JUDGMENT OF THE COURT

11 December 2003 *

In Case C-322/01,

REFERENCE to the Court under Article 234 EC by the Landgericht Frankfurt am Main (Germany) for a preliminary ruling in the proceedings pending before that court between

Deutscher Apothekerverband eV

and

0800 DocMorris NV,

Jacques Waterval,

on the interpretation of Articles 28 EC and 30 EC and of Article 1(3) and (4) and Articles 2 and 3 of Council Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use (OJ 1992 L 113, p. 13), in conjunction with 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 ('the Directive on electronic commerce') (OJ 2000 L 178, p. 1),

* Language of the case: German.

THE COURT,

composed of: V. Skouris, President, P. Jann, C.W.A. Timmermans, C. Gulmann, J.N. Cunha Rodrigues and A. Rosas (Presidents of Chambers), D.A.O. Edward (Rapporteur), A. La Pergola, J.-P. Puissochet, R. Schintgen, F. Macken, N. Colneric and S. von Bahr, Judges,

Advocate General: C. Stix-Hackl,
Registrar: H.A. Rühl (Principal Administrator),

after considering the written observations submitted on behalf of:

— Deutscher Apothekerverband eV, by C. Dechamps, Rechtsanwalt, assisted by J. Schwarze,

— 0800 DocMorris NV and J. Waterval, by Professor C. Koenig,

— the German Government, by W.-D. Plessing and B. Muttelsee-Schön, acting as Agents,

— the Greek Government, by F. Georgakopoulos, D. Kalogiros and E.-M. Mamouna, acting as Agents,

— the French Government, by G. de Bergues and R. Loosli-Surrans, acting as Agents,

— the Irish Government, by D.J. O'Hagan, acting as Agent, and N. Hyland, Barrister,

— the Austrian Government, by C. Pesendorfer, acting as Agent,

— the Commission of the European Communities, by J.-C. Schieferer, acting as Agent, assisted by M. Núñez Müller, Rechtsanwalt,

having regard to the Report for the Hearing,

after hearing the oral observations of Deutscher Apothekerverband eV, represented by C. Dechamps, assisted by J. Schwarze, 0800 DocMorris NV and J. Waterval, represented by C. Koenig, the German Government, represented by W.-D. Plessing, the Greek Government, represented by D. Kalogiros and M. Apessos, acting as Agent, the French Government, represented by R. Loosli-Surrans, and the Commission, represented by J.-C. Schieferer, at the hearing on 10 December 2002,

after hearing the Opinion of the Advocate General at the sitting on 11 March 2003,

gives the following

Judgment

1 By order of 10 August 2001, received at the Court Registry on 21 August 2001, the Landgericht Frankfurt am Main (Regional Court, Frankfurt am Main) referred to the Court for a preliminary ruling pursuant to Article 234 EC three questions concerning the interpretation of Articles 28 EC and 30 EC and of Article 1(3) and (4) and Articles 2 and 3 of Council Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use (OJ 1992 L 113, p. 13), in conjunction with 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 ('the Directive on electronic commerce') (OJ 2000 L 178, p. 1).

2 Those questions arose in proceedings between (i) Deutscher Apothekerverband eV ('the Apothekerverband') and (ii) 0800 DocMorris NV ('DocMorris') and Mr Waterval concerning internet sales of medicinal products for human use in a Member State other than that in which DocMorris and Mr Waterval are established.

Legal background

Community legislation

Directives regulating the sale of medicinal products

3 Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (OJ, English Special Edition 1965-1966, p. 20), as amended by Council Directive 93/39/EEC of 14 June 1993 (OJ 1993 L 214, p. 22), ('Directive 65/65'), makes the placing on the market of medicinal products subject to prior authorisation. Article 3 of the directive provided:

'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 Council 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 [OJ 1993 L 214, p. 1].

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.'

4 With effect from 18 December 2001, Directive 65/65 was repealed and 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 (OJ 2001 L 311, p. 67; 'the Community Code'). Article 6(1) of the Community Code, which is in Title III ('Placing on the Market'), Chapter 1, concerning 'marketing authorisation', 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.'

