests of pharmacists. Its members are the regional associations and organisations of pharmacists, which in turn represent more than 19 000 pharmacy directors.

30. 0800 DocMorris NV (hereinafter: DocMorris) is a Netherlands pharmacy established in Kerkrade, the Netherlands. Jacques Waterval is a pharmacist and one of the legal representatives of DocMorris. He is also one of the initiators of the 'internet pharmacy', one of the leaders of its editorial team, and the head of its advisory committee of experts.

31. Since 8 June 2000 DocMorris and Mr Waterval have been offering for sale, at the internet address 'www.0800DocMorris.com', prescription and non-prescription medicinal products for human use, in languages including German, for end users in Germany. Some of the medicinal products in question are authorised in Germany and most of them are authorised in another Member State. DocMorris's internet portal refers to an interlocutory judgment of the Landgericht (Regional Court) Frankfurt of 9 November 2000, which temporarily prohibited the commercial mail order sale to consumers in the Federal Republic of Germany of medicinal products required to be sold only through pharmacies and likewise prohibited advertising in connection with such sale. On an appeal by DocMorris and Mr Waterval, that judgment was essentially upheld by a judgment of the Oberlandesgericht (Higher Regional Court) Frankfurt am Main on 13 May 2001.

The remainder of the defendants' internet site is divided under the headings 'Pharmacy', 'Health forum', 'About us', 'Contact' and 'Help'. In the 'Patients' Forum', consumers can exchange views over the internet. German, English or Dutch can be chosen as the language used. Consumers also have the possibility of obtaining health advice from the advisory committee of experts at the 'internet pharmacy'. Generally, the consumer can contact DocMorris and Mr Waterval not only via the internet, but also on a freephone telephone number or by letter.

The individual medicines are divided into product groups under headings such as 'Painkillers', 'Blood-pressure reducers', 'Cancer therapy', 'Immunostimulants', 'Cholesterol reduction', 'Urologics/potency', 'Detoxification', etc. Each heading first contains an introduction of a few sentences. The medicines are then listed alphabetically under their product name, the contents of the package are described and the price is stated in euro. Beside the indication as to any prescription requirement, there is a box. By clicking on that box, the medicine in question is ordered. Further information about the product itself may be obtained by clicking on the product name. The consumer also has the opportunity, by clicking on the appropriate icon, to search for a particular product from the range. The defendants also offer services via the internet (doctor search, personal health service, book tips, etc.). A given medicine is classified by DocMorris

and Mr Waterval as available only on prescription where it is classified as such in the Netherlands or in the Member State in which the consumer resides. Medicines of this type are supplied only on production of the original prescription.

32. Delivery itself can take a number of forms. The customer may collect the order in person from DocMorris. Alternatively, they may, at no additional cost, use a courier service recommended by DocMorris to collect the order and take it to the address given by the recipient. Finally, the customer can use another courier service at their own expense.

33. Before the Landgericht Frankfurt am Main, the Apothekerverband is challenging the offer of medicinal products for sale in the way described above and their supply by cross-border mail order. It takes the view that the provisions of the AMG and of the HWG do not allow such activity. Such a prohibition is not open to challenge under Articles 28 EC and 30 EC either.

34. DocMorris and Mr Waterval take the view that their activity is in fact permissible under national law, but that, in any event, a national prohibition would be contrary to Community law.

35. The Landgericht questioned in particular whether, in view of the time which has since elapsed and the changed requirements for the authorisation of medicinal products for human use in the Member States of the European Community, the principles set out in the judgment in *Ortscheit* [10] are still applicable.

36. With regard to the HWG, the Landgericht states that DocMorris' presentation on the internet, naming individual medicinal products with their product name, prescription status, package size and price, whilst at the same time offering the possibility of ordering the medicinal product, is to be classified as advertising within the meaning of those provisions. To prohibit advertising in such a way could mean that a presentation of an internet pharmacy with the simultaneous possibility of ordering individual medicinal products would be made considerably more difficult, as the minimum information required for making

10 — Case C-320/93 *Ortscheit* [1994] ECR I-5243.

an order could no longer be given on online order forms. The question therefore arises whether such a national prohibition on advertising is compatible with the principles of free movement of goods and free movement of information society services under the E-commerce directive.

37. The Landgericht did not consider itself to be bound by the judgment in *Ortscheit*, because, in the first place, that decision concerned only the prohibition in Paragraph 8(2) of the HWG, which is not relevant here, and, secondly, because, in the light of the above considerations, the concept of 'advertising' in the case of the internet presentation of a pharmacy might need to be assessed separately. In that connection, the question arises whether the recent extensive harmonisation of procedures for the authorisation of medicinal products for human use and the intended Community law authorisation of advertising of non-prescription medicinal products require a different, more restrictive definition of 'advertising' in Community law. It is possible that the principle of free cross-border movement of goods may not be effectively realised if DocMorris' internet presentation were to be made wholly or partially impossible on the ground that it was carrying on unlawful advertising for medicinal products for human use.

IV — Questions referred for a preliminary ruling

38. The Landgericht Frankfurt am Main therefore referred the following questions to the Court of Justice, by an order of 10 August 2001, received by the Registry of the Court of Justice on 21 August 2001, for a preliminary ruling:

1. Are the principles of the free movement of goods under Article 28 et seq. EC infringed by national legislation which prohibits human medicines, which are required to be handled only through pharmacies, from being imported commercially from other EU Member States in mail-order business through authorised pharmacies on the basis of individual orders placed by consumers over the internet?

   (a) Does such a national prohibition constitute a measure having equivalent effect to a quantitative restriction on imports within the meaning of Article 28 EC?

   (b) If it does, is Article 30 EC to be interpreted as meaning that a national prohibition designed to protect the health and life of humans is justified if, before prescription medicines are sent out, a doctor's original prescription must have been produced to the pharmacy sending out the medicines? In

such a situation, what requirements should be placed on that pharmacy as regards control of the order, packaging and receipt?

(c) Are Questions 1, l(a) and l(b) to be assessed differently in the light of Articles 28 and 30 EC if the imported medicines in question are medicines authorised in the importing State, which a pharmacy in an EU Member State previously obtained from wholesalers in the importing State?

2. Is it compatible with Articles 28 and 30 EC for a national prohibition on advertising medicines by mail order, prescription medicines and medicines available only through pharmacies that are authorised in the State of origin but not the importing State to be interpreted so broadly that the internet presentation of a pharmacy of an EU Member State, which in addition to presentation of its business describes individual medicines with their product name, prescription status, package size and price and at the same time offers the possibility of ordering those medicines by means of an online order form, is classified as prohibited advertising, with the result that cross-border orders of medicines by internet including delivery of those orders is at the very least made substantially more difficult?

(a) Having regard to Article 1(3) of Directive 2000/31/EC of 8 June 2000 ('Directive on electronic commerce'), do Articles 28 and 30 EC require the internet presentation of a pharmacy of an EU Member State, as described above, or parts of that presentation, to be excluded from the definition of advertising to the general public for the purposes of Articles 1(3) and 3(1) of Council Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use, in order to make it practically possible to offer certain information society services?

(b) Can any restriction of the definition of advertising that may be required under Articles 28 and 30 EC be justified by the consideration that online order forms containing only the minimum information necessary for placing an

order, and/or other parts of the internet presentation of a pharmacy of an EU Member State, are comparable with trade catalogues and/or price lists within the meaning of Article 1(4) of Directive 92/28/EEC?

3. If some aspects of the internet presentation of a pharmacy of an EU Member State infringe provisions concerning the advertising of medicines, is it to be inferred from Articles 28 and 30 EC that cross-border trade in medicines which does take place with the help of such a presentation must be regarded as legally permissible despite the prohibited advertising, in order more effectively to implement the principle of the free movement of goods across borders?

V — The first question

39. By the first question, the referring court expressly asks the question whether the national prohibition on medicinal products 'being imported commercially from other EU Member States in mail-order business' [11] (hereinafter: the prohibition on mail order) infringes the principle of free movement of goods. It should be pointed out in this regard that the Court does not have jurisdiction, in preliminary ruling proceedings under Article 234 EC, to give a ruling on the compatibility of national law with Community law. However, it does have jurisdiction to supply the national court with a ruling on the interpretation of Community law so as to enable that court to determine whether such compatibility exists in order to decide the case before it. [12]

40. As is clear from Question 1(c), Questions 1, 1(a) and 1(b) concern medicinal products not authorised in Germany. On the other hand, Question 1(c) relates to medicinal products authorised in Germany. This distinction forms the basis for the following structure.

11 — In the words of the description by the referring court, which refers expressly neither to Paragraph 43 of the AMG nor to Paragraph 73 of the AMG.

12 — Case C-399/98 *Ordine degli Architetti and Others* [2001] ECR I-5409, paragraph 48 and Joined Cases C-37/96 and C-38/96 *Sodiprem and Others and Albert* [1998] ECR I-2039, paragraph 22.

A — *Unauthorised medicinal products: Questions 1, 1(a) and 1(b)*

1. General applicability of Directive 97/7 to the contested prohibition on mail order

(a) The submissions of the parties

41. DocMorris takes the view that Article 14 of Directive 97/7 cannot justify a general prohibition on mail-order sales of medicinal products, because that provision expressly stipulates that due regard must be had to the provisions of higher-ranking primary law.

42. The Apothekerverband argues that the detailed rules on the sale and delivery of medicinal products have not yet been harmonised with regard to the prescription requirement and internet-based mail order trade.

43. In its observations on secondary law, the German Government refers to Directive 65/65 and the Community code, and the prohibition on bringing into circulation unauthorised medicinal products laid down therein. The prohibition on mail order is intended to prevent the circumvention of that prohibition.

44. The Greek Government, relying on Directive 89/552/EEC,[13] argues that the prohibition on mail order is lawful.

45. The French Government points out that the sale of medicinal products is not harmonised.

46. The Austrian Government refers to the option the Member States have of prohibiting marketing under Article 14 of Directive 97/7. Since the marketing of medicinal products is not fully harmonised, the Member States still have the power to adopt national rules.

47. The Commission takes the view that the prohibition on mail order is covered by Article 3 of Directive 65/65 and/or Article 6 of the Community code.

13 — Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities (OJ 1989 L 298, p. 23).