Directives concerning the classification for the supply of medicinal products

5 Article 2(1) of Council Directive 92/26/EEC of 31 March 1992 concerning the classification for the supply of medicinal products for human use (OJ 1992 L 113, p. 5) provided that when the competent authorities of a Member State granted a marketing authorisation for a medicinal product, they were to specify its classification as either a medicinal product subject to medical prescription or a medicinal product not subject to medical prescription and, to that end, they were to apply the criteria laid down in Article 3(1) of the directive. Under Article 3(1):

'Medicinal products shall be subject to medical prescription where they:

— are likely to present a danger either directly or indirectly, even when used correctly, if utilised without medical supervision, or

— are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health, or

— contain substances or preparations thereof the activity and/or side effects of which require further investigation, or

— are normally prescribed by a doctor to be administered parenterally.'

6 Article 4 of Directive 92/26 provided that medicinal products not subject to medical prescription were those which did not meet the criteria listed in Article 3 thereof. The directive was repealed and replaced by the provisions of Title VI of the Community Code, 'Classification of Medicinal Products'. Article 70 of the Code reproduces, in similar terms, Article 2 of Directive 92/26, whilst Articles 71(1) and 72 of the Community Code reproduce, likewise in similar terms, Articles 3(1) and 4 of the directive.

Directives concerning the advertising of medicinal products

7 Article 1(3) and (4) of Directive 92/28 provided:

'3. 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,

— 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.

4. The following are not covered by this Directive:

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

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

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

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

8 Article 2(1) of Directive 92/28 provided:

'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.'

9 Article 3 of Directive 92/28, in Chapter II thereof, headed 'Advertising to the general public', provided:

'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,

— 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.

...

3. Member States shall also be able to ban on their territory advertising to the general public of medicinal products the cost of which may be reimbursed.'

10 Article 5 of Directive 92/28 gives details of the material which may not be contained in any advertising of a medicinal product to the general public.

11 Directive 92/28 was also repealed and replaced by the Community Code with effect from 18 December 2001. Article 86, which forms part of Title VIII of the Code ('Advertising'), reproduces Article 1(3) and (4) of the directive in almost identical terms.

12 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.'

13 Article 88 of the Community Code restates Article 3 of Directive 92/28 in similar terms, referring, instead of to Directive 92/26, to Title VI of the Code concerning the classification of medicinal products. Under Article 88(1) and (2):

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

— are available on medical prescription only, in accordance with Title VI,

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

— may not be advertised to the general public in accordance with the second subparagraph of 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.

...'

14 Article 90 of the Community Code restates Article 5 of Directive 92/28.

Directives concerning distance sales and electronic commerce

15 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 (OJ 1997 L 144, p. 19) regulates distance sales. According to Article 1 thereof, its object is to approximate the laws, regulations and administrative provisions of the Member States concerning distance contracts between consumers and suppliers.

16 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 [EC] 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.'

17 The directive on electronic commerce seeks to ensure the free movement of information society services between the Member States. The 11th recital in the preamble to the directive states:

'This Directive is without prejudice to the level of protection for, in particular, public health and consumer interests, as established by Community acts; amongst others,... Directive 97/7... form[s] a vital element for protecting consumers in contractual matters;... that same Community *acquis*, which is fully applicable to information society services, also embraces in particular... Directive 92/28...'

18 The 21st recital in the preamble to the directive on electronic commerce states:

'The scope of the coordinated field is without prejudice to future Community harmonisation relating to information society services and to future legislation adopted at national level in accordance with Community law; the coordinated

field covers only requirements relating to on-line activities such as on-line information, on-line advertising, on-line shopping, on-line contracting and does not concern Member States' legal requirements relating to goods such as safety standards, labelling obligations, or liability for goods, or Member States' requirements relating to the delivery or the transport of goods, including the distribution of medicinal products; the coordinated field does not cover the exercise of rights of preemption by public authorities concerning certain goods such as works of art.'

19 Article 1 of the directive on electronic commerce, entitled 'Objective and Scope', provides at paragraphs (1) to (3):

'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.

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.'

20 Article 3(2) of the directive provides:

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

21 Article 3(4) of the directive provides:

'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,

— ...

(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.'

22 Article 22(1) of the directive on electronic commerce provides that Member States are to bring into force the laws, regulations and administrative provisions necessary to comply with the directive before 17 January 2002.

National legislation

The sale of medicinal products

23 The sale of medicinal products in Germany is regulated by the Arzneimittelgesetz (Law on Medicinal Products), in the version of 7 September 1998 (BGBl. 1998 I, p. 2649; 'the AMG').

24 Paragraph 43(1) of the AMG prohibits the sale by mail order of medicinal products which may be sold only in pharmacies. Pursuant to that provision:

'Medicinal products... 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 consumer only in pharmacies and not by mail order...., 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.'

25 The AMG lays down a number of exceptions to that prohibition, which do not apply, however, in the case before the national court. Thus, under Paragraph 44 of the AMG, certain medicines which are not intended to serve as medicinal products for human use may be sold otherwise than in pharmacies. 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 exceptions so that doctors and hospitals may be supplied directly without recourse to pharmacies.

26 Further, Paragraph 73(1) of the AMG imposes a prohibition in respect of medicinal products which are not in conformity with it in the following terms:

'Medicinal products which are subject to authorisation or registration may be brought into the territory in which this Law applies... 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:

1. 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

2. ...'

27 Paragraph 73(2), point 6a, of the AMG provides for an exception to that prohibition for medicinal products which 'may be marketed in their country of origin and which have been purchased, without a professional or commercial 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'. According to the German Government, the expression 'without a professional or commercial intermediary' was included in order to prevent individual importation for personal requirements being developed professionally, including by means of mail-order selling, thus circumventing the prohibition.

28 As regards the sale of medicinal products in pharmacies, the latter must comply with the provisions of the Apothekenbetriebsordnung (Pharmacists' professional code; 'the ABO'). Paragraph 2(2) of the ABO provides:

'The manager of the pharmacy must direct the pharmacy in person. He is responsible for ensuring that the pharmacy is operated in compliance with the law in force.'

29 The ABO also requires pharmacists to examine the medicinal products with which they are supplied before selling them (Paragraph 12 of the ABO), to stock the full range of preparations needed by their customers, or to be in a position to procure those preparations within a few hours (Paragraph 15), to hand the medicines to the customer himself or arrange for dispensing staff with specialised knowledge to do so (Paragraph 17(1)), to advise and consult with the customer and to ascertain, where necessary, whether the prescription contains errors (Paragraph 17(2)), in cases of doubt to contact the doctor who issued the prescription (Paragraph 17(5)) and to postpone supplying the medicines where there is a reasonable suspicion of intentional misuse (Paragraph 17(8)).

30 It should be added that the Arzneimittelpreisverordnung (Regulation on the prices of medicines; 'the APO') regulates the prices at which prescription drugs are sold to end consumers. Although pharmaceutical manufacturers may set their prices freely, the prices at which medicinal products are sold for end use are set by the APO, with the result that a given medicinal product is sold at the same price in all German pharmacies.

National law regulating the advertising of medicinal products

31 Under Paragraph 3a of the Heilmittelwerbegesetz (Law on the advertising of medicinal products; 'the HWG'), in the version published on 19 October 1994 (BGBl. 1994 I, p. 3068):

'Any advertising of medicinal products which require authorisation and which are not authorised or deemed to be authorised under the law on pharmaceutical products is illegal.'

32 Paragraph 8 of the HWG states:

'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 (i) medicinal products by way of teleshopping or (ii) 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.'

33 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 problems, or which are psychotropic, may not be advertised otherwise than in professional circles.'

The main proceedings and the questions referred for a preliminary ruling

34 The Apothekerverband, the claimant in the main proceedings, is an association whose aim is to protect and promote the economic and social interests of pharmacists. Its members are the Landesapothekerverbände and the Landesapothekervereine (federations and associations of pharmacists at Länder level), which, since they represent more than 19 000 managers of pharmacies, bring together the majority of the 21 600 dispensing pharmacies in Germany.

35 DocMorris, the first defendant in the main proceedings, is a limited company established in Landgraaf (Netherlands). As well as selling medicinal products by mail order, it carries on a 'standard' pharmaceutical business via a traditional dispensary in the Netherlands, to which the public has access. Both that activity and its internet site are covered by a licence issued by the Netherlands authorities and are subject to control by the latter. Mr Waterval, the second defendant in the main action, a Netherlands national, is an authorised pharmacist in the Netherlands. He was, until 30 May 2001, a director of DocMorris and is still one of its legal representatives.