(b) Assessment

48. First of all, reference should be made to the general principle that rules of secondary law may take precedence over provisions of primary law. This means that, where a matter is regulated exhaustively in a harmonised manner at Community level, national measures must be assessed in the light of the provisions of the harmonising measure and not of Articles 28 and 30 EC. [14]

49. If, therefore, in the present case Directive 97/7 harmonised the matter exhaustively, these rules of secondary law would apply and not primary law, in this case free movement of goods. Nevertheless, in such cases primary law still plays a role despite the precedence of secondary law. First of all, the rules of secondary law must be interpreted in the light of primary law and, secondly, provisions of secondary law may themselves refer to primary law.

50. This is the case with Article 14 of Directive 97/7, to which some of the parties have expressly referred. That provision expressly states that the Member States may 'ban... the marketing of certain goods or services, particularly medicinal products, within their territory by means of distance contracts...'. However, at the same time Article 14 provides for a limitation on that power. It may be exercised only 'with due regard for the Treaty'.

51. The rules of the 'Treaty', to which express reference is made in Directive 97/7, include the fundamental freedoms, in particular free movement of goods, which is relevant in the present case. That freedom therefore continues to apply within the scope of Directive 97/7.

52. With regard to the E-commerce directive, it should be observed that it did not have to be transposed into national law until 17 January 2002 and is not therefore applicable to the facts in the main proceedings.

2. Member States' regulatory powers: Limits deriving from free movement of goods

53. In view of the fact that secondary law contains relevant provisions on trade in medicinal products, but free movement of

14 — See Case C-150/88 *Parfümerie-Fabrik* [1989] ECR 3891, paragraph 28, Case C-37/92 *Vanacker and Lesage* [1993] ECR I-4947, paragraph 9, Case C-324/99 *DaimlerChrysler* [2001] ECR I-9897, paragraph 32, and Case C-99/01 *Linhart and Biffl* [2002] ECR I-9375, paragraph 18.

goods still remains an area of application, consideration must be given below to free movement of goods. First of all, the question must be raised whether the contested German provisions actually fall within the scope of free movement of goods. It must then be examined whether a restriction exists and, if so, whether this can be justified.

(a) Applicability of free movement of goods: prohibition on mail order as a selling arrangement?

54. In this connection it is necessary to examine whether the prohibition on mail order satisfies the requirements of the '*Keck* formula', i.e. should be classified as a selling arrangement, and whether Article 28 EC is therefore not applicable at all.

(i) Submissions of the parties

55. In the view of DocMorris, the prohibition on mail order should not be regarded as a selling arrangement, because it does not satisfy the requirements of the *Keck* formula. For example, the prohibition does not affect sales of domestic and foreign medicinal products in the same way. Because of the strict rules of the German law governing pharmacies, direct sales have fundamental importance and the prohibition on mail order is a measure having equivalent effect.

56. The Apothekerverband, the French and Austrian Governments and the Commission classify the prohibition on mail order as a simple selling arrangement.

57. The German Government takes the view that the prohibition on mail order is a selling arrangement and that the authorisation requirement under secondary law cannot preclude free movement of goods.

(ii) Assessment

58. In order to determine whether the prohibition on mail order should be regarded as a selling arrangement, it is necessary to examine in detail below the

Keck formula requirements laid down in the Court's case-law. [15]

— Examples of selling arrangements in existing case-law

59. In order to be covered by the exception laid down by the *Keck* formula, national measures must satisfy the following requirements. First of all, they must apply to all relevant traders operating within the national territory (universality). [16] Secondly they must affect in the same manner, in law and in fact the marketing of domestic products and of those from other Member States [17] (neutrality).

60. It is clear from these criteria that only certain selling arrangements are covered by the *Keck* formula, although the case-law must not be misinterpreted as meaning that there is a so-called third category. [18] There are logically only two categories of cases: cases covered by the *Keck* formula and cases not covered by it.

61. The Court has previously included the following national measures under the *Keck* formula: time restrictions, such as the ban on Sunday trading; [19] restrictions on the persons who offer goods for sale and on the persons from whom they may be obtained, such as the prohibition on the marketing other than by pharmacies of processed milk for infants; [20] the prohibition on the sale of tobacco products other than by specially authorised retailers [21] and the prohibition on obtaining beverages from anyone other than a holder of a production or wholesale licence. [22] Furthermore, the Court has recognised a prohibition on pharmacists advertising products usually sold in pharmacies outside the pharmacy [23] and a prohibition on televised advertising in the distribution sector as selling arrangements within the meaning of the *Keck* formula. [24] Other selling

15 — Joined Cases C-267/91 and C-268/91 *Keck and Mithouard* [1993] ECR I-6097, paragraphs 16 and 17.

16 — Terminology used by González Vaqué, 'La sentencia "Laura"', *Gaceta Jurídica de la C.E. y de la Competencia — Boletín* 1998, No 135, 15 (19).

17 — Sometimes wrongly described as discrimination. See, for example, Picod, 'La nouvelle approche de la Cour de justice en matière d'entraves aux échanges', *Revue trimestrielle de droit européen*, 1998, 169 (178).

18 — See Hénin, 'Libre circulation, conditionnement des médicaments et marques', in: *Droit communautaire et médicament*, 1996, 65 (87).

19 — Joined Cases C-418/93, C-419/93, C-420/93, C-421/93, C-460/93, C-461/93, C-462/93, C-464/93, C-9/94, C-10/94, C-11/94, C-14/94, C-15/94, C-23/94, C-24/94 and C-332/94 *Semeraro Casa Uno and Others* [1996] ECR I-2975 and Joined Cases C-401/92 and C-402/92 *Tankstation 't Heukske and Boermans* [1994] ECR I-2199.

20 — Case C-391/92 *Commission* v *Greece* [1995] ECR I-1621.

21 — Case C-387/93 *Banchero* [1995] ECR I-4663.

22 — Case C-189/95 *Franzén* [1997] ECR I-5909.

23 — Case C-292/92 *Hünermund and Others* [1993] ECR I-6787.

24 — Case C-412/93 *Leclec-Siplec* [1995] ECR I-179.

arrangements are rules on physically separate advertising [25] and on sales yielding low profit margins. [26]

62. According to the Court's case-law, the *Keck* formula does not cover, first of all, national measures that are designed to regulate trade in goods between Member States. [27]

63. Secondly, the Court has not subsumed under the *Keck* formula — expressly or implicitly — national measures that impose additional costs on the imported goods. [28] This relates primarily to measures which necessitate the adaptation of the intrinsic characteristics, such as composition, or the external characteristics, such as the designation or packaging, of imported products. [29] The question of costs therefore serves as a criterion for assessing the effect on trade, [30] as DocMorris rightly points out.

64. This is particularly clear in the *TK-Heimdienst* judgment, which relates to legislation that requires certain undertakings 'who already have a permanent establishment in another Member State and who wish to sell their goods on rounds in a particular administrative district... to set up or purchase another permanent establishment in that administrative district or in an adjacent municipality, whilst local economic operators already meet the requirement as to a permanent establishment. Consequently, in order for goods from other Member States to enjoy the same access to the market of the Member State of importation as domestic goods, they have to bear additional costs'. [31]

65. It is therefore necessary to examine below whether the requirements of the *Keck* formula are satisfied.

25 — This follows *a contrario* from the judgments in Case C-470/93 *Mars* [1995] ECR I-1923 and in Case C-368/95 *Familiapress* [1997] ECR I-3689.

26 — Case C-63/94 *Belgapom* [1995] ECR I-2467.

27 — Joined Cases C-267/91 and C-268/91 (cited in footnote 15), paragraph 12, and Case C-412/93 (cited in footnote 24), paragraph 19.

28 — Case C-323/93 *Crespelle* [1994] ECR I-5077, paragraph 29, Case C-189/95 (cited in footnote 22), paragraph 71, and Case C-368/95 (cited in footnote 25), paragraph 12.

29 — Advocate General Van Gerven in his Opinion in Joined Cases C-401/92 and C-402/92 (judgment cited in footnote 19); Hénin (cited in footnote 18), 71 et seq.; see also Gormley, 'Two years after Keck', *Fordham International Law Journal*, 1996, 866 (880); Greaves, 'Advertising restrictions and the free movement of goods and services', *European Law Review*, 1998, 305 (310 and 318); Heermann, 'Artikel 30 EGV im Lichte der "Keck"-Rechtsprechung', *Gewerblicher Rechtsschutz und Urheberrecht: Internationaler Teil*, 1999, 579 (585).
On the other hand, see Mattera, 'De l'arrêt "Dassonville" à l'arrêt "Keck": l'obscure clarté d'une jurisprudence riche en principes novateurs et en contradictions', *Revue du marché unique européen*, 1994, 117 (149), who opposes the argument that any adaptation to satisfy a rule of the importing State is regarded as an impairment. Critical of costs as a general criterion: Rolf Sack, 'Staatliche Werbebeschränkungen und die Art. 30 und 59 EG-Vertrag', *Wettbewerb in Recht und Praxis*, 1998, 103 (107).

30 — *Picod* (cited in footnote 17), p. 188 et seq.

31 — Case C-254/98 *TK-Heimdienst* [2000] ECR I-151, paragraph 26.

— Validity for all economic operators who carry on their business in their home country

66. It can be seen from the wording of the relevant national law, the German Arzneimittelgesetz, that the prohibition on mail order applies to both domestic and foreign pharmacists. The contested prohibition therefore satisfies the first requirement of the *Keck* formula, according to which the measure must apply to all relevant traders operating within the national territory. [32]

— Impact on sales of products

67. The *Keck* formula covers only measures that affect domestic and foreign products in law and in fact in the same manner. [33]

68. In this connection, it is necessary first of all to consider whether the effects of a measure on the volume of sales constitutes a relevant criterion for assessing its impact on sales. Whilst this is suggested by the Court in the judgment in *Ortscheit*, too much importance should not be attached to the statements by the Court in that judgment, since, first of all, the potential restraint on trade in goods is also the focus in *Ortscheit* [34] and, secondly, the Court has already qualified the importance of this criterion in *Keck* itself [35] and in *Hünermund* [36] and — later — in *Lerclerc-Siplec*. [37] [38]

69. As regards the requirement that domestic and foreign products must be affected in the same manner in law and in fact, it should be observed that the contested provision applies in the same manner to domestic and foreign medicinal products, that is to say it does not discriminate according to origin.