36 Since 8 June 2000 DocMorris and Mr Waterval have been offering for sale, at the internet address 0800 DocMorris, prescription and non-prescription medicines for human use, in languages including German, for end consumers in Germany. The defendants in the main action sell only authorised medicines, some of which have been authorised in Germany and others in the Netherlands.

37 According to the order for reference, the internet site is divided under the headings 'Pharmacy', 'Health Forum', 'About us', 'Contact' and 'Help'. The individual medicines are divided into product groups, under headings such as 'Painkillers', 'Blood-pressure reducers', 'Cancer therapy', 'Immunostimulants',

'Cholesterol reduction', 'Urologics/Potency', 'Detoxification' and others. 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 being described and the price stated in euro. Finally, further information about the product itself may be obtained by clicking on the product name.

38 The order for reference also explains that, where a particular medicinal product is available only on prescription, notice of that is given next to the product description. A given medicine is classified as available only on prescription where it is regarded as such in the Netherlands or in the Member State in which the consumer resides. In that regard, the rules in relation to prescription applied are always those which are the most strict, and may be the rules of the country of origin or those of the country to which the relevant product is being sent. This type of medicine is supplied only on production of the original prescription.

39 The consumer also has the opportunity, if he clicks on the appropriate icon, to look for a particular product from the range offered by the defendants in the main proceedings and to consult a group of experts on health issues. Generally, the consumer can contact the defendants not only via the internet but also on a free telephone number or by letter.

40 Delivery can take place in a number of ways. The customer may collect the order in person from the pharmacy at Landgraaf, a town near the border between the Netherlands and Germany. Alternatively he may, at no additional cost, use a courier service recommended by the defendants in the main action to collect the order and bring it to the address given by the recipient. In addition, the customer

can use at his own expense another courier service, which is also recommended by the defendants and which collects the order and delivers it to the recipient's address. It is also open to the customer to use another courier service at his own expense.

41 The Apothekerverband is challenging before the Landgericht Frankfurt am Main the offer of medicines for sale in the way described in paragraphs 36 to 40 of this judgment and their delivery by international mail order. It submits that the provisions of the AMG and the HWG do not permit the defendants in the main proceeding to carry on a business of that kind, and that the prohibition imposed by those two laws cannot be challenged on the basis of Articles 28 EC and 30 EC.

42 The defendants in the main proceedings contend that their business is permitted even under national law and that, in any event, a prohibition on the sale of medicinal products by mail order is incompatible with Community law.

43 In that regard, the Landgericht Frankfurt am Main first expresses doubt as to whether prohibitions such as those laid down by Paragraphs 43(1) and 73(1) of the AMG violate the principle of the free movement of goods. Next, assuming that there is an infringement of Article 28 EC, it seeks to ascertain whether the German legislation at issue in the main action is necessary for the effective protection of the health and life of humans for the purposes of Article 30 EC or whether, in view of the increasing harmonisation of procedures for authorising medicinal products, human health and life may be protected as effectively by measures which are less restrictive of intra-Community trade, in accordance with the principles laid down by the Court in Case C-320/93 *Ortscheit* [1994] ECR I-5243. Finally, it asks whether advertising bans such as those imposed by the HWG are compatible with the principles of the free movement of goods and the free movement of information society services within the meaning of Article 1(1) and (2) of the directive on electronic commerce.

44 In those circumstances, the Landgericht Frankfurt am Main decided to stay proceedings and refer the following questions to the Court for a preliminary ruling:

'1. Are the principles of the free movement of goods under Article 28 EC et seq. infringed by national legislation whereby medicinal products for human use the sale of which is restricted to pharmacies may not be imported commercially by way of mail order through authorised pharmacies in other Member States on the basis of individual orders placed by consumers over the internet?

(a) Does such a national prohibition constitute a measure having an effect equivalent 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 orders, packaging and receipt?

(c) Are Questions 1(a) and 1(b) to be assessed differently in the light of Articles 28 EC 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 EC and 30 EC for a national prohibition on advertising medicines by mail order or medicines for human use available only on prescription or through pharmacies 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 the mere 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 on-line order form, is classified as prohibited advertising, with the result that cross-border orders of medicines by internet, including cross-border delivery of those orders, is at least made substantially more difficult?

(a) Having regard to Article 1(3) of Directive 2000/31..., do Articles 28 EC 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 Directive 92/28... in order to make it possible in practice as well to offer certain information society services?

(b) Can any restriction of the definition of advertising required by Articles 28 EC and 30 EC be justified by the consideration that on-line order forms containing only the minimum information necessary for placing an order, and/or other parts of the internet site 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 EC and 30 EC that cross-border trade in medicines which takes place with the aid of such a presentation must be regarded as lawful despite the prohibited advertising, in order more effectively to implement the principle of the free cross-border movement of goods?'

The first question

45 By its first question, the national court is asking essentially whether the principle of the free movement of goods under Articles 28 EC to 30 EC is infringed by national legislation, such as that at issue in the main proceedings, whereby medicinal products for human use the sale of which is restricted to pharmacies in the Member State concerned may not be imported commercially by way of mail order through pharmacies approved in other Member States in response to individual orders placed by consumers over the internet.

46 In the light of the arguments put forward, particularly by the defendants in the main proceedings, it is appropriate to examine this question, first, in relation to medicinal products which have not been authorised in Germany. The question will then be examined in relation to products which are authorised there. The latter category can be further subdivided into non-prescription and prescription-only medicines.

Medicinal products which are not authorised in Germany

47 Of the national provisions at issue in the main proceedings, Paragraph 73(1) of the AMG prohibits, as a general rule, the importation of medicinal products subject to authorisation or registration within the national territory on the sole ground that they have not been authorised or registered for being placed on the market there. Consequently, the importation of such products into German territory is precluded for the sole reason that they have not been authorised, irrespective of the method of sale.

48 If a provision such as Paragraph 73(1) of the AMG is compatible with Community law, it will not be necessary to consider whether, in respect of this category of medicines, Articles 28 EC to 30 EC preclude national legislation which prohibits the sale by mail order of medicinal products the sale of which is restricted to pharmacies.

Observations submitted to the Court

49 Both the German Government and the Commission submit that Paragraph 73 of the AMG, which prohibits imports of medicinal products which have not obtained the requisite authorisation, corresponds to the prohibition on placing on the market medicinal products which have not been authorised in the Member State concerned, which is laid down in Article 3 of Directive 65/65, as replaced by Article 6(1) of the Community Code. Thus, the national legislation is intended to ensure that there is no circumvention of the existing obligation to obtain authorisation.

50 The Greek Government supports that view, arguing that if medicinal products which have not obtained the authorisation required by the importing Member States can be ordered over the internet, the system of marketing authorisations

for pharmaceutical products will be fatally undermined. Manufacturers of medicinal products will be able to obtain authorisation in the Member State with the least stringent legislation in this domain and release the products into circulation in Member States in which they are not authorised. Such a situation is tantamount to a complete absence of controls on the importation of medicinal products, whether authorised or not, which would make any control of parallel imports impossible.

51 The defendants in the main proceedings submit, for the reasons put forward in relation to authorised medicines (see paragraphs 61 and 62 of this judgment), that Paragraph 73(1) of the AMG must be regarded as a measure having an effect equivalent to a quantitative restriction on the free movement of goods within the meaning of Article 28 EC.

The Court's reply

52 As the German and Greek Governments and the Commission rightly observe, the general prohibition imposed by Paragraph 73(1) of the AMG corresponds to the prohibition, at Community level, on placing on the market medicinal products which have not been authorised in the Member State concerned, which was laid down in Article 3 of Directive 65/65, now replaced by Article 6(1) of the Community Code. According to those provisions, medicinal products, even if they are authorised in one Member State, must also, if they are to be placed on the market of another Member State, have been authorised either by the competent authority of that State or under the Community rules referred to in those provisions.

53 Consequently, a national rule such as Paragraph 73(1) of the AMG, whereby a Member State discharges its obligations under Directive 65/65 and the

Community Code, cannot be characterised as a measure having equivalent effect to a quantitative restriction on imports within the meaning of Article 28 EC (see, to that effect, in the context of Council Directive 86/469/EEC of 16 September 1986 concerning the examination of animals and fresh meat for the presence of residues (OJ 1986 L 275, p. 36), Case C-246/98 *Berendse-Koenen* [2000] ECR I-1777, paragraph 25). Accordingly, Articles 28 EC to 30 EC cannot be relied on in order to circumvent the system of national authorisation provided for by Directive 65/65 and the Community Code, which is implemented in national law by Paragraph 73(1) of the AMG.