70. If the judgment in *TK-Heimdienst*, mentioned by several parties, is applied to the contested provision, then in the event

32 — Case C-292/92 (cited in footnote 23), paragraph 23, Joined Cases C-401/92 and C-402/92 (cited in footnote 19), paragraph 14, and Case C-412/93 (cited in footnote 24), paragraph 23.

33 — Case C-292/92 (cited in footnote 23), paragraph 23, Joined Cases C-401/92 and C-402/92 (cited in footnote 19), paragraph 14, and Case C-412/93 (cited in footnote 24), paragraph 23.

34 — Case C-320/93 (cited in footnote 10), paragraph 10.

35 — Joined Cases C-267/91 and C-268/91 (cited in footnote 15), paragraph 13.

36 — Case C-292/92 (cited in footnote 23), paragraph 20.

37 — Case C-412/93 (cited in footnote 24), paragraph 20.

38 — Advocate General Lenz also disagrees in his Opinion in Case C-391/92 (judgment cited in footnote 20), point 20.

that the opening of a pharmacy in Germany, i.e. a domestic establishment, is the only means of marketing medicinal products, preferential treatment would be given to domestic — German — pharmacies, because they already have such an establishment. [39]

73. However, as will be seen below, an interpretation of such a central rule of Community law as free movement of goods, that is to say Article 28 EC, cannot be limited to a mechanical application of the two traditional requirements laid down in the *Keck* formula.

— Decisive factor: impact on market access

71. Lastly, the fact that the present case differs from the situation in *TK-Heimdienst* in that the prohibition on mail order applies to all pharmacies and there are no exceptions for pharmacies established domestically suggests that the *Keck* formula has been satisfied. German law provides for a general prohibition on internet marketing.

74. The two — traditional — requirements of the *Keck* formula are, strictly speaking, only expressions of the general requirement that the measure should be 'not by nature such as to prevent... access to the market or to impede access any more than it impedes the access of domestic products'. [40] This is therefore neither a derivative, nor a third requirement, but, as it were, the — overriding — general criterion. [41]

72. Consequently, if consideration is given solely to the fact that German law does not draw a formal distinction according to the origin of goods, the analysis on the basis of the *Keck* formula could be ended at this point and it could be concluded that the prohibition on mail order satisfies the requirements of the *Keck* formula and is therefore a selling arrangement.

75. It is clear that a narrow view of the *Keck* formula based only on the two requirements and the resulting restrictive analysis is not satisfactory from the fact that the rule in the Arzneimittelgesetz, i.e. the prohibition on mail order, does treat domestic and foreign goods and pharmacies formally in the same manner, but

39 — See Clarke, 'E-commerce and pharmacy law', *The Bar Review*, 2001, 357 (362); Thurnher/Hohensinner, 'Fragen Sie Ihren Internetapotheker', *ecolex* 2001, 493 (496).

40 — Joined Cases C-267/91 and C-268/91 (cited in footnote 15), paragraph 17.

41 — But see Rolf Sack (cited in footnote 29), 105.

foreign pharmacies are placed at a disadvantage because, unlike German pharmacies, they are more heavily reliant on the prohibited form of marketing. This is demonstrated, for example, by the fact that it may be more difficult for German customers to make a personal call on them than on their domestic pharmacies.

76. The present case shows that the two requirements of the *Keck* formula — interpreted narrowly — in particular the criterion of domestic and foreign goods being affected in the same manner, are not effective in the case of strict, i.e. very restrictive national measures, even if those national measures are selling arrangements. [42] For example, rules on distribution channels can restrict market access in exactly the same way as product rules. [43]

77. It must be stated that in principle the *Keck* formula is intended to apply only in cases where the arrangements apply *after* goods have gained access to the market, but not in the case of restrictions on market access itself. [44]

78. The decisive factor should therefore be whether or not a national measure significantly impedes access to the market. This view has been supported not only by influential figures in legal doctrine, [45] but also by the Court itself — or at least the trend has been to that effect.

79. Thus, the Court has found, with regard to free movement of goods, 'that a prohibition of advertising... would render commercialisation, and consequently access to the market for those goods, appreciably more difficult'. [46] With regard to freedom to provide services, the Court has stated that a prohibition that directly affects access to the market in services is capable of hindering intra-Community trade in

42 — Problem highlighted by Gormley (cited in footnote 29), 884 et seq., and Oliver, 'Some further reflections on the scope of articles 28-30 (ex 30-36) EC', *Common Market Law Review*, 1999, 783 (795).

43 — Schwintowski, 'Freier Warenverkehr in europäischen Binnenmarkt: eine Fundamentalkritik des EuGH zu Art. 28 EGV', in: *Systembildung und Systemlücken in Kerngebieten des europäischen Privatrechts*, 2000, 457 (468).

44 — Cf. Advocate General Elmer in his Opinion in Case C-189/95 *Franzén* (judgment cited in footnote 22).

45 — See, for example, Advocate General Jacobs in his Opinion in Case-412/93 (judgment cited in footnote 24).
See also Dauses, 'Die Rechtsprechung des EuGH zum Verbraucherschutz und zur Werbefreiheit im Binnenmarkt', *Europäische Zeitschrift für Wirtschaftsrecht*, 1995, 425 (428); Rolf Sack, (cited in footnote 29), 109: the articles in Schwarze (ed.), *Werbung und Werbeverbote im Lichte des europäischen Gemeinschaftsrechts*, 1999; Weatherill, 'After Keck: some thoughts on how to clarify the clarification', *Common Market Law Review*, 1996, 885 (897).

46 — Case C-337/95 *Dior* [1997] ECR I-6013, paragraph 51.

services. [47] Merely for the sake of completeness, it should be mentioned that a national measure that restricts the exercise of an economic activity — arbitrarily — falls within the scope of freedom to provide services. [48]

80. In addition, in the present case the contested provisions do not concern further distribution, but the importation of goods in a certain form, and thus make access to the market of the Member State in question more difficult. If, for example, the effect of a prohibition is that a product practically disappears from the market, such a provision could even be classified as a product-related rule. [49]

81. The approach thus taken here, focusing on the impact on market access, cannot, however, be construed as meaning that the crucial factor is the extent of the impact of the national measure. [50] In contrast with a *de minimis* provision, such as in competition law, no economic data requires evaluation here. [51]

82. However, an important criterion for whether market access is made appreciably more difficult is whether other lawful and effective forms of distribution exist. [52]

— Alternatives for market access: existence of other forms of distribution

83. National measures that channel products to certain locations, for example reserving the distribution of medicinal products — in the case at issue — in principle for pharmacies are distribution rules in an extreme form. It is not necessary to examine here whether it is important that the measures have the purpose of [53] or merely can give rise to [54] channelling.

47 — Case C-384/93 *Alpine Investments* [1995] ECR I-1141, paragraphs 35 and 38.

48 — Case C-76/90 *Säger* [1991] ECR I-4221, paragraph 12.

49 — Kröck, *Der Einfluß der europäischen Grundfreiheiten am Beispiel der Ärzte und Arzneimittel*, 1998, 200.

50 — For such an alternative solution see Rolf Sack, 'Staatliche Regelung so genannter "Verkaufsmodalitäten" und Art. 30 EG-Vertrag', *Europäisches Wirtschafts- & Steuerrecht*, 1994, 37 (45).

51 — With regard to the contrast see Oliver (cited in footnote 42), 799.

52 — See Advocate General Jacobs in his Opinion in Joined Cases C-34/95 to C-36/95 *De Agostini and TV-Shop* [1997] ECR I-3843.

53 — With regard to such a rule see Advocate General Van Gerven in his Opinion in Joined Cases C-401/92 and C-402/92 (judgment cited in footnote 19), point 22, see also *Thurnher/Hohensinner* (cited in footnote 39), 496.

54 — Case C-387/93 (cited in footnote 21, paragraph 43); Advocate General Lenz in his Opinion in Case C-391/92 (judgment cited in footnote 20), point 19.

84. However, as is shown by the Court's judgment in the Greek pharmacies case, [55] such rules concerning distribution by certain traders do not fall within the scope of Article 28 EC either.

85. In the present case, however, not only is distribution reserved for a certain group of traders, but a whole form of distribution is prohibited. The contested German rules therefore go further than the provisions at issue in the Greek pharmacies case.

86. The Court held in *Hünermund* [56] that the crucial factor is whether or not the goods may be distributed by traders other than pharmacists. In the present case, in addition to the prohibition of a certain form of distribution, there is therefore also the restriction that the medicinal products may not be distributed by economic operators other than pharmacists.

87. As regards channelling to certain outlets, however, it follows from the Court's case-law that both in relations between wholesalers and retailers and in relations between retailers and consumers there must be sufficient freedom of choice of sources of supply and therefore appropriate alternatives.

88. The contested prohibition applies to just one form of distribution, [57] but it cannot be ruled out that even a measure of this kind may in principle constitute a restriction within the meaning of Article 28 EC. In this connection, the crucial factor is whether the form of distribution affected by the prohibition is important to the development of a market. [58] It is irrelevant in this connection that access by normal German public pharmacies to the German end user market is restricted in so far as they have only a restricted catchment area.

89. According to the judgment in *Leclerc-Siplec*, the relevant factor is whether a national measure 'does not prevent distributors from using other forms of advertising'. [59]

55 — Case C-391/92 (cited in footnote 20).

56 — Case C-292/92 (cited in footnote 23), paragraph 19.

57 — See, in general terms, Ernst, 'Arzneimittelverkauf im Internet', *Wettbewerb in Recht und Praxis*, 2001, 863 (896 with further references).

58 — For example, Clarke (cited in footnote 39), p. 362.

59 — Case C-412/93 (cited in footnote 24), paragraph 19.

90. It is therefore important whether other — effective — forms of distribution and promotion [60] are available or whether the national measure makes market access virtually impossible.