54 It follows from that finding that, as regards medicinal products which are subject to, but which have not obtained, authorisation there is no need to consider whether the national provisions at issue in the main proceedings are precluded by Articles 28 EC to 30 EC.

Medicinal products which are authorised in Germany

55 The first question is more germane as regards medicinal products which have obtained marketing authorisations for the German market. More specifically, this question seeks to ascertain whether the prohibition on the sale by mail order of medicinal products which may be sold only in pharmacies in the Member State concerned, such as the prohibition laid down in Paragraph 43(1) of the AMG, is compatible with the principle of the free movement of goods. That question is divided into three parts, which must be dealt with separately.

Is the national prohibition on mail-order sales a measure having equivalent effect within the meaning of Article 28 EC? (Question 1(a))

Observations submitted to the Court

56 The Apothekerverband and the Commission, supported on this point by the German, Greek, French and Austrian Governments, submit that the free movement of goods is not impeded. They maintain that the prohibition laid down in Paragraph 43(1) of the AMG, which does not concern the production or composition of particular products but solely the ways in which they are marketed, applies in the same way, both in law and in fact, to the marketing of domestic products and those from other Member States alike. Such a prohibition therefore falls outside the scope of Article 28 EC for the reasons given by the Court in Joined Cases C-267/91 and C-268/91 *Keck and Mithouard* [1993] ECR I-6097, paragraphs 15 to 17, and Case C-292/92 *Hünermund and Others* [1993] ECR I-6787, paragraph 21.

57 The French Government supports that view, pointing to the judgment in Case C-391/92 *Commission* v *Greece* [1995] ECR I-1621, in which the Court, in paragraphs 11 to 13, acknowledged the compatibility with the Treaty of a monopoly for pharmacies on the sale of baby milk and also pointed out that that monopoly was not designed to regulate trade in goods between Member States.

58 As regards the Court's subsequent clarification in Case C-368/95 *Familiapress* [1997] ECR I-3689 and Case C-254/98 *TK-Heimdienst* [2000] ECR I-151, the Apothekerverband, supported by the Commission and by the German, French and Austrian Governments, submits that the effect of the prohibition at issue

before the national court is neither to give rise to any unequal treatment between domestic pharmacies and those established in other Member States as regards their scope for using mail-order selling, nor to make release into circulation more difficult for foreign products than for domestic ones, in particular by making such release subject to additional costs or to duties to which domestic products are not subject.

59 Although the Apothekerverband and the Commission challenge the argument that access to the German market is barred, maintaining that under the current provisions of the AMG pharmaceutical products may be, and are frequently, imported and reimported, the German Government acknowledges that the fact that the sale of medicinal products by mail order is precluded makes it more difficult for foreign pharmacies to gain access to the German market. They are in fact obliged to open their own pharmacy in Germany. However, in view of the requirements of the ABO that the pharmacist be present in person, even pharmacies established in Germany do not have unfettered access to the whole German market either. It follows that any difficulty in exploiting the German market as a whole affects domestic and foreign pharmacists in the same way and thus does not amount to a discriminatory 'measure having equivalent effect' for the purposes of Article 28 EC.

60 In the alternative, both the Apothekerverband and the German and Austrian Governments submit that the scope of Article 28 EC should be limited so as to permit the Member States to retain sufficient latitude to regulate general aspects of the sale of medicinal products which are in the public interest. For that reason, the general prohibition on the sale by mail order of medicinal products the sale of which is restricted to pharmacies cannot be considered to be a measure having an effect equivalent to a quantitative restriction on imports for the purposes of Article 28 EC.

61 The defendants in the main proceedings reject that interpretation of the national legislation as too superficial. In their submission, the prohibition on marketing pharmaceutical products by mail order does not affect the sale of domestic medicinal products and that of medicinal products imported from other Member States in the same manner. The prohibition, in conjunction with the rules of professional conduct laid down in the ABO, makes it virtually impossible for pharmacies established in other Member States to gain access to the German market of end consumers of medicinal products. More specifically, under the ABO, DocMorris cannot gain access to that market unless the pharmacist responsible for the company gives up his pharmaceutical business in the Netherlands and opens a 'traditional' pharmacy in Germany. Furthermore, foreign pharmacists are not entitled to apply for authorisation to sell medicines by mail order in Germany unless they have already operated their pharmacy there for at least three years.