— Burden of proof for the existence of a restriction

92. It was held in *De Agostini* [63] that the efficacy of the various types of sales (promotion) is a question to be determined in principle by the referring court. It would have to be shown before the referring court in particular that the 'ban does not affect in the same way, in fact and in law, the marketing of national products and of products from other Member States'. [64]

91. If the national measure at issue does make market access virtually impossible, as is claimed by DocMorris and is not essentially disputed by the other parties, this would be a restriction of free movement of goods within the meaning of Article 28 EC. This would also be the case if it is assumed, as the Court did in its judgment in *De Agostini*, that the 'ban does not affect in the same way, in fact and in law, the marketing of national products and of products from other Member States'. [61] This is because the contested rules are capable of adversely affecting imports of medicinal products from other States by compulsorily excluding an important sales channel, albeit not the only effective channel. [62]

93. If the contested German rules were to be classified as a selling arrangement, the presumption made in *De Agostini* that the rules do not fall within the scope of Article 28 EC would arise. However, that presumption could be rebutted before the national court.

94. However, if it is assumed, as is suggested here, that where market access is made appreciably more difficult, the *Keck* exception does not apply, i.e. there is no selling arrangement, it would be necessary

60 — With regard to such a prohibition on advertising see Advocate General Jacobs in his Opinion in Joined Cases C-34/95, C-35/95 and C-36/95 (cited in footnote 52), paragraphs 97 and 99.

61 — Judgment in Joined Cases C-34/95, C-35/95 and C-36/95 (Opinion cited in footnote 52), paragraph 44.

62 — With regard to the sales monopoly of pharmacists see Advocate General Lenz in his Opinion in Case C-391/92 (judgment cited in footnote 20), paragraph 19.

63 — Judgment in Joined Cases C-34/95, C-35/95 and C-36/95 (Opinion cited in footnote 52), paragraph 43.

64 — Judgment in Joined Cases C-34/95, C-35/95 and C-36/95 (Opinion cited in footnote 52), paragraph 44.

to show that market access is made appreciably more difficult. [65]

(iii) Interim conclusion on Questions 1 and 1(a)

95. The contested rules have some peculiar features in the context of the situation on the product market in question which play an important role in the assessment. These include the fact that already established domestic pharmacies are not reliant on the prohibited form of marketing and are therefore given preferential treatment. It must also be taken into consideration that the national measure not only governs the marketing of goods after they have been imported, but even prevents such importation in a specific form.

96. In view of these peculiar features, the interim conclusion can only be that the prohibition on mail order cannot fall within the scope of the *Keck* exception and is to be classified as a measure having equivalent effect within the meaning of Article 28 EC.

65 — See also the articles in Schwarze (cited in footnote 45).

(b) Possible justification of the prohibition on mail order (Question 1b)

(i) Submissions of the parties

97. DocMorris is the only party in the written procedure to dispute the possibility that the prohibition on mail order can be justified. It claims that, first of all, the prohibition laid down in Paragraph 43 of the AMG and Paragraph 73 of the AMG is not necessary to guarantee effective health protection, and, secondly, regulated authorisation of mail order makes it possible to improve health protection.

98. In order to achieve a high level of health protection, pharmacies would have to guarantee effective monitoring of orders, packaging and receipt, and in particular ensure multiple prescription monitoring by nationally authorised pharmacies, packaging of medicinal products in specially designed containers and documentation of receipt.

99. In the view of DocMorris, Article 30 EC should be interpreted as allowing a Member State — as the importing

State — to prohibit commercial importation of medicinal products by way of mail order only if that Member State can substantiate and prove that actual dangers to health result from the pharmacy mail order operated, authorised and supervised in the Member State of origin because of deficiencies in safety precautions.

100. The Apothekerverband and the Austrian, French, German, Greek and Irish Governments take the view that the German rules are justified on grounds of protection of the health and life of humans.

101. The Apothekerverband first points out that supply by mail by a foreign pharmacy is permitted in an individual specific case. The prohibition on mail order serves to improve safety of medicinal products by guaranteeing consultation by pharmacists. Furthermore, the Apothekerverband relies on the national case-law on the system of supply of medicinal products, which includes price-fixing for medicinal products. In addition, the existence of traditional pharmacies is jeopardised. In the view of the Apothekerverband, the prohibition on mail order is also proportionate.

102. The German Government submits, in the alternative only, given its view that there is no restriction of free movement of goods, that the rules are justified and also proportionate on grounds of health protection and do not infringe Article 28 EC. If, however, that were the case, it could be justified by Article 30 EC.

(ii) Assessment

103. As regards a possible justification of the prohibition on mail order, it should first be noted that the following arguments are made in the event that the Court takes the view that the prohibition on mail order falls within the scope of Article 28 EC and constitutes a restriction on free movement of goods.

104. In view of the occasionally unclear arguments of the parties, it must be pointed out that before examining any justification under Article 30 EC it must be assessed whether the national measure is applicable without discrimination, since if that is the case justification can be found in

Article 28 EC, i.e. in the *Cassis de Dijon* case-law adopted on that provision. Reliance on Article 30 EC is therefore no longer necessary, contrary to the view taken in some of the German legal literature. [66]

— Justification for the measure

105. It is common ground that the Court's case-law has recognised the protection of health not only in the context of Article 30 EC, but also as a mandatory requirement under Article 28 EC. [67]

106. It cannot be denied that the contested rules of the AMG are intended to serve the protection of health.

66 — See, for example, Heermann, 'Artikel 30 EGV im Lichte der "Keck"-Rechtsprechung: Anerkennung sonstiger Verkaufsmodalitäten und Einführung eines einheitlichen Rechtfertigungstatbestands?', *Gewerblicher Rechtsschutz und Urheberrecht*, 1999, 579 (594), who concludes that, in the event that the requirements laid down in Article 30 EC are satisfied, Article 28 EC is not applicable. Against this view it can be contended that Article 30 EC can apply only where Article 28 EC is applicable and will also infringe the prohibition laid down therein. On the other hand, the application of the *Cassis de Dijon* case-law means that there is not even an infringement of Article 28 EC.

67 — Case 120/78 *Rewe* [1979] ECR 649 and Case C-317/92 *Commission* v *Germany* [1994] ECR I-2039.

— Proportionality of the measure

107. For a national measure to be compatible with Article 28 EC, however, it must not only have a recognised justification, but also be consistent with the principle of proportionality.

108. The proportionality test must not be based on specific individual cases, but be general. The principle of proportionality is infringed even if the infringement is merely a typical characteristic. To this end it is necessary to examine the appropriateness, the necessity and the reasonableness of the national measure.

— Appropriateness of the national measure

109. It is first necessary to examine whether the rules of the AMG are actually fit for the purpose of protecting health.

110. As the German Government rightly argues, the measures laid down therein are

appropriate in principle to serve that objective. This is not affected by the fact that different rules allowing internet sales could serve the objective of health protection.

— Necessity of the national measure

111. Secondly, the necessity of the national measure must be examined with respect to health protection. [68]

112. Our starting point must be that the Member States are not required to opt for the lowest degree of protection. [69]

113. However, the fact that such a prohibition is not regarded as necessary by all Member States and does not exist in all the Member States militates against the necessity of the contested rules.

— Reasonableness of the national measure

114. Thirdly, in order to test whether the contested provisions of the AMG are consistent with Community law, they must be examined in the light of the proportionality principle in the narrow sense, or reasonableness. The important factor is whether the health and life of humans can be protected as effectively by measures that are less restrictive of intra-Community trade.

115. With respect to Question 1(b), it is appropriate to confine the examination to the justification based on 'protection of national authorisation rules against circumvention', which was mentioned by several parties.

116. In practice there are workable measures, i.e. measures that are effective, but are less restrictive of free movement of goods, even though — at least according to one branch of case-law [70] — this is not in itself an argument for the disproportionality of national provisions.

68 — Case C-347/89 *Eurim-Pharm* [1991] ECR I-1747, paragraph 27, Case C-62/90 *Commission v Germany* [1992] ECR I-2575, paragraph 12, Case C-55/99 *Commission v France* [2000] ECR I-11499, paragraph 42 and Case C-172/00 *Ferring* [2002] ECR I-6891, paragraph 34.

69 — Joined Cases C-1/90 and C-176/90 *Aragonesa and Publivía* [1991] ECR I-4151, paragraph 16.

70 — Case C-124/97 *Läärä and Others* [1999] ECR I-6067, paragraph 36.

117. As regards the danger that national authorisation rules could be circumvented by internet pharmacies where medicinal products that are not authorised in the importing Member State are ordered over the internet and then imported into that Member State, several parties examined the state of harmonisation of the law governing authorisation of medicinal products and the importance of the judgment in *Ortscheit* for the issue of authorisation.

118. In the present proceedings, the importance of the different possibilities for authorisation and the possibility of recognition can remain open, however, since the differences between the possibilities mentioned by the parties are irrelevant to the answer to Question 1(b).

119. The solution can in fact be found in the relevant provision of Article 3 of Directive 65/65. Under that provision, no medicinal product 'may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or an authorisation has been granted in accordance with Regulation (EEC) No 2309/93'.

120. If the medicinal products have not been authorised in the importing State and their authorisation has not been recognised, that Member State may prohibit their placing on the market. Consequently, a prohibition on mail order that is intended to prevent those medicinal products being placed on the market is also proportionate.

121. The other justifications submitted will be examined only with reference to authorised medicinal products, that is to say in connection with the examination of Question 1(c).

(iii) Interim conclusion on Question 1(b)

122. Articles 28 EC and 30 EC are to be interpreted as meaning that national provisions prohibiting the commercial cross-border import by mail order from authorised pharmacies in other Member States of medicinal products for human use which are required to be sold through pharmacies, on the basis of individual orders placed by end users on the internet, is justified in order to protect the health and life of humans as regards medicinal products which require authorisation in the State into which they are imported, but which are neither authorised or recognised at national level, nor centrally approved at Community level.

B — *Authorised medicinal products: Question 1(c)*

1. Submissions of the parties

123. DocMorris points out that the reimportation of — authorised — medicinal products, which is recognised by the Court, serves the completion of the Internal Market and that there is no abuse in the present circumstances.

124. In the view of the Apothekerverband, the prohibition on mail order is also justified for medicinal products authorised in the importing State.

125. The Austrian and Greek Governments also consider the prohibition on mail order to be expressly justified even for authorised medicinal products.

126. The German Government also takes the view with regard to authorised medicinal products that the prohibition on mail order is merely a selling arrangement.

127. The Commission also takes the view with regard to authorised medicinal products that secondary Community law permits a prohibition on distance sales. In this connection it refers to Article 14 of Directive 97/7 and Article 1(3) and Article 3(4) of the E-commerce directive.

128. Furthermore, the Commission considers that the requirements laid down in the *Keck* formula are also satisfied by the prohibition on mail order in the case of authorised medicinal products.

2. Assessment

129. Question 1(c) concerns the marketing and importation of medicinal products that are authorised in the importing State, i.e. reimportation. However, the present case does not relate to the usual questions of industrial property or the requirement of a further authorisation. It concerns the fundamental question of whether free movement of goods applies at all and the justification of protection of health.

(a) Danger of circumvention of national rules

130. In the proceedings the applicability of free movement of goods was contested on the ground that the situation in the present case, reimportation via an internet pharmacy, is an artificial commercial transaction, which is not therefore covered by this fundamental freedom. It should be pointed out in this respect that a characteristic of the structure of the internet trade in medicinal products in the present case is that the internet pharmacy does not import the medicinal products from Germany itself in order to re-export them there. [71]

131. In fact, a distinction must be drawn between two legally and economically separate processes: the acquisition of the medicinal product by the internet pharmacy from a wholesaler, where the product can be exported from Germany by the wholesaler, and the sale of the medicinal product by the internet pharmacy to consumers, e.g. in Germany.

132. Consequently, first of all, there are two transactions at different commercial levels (between the wholesaler and the internet pharmacy and between the internet pharmacy and the consumer) and, secondly, the cross-border trade can occur at either of the two levels. As DocMorris rightly stresses, free movement of goods protects each commercial level in itself.

133. Reimportation therefore takes place at a different level from exportation, namely in the relationship between the retailer (DocMorris) and the consumer, who are both in a different Member State.

134. The fact that the internet pharmacies also wish to develop their business in the Member States from which they obtain medicinal products suggests that this structure for the distribution of medicinal products — which exists in the present case — does not constitute abuse of free movement of goods. However, activity in other Member States, in particular cross-border trade, is an essential feature of the internal market, and of the exercise of the fundamental freedoms. [72]

135. This finding is confirmed by the Court's case-law, according to which the

71 — With regard to such a situation see the judgment in Case 229/83 *Leclerc* [1985] ECR 1.

72 — With regard to freedom of establishment: Case C-212/97 *Centros* [1999] ECR I-1459, paragraph 26 et seq.

importation of goods that are authorised in the importing State, even where they are medicinal products, falls within the free movement of goods, even with regard to medicinal products, [73] therefore including reimportation.

(b) Proportionality of the prohibition on mail order

136. Consideration will be given below only to those aspects that have been put forward by the parties as grounds to justify the prohibition on mail order and that are relevant for assessing the necessity and the reasonableness of the contested provisions.

137. In this regard, it is necessary to proceed from the principle that 'the fact that the doctor who prescribed the medicinal product or the pharmacist who sold it are established in a Member State other than that in which the medicinal product is used does not prevent those practitioners from supervising the use of the imported medicinal product, where appropriate with the aid of a colleague established in the importing Member State'. [74]

73 — See Case C-201/94 *Smith & Nephew and Primecrown* [1996] ECR I-5819 relating to Directive 65/65 and Case C-379/97 *Upjohn* [1999] ECR I-6927 relating to trade mark rights in the medicinal products sector.

74 — Case C-62/90 *Commission* v *Germany* [1992] ECR I-2575, paragraph 19.

138. It should also be pointed out that internet pharmacies are subject to the rules of the State in which they are registered, which is also responsible for any necessary supervision.

(i) Assessment with regard to the objectives of the prohibition on mail order

— Lack of expert advice?

139. The parties have pointed out some benefits of advice which they believe exist in a normal public pharmacy, but not in the case of internet pharmacies. In the case of internet pharmacies, for example, they allege that there is no opportunity for the pharmacists to take the initiative themselves to provide advice. However this possibility does also exist as a rule in the case of internet pharmacies. Furthermore, it was not possible to demonstrate or prove with regard to normal public pharmacies with what frequency and in what circumstances information was actually provided by the pharmacist, either on the initiative of the patient or on the initiative of the pharmacist.

140. Moreover, the Apothekerverband pointed out the danger of the importation of counterfeit, untested, unsafe or ineffective medicinal products that arises in the absence of advice. Specific figures for Germany in this regard were not given.

141. It was further pointed out that where medicinal products are purchased from an internet pharmacy they would not be delivered personally by a courier service. In this respect it is sufficient to note that it is very common for medicinal products not to be collected in person even from normal public pharmacies.

142. With regard to advice issued on the initiative of the pharmacist and personal delivery, it should be stated that the German legislature does not make provision for any specific controls. However, the Court has held [75] that the lack of controls is an important aspect in assessing the need for national measures.

143. It is also necessary to bear in mind the Court's case-law according to which advice provided by a pharmacist from another Member State is to be regarded as having equivalent value. [76]

144. Lastly, attention should be drawn to the differences mentioned by several parties between personal consultation and remote consultation, i.e. personal attention from the pharmacist, the pharmacist's local knowledge and the opportunity that the pharmacist has to work with other health professionals. These distinctive features of the normal public pharmacy can undoubtedly be retained by these pharmacies and will not change — legally — as a result of the authorisation of internet pharmacies.

145. In order to guarantee the required standard of advice, however, internet pharmacies must also meet certain requirements with regard to advice and orders.

146. For example, they must monitor the order, and in particular reply to possible queries and draw up a list of recommen-

75 — Case 215/87 *Schumacher* [1989] ECR 617, paragraph 21, concerning the lack of controls for certain types of imports.

76 — Case 215/87 *Schumacher* (cited in footnote 75), paragraph 20.

dations. In certain cases, they must issue information on their own initiative, in particular where there are doubts as to the content of the medicinal product. In order to prevent any misuse, the maximum quantity of the medicinal products to be dispensed could also be laid down. Labels and information must be written or appended in the language of the patient. Lastly, internet pharmacies must always be contactable.

147. In the case of prescription medicinal products, internet pharmacies have to take additional measures. For example, they are in any case subject to the prescription rules of the importing State. Furthermore, the medicinal products may be sent only on presentation of an original prescription, which must be filed if necessary.

148. Lastly, however, it should not be overlooked that orders placed on the internet may in some cases offer better technical possibilities for advice. For example, internet pharmacies that have an automated medication record can contact patients more easily on their own initiative.

— Need to guarantee patient protection in the delivery of medicinal products

149. The parties pointed out the need to guarantee patient protection in the delivery of medicinal products. The protection of patients in the delivery of medicinal products can be guaranteed by appropriate measures for checks on packaging and receipt. For example, it would have to be verified that the content and quantity of the goods sent corresponded to the medicinal products ordered. In addition, proper transport must be ensured, in particular for heat and light-sensitive medicinal products. Lastly, adequate checks on receipt must be guaranteed. These essentially include documentation of the delivery operation, possibly by the courier, and, if necessary, delivery only to the authorised person, which must in that event be confirmed by a signature.

150. In order to prevent the emergence of unscrupulous suppliers, DocMorris has also rightly drawn attention in the present case to the various information requirements laid down in the E-commerce directive, in particular in Articles 5, 6 and 10 of that directive.

— Need to guarantee a comprehensive supply that meets requirements

151. Several parties argued that the authorisation of internet pharmacies would have negative economic consequences for normal public pharmacies or even jeopardise the very basis of their existence. In this connection, several parties pointed out the resulting risk to security of supply.

152. In this regard it should be stated that security of supply is one of the grounds recognised by the Court's case-law which can justify certain national measures. However, it is also a requirement here that the measure must be necessary to maintain a certain level of supply. [77]

153. It is therefore also necessary in this respect for the Member State in question to show that the relevant supply can be guaranteed only by the measure taken. However, the German Government failed to demonstrate — forecasts and fears notwithstanding — that the contested provisions are necessary for the security of supply.

154. In addition, the authorisation of mail order trade certainly does not automatically mean the end of normal public pharmacies. The coexistence of different forms of distribution is perfectly possible from a legal point of view. Thus, it cannot be ruled out that normal public pharmacies will continue to be able to make a profit by exploiting the advantages they offer, such as quicker supply in the absence of delays due to delivery and emergency supply at night and at weekends.

(ii) Burden of proof on the Member State in question

155. Finally, reference is made to the duty, which has also been established by the Court's case-law in preliminary ruling proceedings, for a Member State that considers a measure restricting the movement of goods to be justified and proportionate to show this to be the case. [78] Thus, it must show 'that the contested measure was the most appropriate means... whilst being the least restrictive of intra-Community trade'. [79]

77 — See Case C-158/96 *Kohll* [1998] ECR I-1931, paragraph 48 et seq., Case C-368/98 *Vanbraekel and Others* [2001] ECR I-5363, paragraph 48, and Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, paragraph 73.

78 — Case 178/84 *Commission* v *Germany* [1987] ECR 1227, paragraph 46 and Case C-158/96 (cited in footnote 77), paragraph 52.

79 — Case C-317/92 (cited in footnote 67), paragraph 20.

156. The obligation to present evidence here concerns in particular the question whether the reliability of the internet pharmacy in the country of origin is guaranteed, [80] in this case the State from which the internet pharmacy operates. Furthermore, the Court has expressly required it to be shown 'that the rules at issue were necessary to provide a balanced... service accessible to all'. [81]

157. The Federal Republic of Germany has not shown that the prohibition on mail order is necessary and reasonable, that is to say the objectives pursued could not be safeguarded as effectively by a less onerous measure that laid down a number of conditions for the operation of internet pharmacies.

158. The objectives of expert advice, patient protection and guarantee of supply could also be achieved by less drastic measures than the contested provisions, which lay down a simple prohibition.

80 — Case C-317/92 (cited in footnote 67), paragraph 18.
81 — Case C-158/96 (cited in footnote 77), paragraph 52.

159. Suitable measures are likely to include first and foremost the requirements, mentioned in connection with each of these objectives, relating to marketing of orders, shipment and transportation of packages, and receipt.

160. Whether DocMorris satisfies these requirements is an issue to be resolved in a specific legal dispute. However, it is for the national court to resolve that issue.

(iii) Interim conclusion on Question 1(c)

161. The answer to Question 1(c) must therefore be that Articles 28 EC and 30 EC are to be interpreted as meaning that a national prohibition on the import of medicinal products that are authorised in the importing State, which a pharmacy in another Member State previously obtained from wholesalers in the importing State, is not justified in order to protect the health and life of humans, in so far as this measure is not proportionate.

VI — The second question

A — *Questions 2 and 2(a)*

1. Question 2: Prohibition on advertising medicinal products by mail order and on advertising certain medicinal products

162. The second question must also be reworded so that it is not directed expressly at the compatibility of a certain national measure:

Are Articles 28 and 30 EC to be interpreted as precluding a national prohibition on advertising medicinal products by mail order, prescription medicinal products and medicinal products available only through pharmacies that are authorised in the State of origin but not the importing State, under which the internet presentation of a pharmacy of an EU Member State, which in addition to presentation of its business describes individual medicinal products with their product name, prescription status, package size and price and at the same time offers the possibility of ordering those medicinal products by means of an online order form, is classified as prohibited advertising, with the result that cross-border orders of medicinal products by internet including delivery of those orders is at the very least made substantially more difficult?

(a) Submissions of the parties

163. In the opinion of DocMorris, the possibility of internet orders is essential for the cross-border mail order trade in medicinal products at end user level. A broad interpretation of the expression 'advertising to the general public' means that national prohibitions based on the prohibition laid down in Directive 92/28 restrict free movement of goods. Such measures are not justified in order to prevent self-medication or to protect national authorisation schemes either.

164. In the view of the Apothekerverband, on the other hand, the prohibitions on advertising, including those for authorised medicinal products, do not infringe Articles 28 EC and 30 EC. This follows from the fact that the prohibition on mail order is consistent with Community law.

165. In its arguments, the German Government concentrates on the prohibition laid down in Paragraph 8(2) of the HWG and classifies this as a selling arrangement. If the Court does not share this view, it submits that the prohibition is in any event justified under Article 30 EC.

166. The French Government concludes that, because the prohibition on mail order is lawful, the prohibition on advertising is also permitted. The prohibition on pharmacies advertising themselves does not infringe Article 28 EC either.

167. The Greek and Irish Governments consider the prohibition on advertising medicinal products by mail order and prescription medicinal products that are not authorised in the importing State to be compatible with Articles 28 EC and 30 EC. The Austrian Government, which refers to the Community code, also considers a prohibition on advertising non-prescription medicinal products that are available only through pharmacies to be justified.

168. The Commission is also of the opinion that the prohibitions on advertising prescription and unauthorised medicinal products are essentially selling arrangements within the meaning of the judgment in *Keck*. On the other hand, the prohibition under Paragraph 8(2) of the HWG is to be classified as a measure having equivalent effect within the meaning of Article 28 EC.

(b) Assessment

169. It should first be pointed out that German law on the advertising of medicinal products draws a fundamental distinction between four prohibitions on advertising: concerning unauthorised medicinal products (Paragraph 3a of the HWG), concerning prescription medicinal products (Paragraph 10 of the HWG) and concerning two prohibitions relating to mail order trade in medicinal products. These prohibitions are based on Paragraph 8(1)(1) of the HWG, which prohibits advertising for the purchase of medicinal products that are available only through pharmacies in general, and Paragraph 8(2), which prohibits advertising for individual import.

170. The referring court does not refer expressly to any of these rules of German law in Question 2, but mentions three types of prohibition on advertising: 'medicines by mail order', 'prescription medicines' and

medicines that are not authorised in the importing State. These three prohibitions will be examined in detail below:

(i) Prohibition on medicinal products by mail order

171. Question 2 refers first of all to the prohibition on advertising medicinal products by mail order. It is clear from the file submitted to the Court of Justice by the referring court that, as far as medicinal products by mail order are concerned, the referring court considers that only the prohibition laid down in Paragraph 8(1) of the HWG, and not the prohibition laid down in Paragraph 8(2) of the HWG, is applicable. The latter provision does not, therefore, fall within the legal or factual scope of the main proceedings.

172. The prohibition on advertising medicinal products by mail order laid down in Paragraph 8(1) of the HWG applies only to medicinal products that are required to be sold through pharmacies, but does not relate to an authorisation or prescription requirement.

173. In assessing this rule in the light of Community law, it must first be considered whether the medicinal products advertising sector at issue has been definitively harmonised. If that is the case, the relevant rules of secondary law take precedence. Otherwise, the rules of primary law apply, in this case free movement of goods.

174. The principal rule of secondary law of relevance is Directive 92/28. Article 2(1) of that directive lays down a prohibition on advertising. Since that prohibition is based on the type of medicinal product and not on the form of distribution, however, its scope does not coincide with that of the German prohibition on advertising. Whilst the prohibition contained in the directive applies only to medicinal products for whose marketing no authorisation has been granted under Community law, Paragraph 8(1)(1) of the HWG prohibits advertising for the purchase by mail order of medicinal products that are required to be sold through pharmacies.

175. The criterion for assessing a prohibition on advertising such as Paragraph 8(1) of the HWG under Community law therefore remains free movement of goods. In this respect it is now crucial that Paragraph 8(1), first, does not differentiate according to the origin of the products and, secondly, applies to all economic operators, so that at first glance it satisfies both

traditional *Keck* criteria. On the basis of the *Keck* formula it therefore seems reasonable to classify the prohibition on advertising under Paragraph 8(1) of the HWG as a selling arrangement.

176. However, as has already been explained in connection with the prohibition on mail order, the important factor is not just whether sales of foreign products are affected in the same manner, but whether the prohibition on advertising restricts access to the market in such a way that it is no longer a question of a mere selling arrangement. It then becomes a measure having equivalent effect within the meaning of Article 28 EC. [82]

177. DocMorris observes that prohibitions on advertising inhibit orders of medicinal products on the internet. DocMorris rightly points out that internet pharmacies, unlike normal public pharmacies, have only this means of information at their disposal.

178. The prohibition on advertising within the meaning of Paragraph 8(1) of the HWG therefore restricts access to end customers for internet pharmacies, which are reliant on this means of advertising, in such a way that it cannot be classified as a selling arrangement. This classification applies specifically to national measures that prohibit any form of advertising.

179. However, the prohibition on advertising does not infringe Article 28 EC if it serves a mandatory requirement and is proportionate.

180. In this connection, reference should be made to a judgment by the Court on a prohibition on advertising contained in the HWG. In *Ortscheit* the Court was required to consider the prohibition on advertising contained in Paragraph 8(2) of the HWG. Whilst those proceedings concerned only medicinal products that required authorisation, but were not authorised in Germany, the statements made by the Court are so general that they can be applied to the prohibition on advertising at issue in the present case. In that judgment the Court recognised that the prohibition laid down in Paragraph 8(2) of the HWG is necessary in order to protect national authorisation schemes from circumvention. [83] The principle must also apply to other prohibitions on advertising medicinal products.

82 — With regard to a prohibition on advertising see also Case C-405/98 *Konsumentombudsmannen* [2001] ECR I-1795, paragraph 19.

83 — Case C-320/93 (cited in footnote 10), paragraph 19 et seq.

181. Consequently, whilst the Member States may prohibit the advertising in question for medicinal products that require authorisation, but are not authorised or regarded as approved, the national prohibition, like the prohibition on mail order, is disproportionate with regard to medicinal products that do not require authorisation or are authorised.

183. It is also necessary to interpret Articles 28 EC and 30 EC with regard to the prohibition on advertising unauthorised medicinal products. However, these rules form the Community law framework that is relevant for the decision in the main proceedings only if and in so far as there are no rules of secondary law that would take precedence.

184. With respect to unauthorised medicinal products, Article 2(1) of Directive 92/28 contains an express prohibition on advertising.

(ii) Prohibition on advertising medicinal products that are not authorised in the importing State

185. The prohibition on advertising laid down in Paragraph 3a of the HWG concerns medicinal products that have not been authorised or are not regarded as authorised either under Community procedures or under German law. This provision of German law is therefore merely the national rule implementing the prohibition under Article 2(1) of the directive.

182. Question 2 refers secondly to the prohibition on advertising medicinal products that require authorisation in the importing State, that is to say, Germany, but are not authorised. The relevant German legislation is Paragraph 3a of the HWG. Whilst this rule essentially precedes Article 8(2) of the HWG,[84] the latter provision is not relevant in the main proceedings, as is clear from the order for reference.

186. Consequently, since the application of Directive 92/28 takes precedence, an assessment of Paragraph 3a of the HWG in the light of primary law is ruled out in the present case. It is not therefore necessary to examine whether the national measure is a selling arrangement within the meaning of the *Keck* formula either.

84 — See, for example, Ernst (cited in footnote 57), 897; Koenig/Müller, 'Der werbliche Auftritt von Online-Apotheken im Europäischen Binnenmarkt', *Wettbewerb in Recht und Praxis*, 2000, 1366 (1367 et seq.), according to which Paragraph 3a is applicable where the products offered on the internet include medicinal products not authorised in Germany and contain information that can be classified as advertising for the unauthorised medicinal products (1372).

(iii) Prohibition on advertising prescription medicinal products

187. Thirdly, in Question 2 the referring court also highlights the issue of the compatibility of a national prohibition on advertising prescription medicinal products. This part of the question is therefore directed at the prohibition on advertising under Paragraph 10 of the HWG.

188. With regard to this rule of national law too, it must first be examined whether this aspect has been definitively harmonised by provisions of secondary law.

189. As the Commission rightly states, Directive 92/28 also contains provisions governing advertising of prescription medicinal products. Article 3(1), first indent, of Directive 92/28 expressly requires Member States to prohibit the advertising to the general public of medicinal products which are available on medical prescription only.

190. Paragraph 10 of the HWG can thus be regarded as a rule implementing that prohibition. However, since Article 3(1) of Directive 92/28 concerns only advertising to the general public, the question then arises whether the national prohibition on advertising under Paragraph 10 of the HWG stays within the bounds of the directive or goes further than the requirement laid down in Directive 92/28. For any part of the national legislation that went further than the directive, primary law, i.e. Articles 28 EC and 30 EC, would therefore apply in the absence of harmonisation under secondary law. The legal issue of the compatibility of this German prohibition on advertising with primary law is not the subject of the present case, however.

2. Question 2(a) — Internet presentation as advertising to the general public?

191. Question 2(a) concerns the significance of free movement of goods for the expression 'advertising to the general public' within the meaning of Article 1(3) and Article 3(1) of Directive 92/28.

(a) Submissions of the parties

192. In the view of DocMorris, the expression 'advertising to the general public' within the meaning of Article 1(3) of Directive 92/28 should not be given a broad interpretation, because this would make access to the end customer market appreciably more difficult. The expression should instead be interpreted in accordance with primary law as meaning that online order forms, which contain essential information for the internet pharmacy trade, are not covered by the expression 'advertising to the general public'.

193. In the view of DocMorris, the prohibitions on advertising in Paragraph 3a, Paragraph 8(1) and (2) and Paragraph 10 therefore infringe Article 28 EC.

194. According to DocMorris, it follows from Article 1(3) of the E-commerce directive that information society services may not be restricted disproportionately by prohibitions on advertising laid down in Community law, with the result that the minimum information in digital order forms that is required for internet orders of medicinal products cannot be classified as prohibited advertising.

195. In the opinion of the Apothekerverband, Question 2(a) should be answered in the negative, because otherwise regard would not be had to the scheme and interaction of the Community rules. The E-commerce directive does not completely harmonise information society services and, in particular, does not cover the conditions for the delivery of goods. The directive is not applicable at all to mail order trade in medicinal products which are only available from pharmacies.

196. The German Government takes the view that advertising of medicinal products is excluded from the E-commerce directive. Before the prescribed period within which the directive must be transposed has expired, an interpretation by the national court in accordance with the directive is also ruled out.

197. Article 1(3) and the 11th recital of the E-commerce directive are without prejudice to the level of protection for public health.

198. The prohibition on advertising laid down in Paragraph 8(2) of the HWG is covered by Directive 92/28 and applies notwithstanding the E-commerce directive.

Lastly, the German Government points out that, under Article 3(4) of the E-commerce directive, civil courts may prohibit certain advertising measures that impair the protection of public health.

199. In the view of the Greek Government, the E-commerce directive is without prejudice to the provisions of Directive 92/28.

200. The Irish Government interprets Articles 28 EC and 30 EC as meaning that they do not exclude the internet presentation at issue from the scope of the expression 'advertising to the general public'.

201. The Austrian Government bases its submissions on the Community code. Under Article 86 of the Community code, order lists for medicinal products are to be classified as advertising. It follows from Article 88(1) of the Community code that Member States are required to prohibit advertising for prescription medicinal products. Article 88(2) provides for an exception for certain medicinal products. The E-commerce directive does not preclude the prohibition on advertising either. Under that directive, Member States may prohibit not only mail order trade in medicinal products itself, but also advertising for those products.

202. The Commission also advocates a broad interpretation of the term 'advertising' which includes advertising to the general public. However, the term 'advertising' does not apply to undertakings, i.e. pharmacies, but to goods. In the view of the Commission, neither Articles 28 EC and 30 EC nor the E-commerce directive require a different interpretation of the term 'advertising'. All things considered, Question 2(a) should be answered in the negative.

(b) Assessment

203. Unlike Question 2, Question 2(a) concerns the prohibition of advertising to the general public of certain medicinal products under Article 3(1) of Directive 92/28. This prohibition is based on the expression 'advertising to the general public' which, under Article 1(3) of Directive 92/28, falls within the scope of the term 'advertising'.

204. The expression 'advertising of medicinal products' is defined in Article 1(3) of Directive 92/28 as 'any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products'.

205. On the other hand, Directive 92/28 does not provide for a legal definition of the expression 'advertising of medicinal products to the general public'. The starting point for interpreting that expression therefore remains 'advertising' as a generic term, which also encompasses 'advertising of medicinal products to the general public' under Article 1(3), first indent.

206. The question arises whether or not the internet presentation of a pharmacy of a Member State, which, in addition to a simple presentation of its business, describes individual medicinal products with their product name, prescription status, package size and price, and at the same time offers the possibility of ordering those medicinal products by means of an online order form, is covered by the expression 'advertising to the general public'.

207. On the basis of the deliberately broad formulation of the term 'advertising' [85] in Directive 92/28, a broad interpretation will also have to be given to the expression 'advertising to the general public'. This view is supported by the fact that a fundamental distinction is drawn in practice in advertising for medicinal products in the Member States between advertising for the general public and advertising for specialists. This distinction in the target group alone does not justify any reduction of the expression. Nevertheless, because the general public, i.e. lay people, merit greater protection, special importance is attached to the prohibition on advertising.

208. A broad interpretation of the expression 'advertising to the general public' is also suggested by the fourth and sixth recitals of Directive 92/28, which express a rule-exception relationship. In principle advertising is prohibited; by way of exception it may be permitted.

209. However, the broad definition of 'advertising to the general public' must in any case be narrowed so as not to include general information on an internet pharmacy, i.e. image-based and corporate advertising. The essence of advertising to the general public is product advertising.

210. The information which DocMorris considers to be essential, such as product name, contents, prescription status, package size and price, indicate that product advertising is at issue in the present case.

85 — With regard to the broad interpretation of the term 'advertising', see the judgment in Case C-112/99 *Toshiba Europe* [2001] ECR I-7945, paragraph 28, concerning misleading advertising.

211. The assessment is based essentially on the objective impression given to consumers by the overall appearance of the website. [86] An important indicator is the fact that DocMorris divides its product range into different headings, under which each of the individual medicinal products are shown. These may be ordered by clicking on a box. The range can therefore be specified by product through operations by the internet user. According to a different view, the naming of medicinal products alone is sufficient for the presumption to arise that an internet presentation has an advertising effect. [87]

212. Whilst the mere presentation of DocMorris cannot be classified as advertising within the meaning of Directive 92/28, the description of medicinal products with their product name, prescription status, package size and price, with the possibility of ordering those medicinal products by means of an online order form, most probably can be.

213. Consequently, there is product-related sales advertising in the main proceedings which falls within the scope of 'advertising to the general public' within the meaning of Directive 92/28.

214. An interpretation in the light of higher-ranking primary law does not produce any different conclusion. Free movement of goods does not have sufficiently specific substance to be able to derive from it a reduction of the broad notion of 'advertising to the general public'.

215. It is true, in terms of economics, that the presentation of internet order forms is essential for an internet pharmacy's mail order trade in medicinal products, but that does not alter the conclusion. As the Commission rightly argues, the importation of a product and promotion of a product must be assessed separately.

216. As regards the E-commerce directive, which is expressly referred to in Question 2(a), and its implications for the definition of 'advertising to the general public', it should be pointed out that this directive did not have to be transposed until 17 January 2002. The Court has consistently held [88] that directives whose transposition period has not yet expired when the facts of the case occurred are not applicable.

86 — Koenig/Müller (cited in footnote 84), 1368.

87 — Ernst (cited in footnote 57), 897.

88 — See, with regard to the law governing medicinal products, the judgment in Case C-320/93 (cited in footnote 10), paragraph 15.

217. As a result, the fundamental question of the relationship between the E-commerce directive and Directive 92/28 does not have to be examined here. Because the E-commerce directive does not apply, it is not necessary either to examine the importance of the country of origin principle laid down therein, the possibility that exists under Article 3(4) of the E-commerce directive to derogate for reasons of public health or the scope of the exception on grounds of protection of public health under Article 1(3) of the E-commerce directive.

3. Interim conclusion

218. Articles 28 EC and 30 EC are to be interpreted as precluding a national prohibition on advertising medicinal products by mail order — other than the advertising of medicinal products for human use — unless the prohibition serves to protect national authorisation rules and is proportionate.

219. Article 3(1) of Council Directive 92/28 is to be interpreted as not precluding a national prohibition on the advertising of prescription medicinal products for human use.

220. Article 2(1) of Directive 92/28 is to be interpreted as not precluding a national prohibition on the advertising of medicinal products for human use that are required to be sold in pharmacies which are not authorised in the importing State, but are authorised in the State of origin.

221. The expression 'advertising to the general public' in Article 1(3) of Directive 92/28 is to be interpreted as including an internet presentation by a pharmacy in a Member State which describes the individual medicinal products with their product name, prescription status, package size and price, and at the same time offers the possibility of ordering those medicinal products using an online order form.

B — *Question 2(b): Parts of the internet presentation as trade catalogue and/or price list?*

222. Question 2(b) concerns the possible classification of online order forms containing only the minimum information necessary for placing an order, and/or other parts of the internet presentation, as trade

catalogues and/or price lists within the meaning of Article 1(4) of Directive 92/28/EEC. That provision excludes trade catalogues and price lists from the scope of Directive 92/28 and from the prohibition on advertising.

1. Submissions of the parties

223. DocMorris interprets Article 1(4) of Directive 92/28 purposively and concludes that digital order forms, which lie somewhere between trade catalogues and price lists in terms of their information content and sales incentive, are also excluded from the prohibition on advertising. Information that is required for the trade in medicinal products should not be classified as advertising.

224. The Apothekerverband suggests that, on the grounds put forward in connection with Question 2(a), Question 2(b) should be answered in the negative. The E-commerce directive should not be given precedence in the interpretation of Directive 92/28 in this instance either.

225. The German Government opposes any restriction of the definition of advertising and points out that under Article 1(4) of Directive 92/28 only trade catalogues and price lists that do not include any product claims about the medicinal products are excluded.

226. The Austrian, Greek and Irish Governments also classify the information about the internet pharmacy referred to in the question as advertising within the meaning of Directive 92/28.

Certain governments also point out that trade catalogues and price lists that contain information about medicinal products are expressly not covered by the exception.

227. The Commission interprets Article 1(4) of Directive 92/28 as meaning that online order forms and/or other parts of the internet presentation of a pharmacy do not fall within the scope of the terms 'trade catalogue' and/or 'price list'.

2. Assessment

228. First of all, it must be assumed that Article 1(4) of Directive 92/28 lays down

an exception from the scope of the directive — and therefore from the prohibition on advertising — and for that very reason must be given a restrictive interpretation.

229. It should also be pointed out that the exception at issue, which is laid down in the third indent of Article 1(4) of Directive 92/28, does not contain an illustrative list, but mentions only trade catalogues and price lists. However, this provision does not refer to order forms of any kind, let alone online forms.

230. The classification of online order forms advocated by DocMorris must be concurred with in so far as these forms actually contain more information than a price list. On the other hand, it is not necessarily true that online order forms generally contain less information than trade catalogues. However, even if that were the case, the crucial factor is that online order forms at least contain more information than a simple trade catalogue in so far as trade catalogues do not necessarily include an order form.

231. Furthermore, as the Commission observes, it should be pointed out that the internet presentation of a pharmacy serves to pave the way for business contacts.

232. With regard to the argument made by DocMorris that an online order form is necessary for the mail order trade in medicinal products it must be contended that Article 1(4) of Directive 92/28 makes no reference to necessity.

233. However, a definitive classification of online order forms as trade catalogues or price lists is not necessary for a different reason. Even if online order forms were to be classified as trade catalogues or price lists, that fact alone would not mean that the directive was not applicable.

234. Article 1(4), third indent, of Directive 92/28 excludes only trade catalogues or price lists that satisfy a further condition, that is to say that they must 'include no product claims'.

235. It may be debated how the term 'claims' is to be interpreted, but the internet presentation of DocMorris in any event

contains information that should not appear in trade catalogues or price lists in the light of the objective of Directive 92/28. In its written observations, DocMorris even expressly points out that the order form also includes information about the 'active substances and contents of the medicinal products'. Question 2(b), on the other hand, mentions only a number of other items of information.

236. However, it is not for the Court of Justice but for the national court to determine which information is actually included in the internet presentation of DocMorris, in particular whether it also includes claims about medicinal products.

3. Interim conclusion

237. The answer to Question 2(b) should therefore be that online order forms containing information about medicinal products are not to be regarded as trade catalogues and/or price lists within the meaning of Article 1(4) of Directive 92/28.

C — *Freedom to provide services*

238. With regard to the prohibitions on advertising that apply in Germany, the question of their compatibility with freedom to provide services or — as is appropriate in preliminary ruling proceedings — the question whether freedom to provide services is to be interpreted as precluding the prohibitions on advertising at issue could also be raised.

1. Submissions of the parties

239. With regard to freedom to provide services, the Apothekerverband and the German Government stated in the oral procedure that this fundamental freedom does not apply in the present case.

240. The Greek Government treats the sale of medicinal products over the internet in the same way as teleshopping, which is prohibited under Article 15 of the Television directive. [89]

89 — Council Directive 89/552/EEC (cited in footnote 13).

241. The Commission has already pointed out in its written observation that, with its internet presentation, DocMorris also wishes to reach customers in German-speaking Member States. The German prohibitions on advertising are to be classified as restrictions on the movement of services. However, these restrictions might be justified on grounds of health protection.

2. Assessment

242. In order to address the legal issue of a possible restriction of freedom to provide services, it must first be examined whether freedom to provide services, rather than free movement of goods, is actually applicable.

243. First of all, the question should be asked whether advertising as such, that is to say the service of advertising, is at issue or advertising for something else. In the first case, advertising as a service, a distinction must also be drawn between the activities of advertising undertakings and the activity of undertakings that operate an advertising medium, such as a television company. In the second case, a distinction can be drawn according to whether the advertising is for goods, e.g. a medicinal product, or for a service.

244. A distinction can be drawn between the contested prohibitions on advertising laid down in the HWG in so far as Paragraph 8 concerns the mail order trade in medicinal products, whilst the prohibitions on advertising in Paragraph 3a and Paragraph 10 apply to certain types of medicinal products.

245. A distinctive feature of the economic structure of the mail order trade in medicinal products in the main proceedings is that the important factor is not the economic activity of an advertising undertaking or a media operator, but the fact that a dealer, an internet pharmacy, advertises certain goods and a certain form of purchase itself.

246. This would have to be differentiated from a situation where a pharmacy entrusts the printed media or a television undertaking with advertising its economic activity, namely the mail order trade in medicinal products. Therefore, the comparison drawn by the Commission between DocMorris' internet presentation and a television advertisement for viewers residing in other Member States is only partially apt.

247. Another different situation would be the case where a manufacturer of medicinal

products itself arranges for its products to be advertised, within the limits of Community law.

248. The mail order trade in medicinal products cannot be classified here as an economic activity to be assessed separately. It is merely a certain form of purchase, i.e. delivery of goods. This does not therefore constitute an autonomous service. Whilst the market in advertising is economically and legally distinct from the market in goods, a separate assessment of economic transactions in the main proceedings would be highly artificial. [90]

249. The main proceedings therefore differ considerably from the proceedings where the Court had decided cases concerning television or cable advertising. [91] In particular, the judgment in *De Agostini*, to which the Commission makes reference, is of no relevance as regards restrictions of the dealer's economic activity with the advertised product, [92] for example a pharmacist. This is because in *De Agostini* the Court had concentrated, as far as freedom to provide services was concerned, on the service provided by the undertaking that wished to carry on the advertising activity and the related national restriction, and not on the undertaking whose goods or services were to be advertised.

250. Since the referring court did not refer to freedom to provide services in any of its questions, it is not surprising that it has not passed on any relevant information to the Court. However, it is not possible to infer adequate information from the other papers in order to be able to assess the contested prohibitions on advertising in the light of freedom to provide services.

251. Consequently, in my opinion, the Court cannot comment on the interpretation of freedom to provide services in the present case.

252. It is therefore for the referring court, where it also invokes the principle of freedom to provide services in the dispute

90 — With regard to the difficulties in drawing the distinction, e.g. Todino/Lüder, 'La jurisprudence "Keck" en matière de publicité: vers un marché unique', *Revue du marché unique européen*, 181 et seq.

91 — Case 352/85 *Bond van Adverteerders and Others* [1988] ECR 2085, Joined Cases C-34/95, C-35/95 and C-36/95 (cited in footnote 52) and Case C-6/98 *ARD* [1999] ECR I-7599.

92 — Along these lines, see Stuyck, *Common Market Law Review*, 1997, 1445 (1467).

which it has to decide, to conduct the relevant examination in the light of the specific circumstances. In this connection, it would have to be considered whether the prohibitions on advertising pursue an objective in the general interest, such as the protection of public health. In addition, it would have to be examined whether the prohibitions on advertising are also proportionate, i.e. whether they are appropriate, necessary and reasonable for achieving the objective.

255. The German Government also answers the third question in the negative. The effective implementation of the prohibition on bringing unauthorised medicinal products into circulation also requires a restriction of any form of advertising that seeks to circumvent that prohibition.

256. In the view of the French, Greek and Irish Governments and the Commission, it is not necessary to answer the third question.

VII — The third question

1. Submissions of the parties

253. DocMorris considers that cross-border mail order trade in medicinal products must be guaranteed. This must be the case even if subsidiary aspects of an internet presentation infringe rules on advertising of medicinal products.

254. In the view of the Apothekerverband, cross-border movement of goods, that is to say, mail order trade in medicinal products, cannot be implemented 'at any price'. A modification can be brought about if necessary by a revision of Community law.

2. Assessment

257. The third question also concerns the interpretation of Articles 28 EC and 30 EC — as with the first question — in relation to the trade in medicinal products. Essentially, it seeks to ascertain whether a prohibition on advertising has implications for the assessment of whether the trade in medicinal products is permissible.

258. In this connection it should be stressed that trade and advertising are economically related, but must be treated separately from a legal point of view.

259. In the present case, this is indicated simply by the questions referred for a preliminary ruling, the first of which relates to the trade in medicinal products, the second to advertising for mail order, that is to say, trade, and to advertising for certain medicinal products.

260. With regard to the interpretation of Articles 28 EC and 30 EC in relation to trade in medicinal products, reference can therefore only be made at this juncture to the answer to the first question.

VIII — Conclusion

261. In conclusion, I propose that the Court reply to the questions referred for a preliminary ruling as follows:

1. Article 28 EC is to be interpreted as meaning that national provisions prohibiting the commercial cross-border import by mail order from authorised pharmacies in other Member States of medicinal products for human use which are required to be sold through pharmacies, on the basis of individual orders placed by end users on the internet, constitute a measure having equivalent effect.

   Articles 28 EC and 30 EC are to be interpreted as meaning that national provisions prohibiting the commercial cross-border import by mail order from authorised pharmacies in other Member States of medicinal products for human use which are required to be sold through pharmacies, on the basis of individual orders placed by end users on the internet — even if an original

doctor's prescription must have been received by the pharmacy before it supplies a prescription medicinal product — are justified in order to protect the health and life of humans as regards medicinal products which require authorisation in the State into which they are imported, but which are neither authorised or recognised at national level nor centrally approved at Community level.

Articles 28 EC and 30 EC are to be interpreted as meaning that a national prohibition on the import of medicinal products that are authorised in the importing State, which a pharmacy in another Member State previously obtained from wholesalers in the importing State, is not justified in order to protect the health and life of humans, in so far as attainment of the objectives pursued by the importing State is guaranteed by other means.

2. Articles 28 EC and 30 EC are to be interpreted as precluding a national prohibition on advertising medicinal products by mail order — other than the advertising of medicinal products for human use — unless the prohibition serves to protect national authorisation rules and is proportionate.

Article 3(1) of Council Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use is to be interpreted as not precluding a national prohibition on the advertising of prescription medicinal products for human use.

Article 2(1) of Directive 92/28/EEC is to be interpreted as not precluding a national prohibition on the advertising of medicinal products for human use that are required to be sold in pharmacies which are not authorised in the importing State, but are authorised in the State of origin.

The expression 'advertising to the general public' in Article 1(3) of Directive 92/28/EEC is to be interpreted as including an internet presentation by a pharmacy in a Member State which describes the individual medicinal products with their product name, prescription status, package size and price, and at the same time offers the possibility of ordering those medicinal products using an online order form.

Online order forms containing information about medicinal products are not to be regarded as trade catalogues and/or price lists within the meaning of Article 1(4) of Directive 92/28/EEC.

3. Articles 28 EC and 30 EC are to be interpreted as meaning that cross-border trade in medicinal products effected with the aid of an internet presentation is to be assessed regardless of the permissibility of a prohibition on advertising.