62 The defendants in the main proceedings also rely on Case C-323/93 *Centre d'insémination de la Crespelle* [1994] ECR I-5077, paragraph 29, Joined Cases C-34/95 to C-36/95 *De Agostini and TV-shop* [1997] ECR I-3843, paragraphs 43 to 47, Case C-189/95 *Franzén* [1997] ECR I-5909, paragraphs 67 to 73, and *TK-Heimdienst*, cited above, paragraphs 27 to 37, to show that where, as in the case before the national court, access to end consumers in the Member State into which products are imported is prevented or rendered more difficult than for domestic products by national rules, these rules amount to a restriction on the free movement of goods, even where they merely regulate a selling arrangement which does not relate to the characteristics of the product concerned.

The Court's reply

63 It must be stated at the outset that the prohibition laid down in Paragraph 43(1) of the AMG falls within the scope of Directive 97/7. Article 14 of the directive allows Member States to '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'. Article 14 also states that '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'.

64 A national measure in a sphere which has been the subject of exhaustive harmonisation at Community level must be assessed in the light of the provisions of the harmonising measure and not those of the Treaty (see Case C-37/92 *Vanacker and Lesage* [1993] ECR I-4947, paragraph 9, and Case C-324/99 *DaimlerChrysler* [2001] ECR I-9897, paragraph 32). However, the power conferred on Member States by Article 14(1) of Directive 97/7 must be exercised with due regard for the Treaty, as is expressly stated in that provision.

65 Such a provision does not, therefore, obviate the need to ascertain whether the national prohibition at issue in the main proceedings is compatible with Articles 28 EC to 30 EC.

66 In that regard, there is settled case-law to the effect that all measures which are capable of hindering directly or indirectly, actually or potentially, intra-Community trade are to be regarded as measures having equivalent effect to quantitative restrictions and, on that basis, as prohibited by Article 28 EC (see Case 8/74 *Dassonville* [1974] ECR 837, paragraph 5, and Case C-420/01 *Commission* v *Italy* [2003] ECR I-6445, paragraph 25).

67 Even if a measure is not intended to regulate trade in goods between Member States, the determining factor is its effect, actual or potential, on intra-Community trade. By virtue of that factor, in the absence of harmonisation of

legislation, obstacles to the free movement of goods which are the consequence of applying, to goods coming from other Member States where they are lawfully manufactured and marketed, rules that lay down requirements to be met by such goods constitute measures of equivalent effect prohibited by Article 28 EC, even if those rules apply to all products alike, unless their application can be justified by a public-interest objective taking precedence over the requirements of the free movement of goods (Case 120/78 *Rewe-Zentral (Cassis de Dijon)* [1979] ECR 649, paragraphs 6, 14 and 15; *Keck and Mithouard*, paragraph 15, and *Familiapress*, paragraph 8).

68 Furthermore, as the Court held in *Keck and Mithouard*, even if commercial rules do not relate to the actual characteristics of the products but govern the arrangements for their sale, they may constitute measures of equivalent effect for the purposes of Article 28 EC if they fail to meet two conditions. Those conditions are that such rules must apply to all relevant traders operating in national territory and must affect in the same manner, in law and in fact, the marketing of both domestic products and those from other Member States (see *Keck and Mithouard*, paragraph 16; *Hünermund*, paragraph 21, and Case C-412/93 *Lerclerc-Siplec* [1995] ECR I-179, paragraph 21).

69 As regards the first condition in the preceding paragraph, the prohibition in Paragraph 43(1) of the AMG applies to all the traders concerned, whether German or not, with the result that the first condition is fully met.

70 As to the second condition in paragraph 68 of this judgment, it must be borne in mind that the 'marketing' of a product on a domestic market may entail a number of stages between the time when the product is manufactured and the time when it is ultimately sold to the end consumer.

71 In order to ascertain whether a particular measure affects in the same manner the 'marketing' of both domestic products and those from other Member States, the scope of the restrictive measure concerned must be ascertained. Thus, the Court has found that a prohibition on pharmacists from advertising quasi-pharmaceutical products outside the pharmacy, which they were authorised to offer for sale, did not affect the ability of traders other than pharmacists to advertise those products (see *Hünermund*, paragraph 19). Similarly, the prohibition on broadcasting the advertising at issue in *Leclerc-Siplec* was not extensive, since it covered only one particular form of promotion (television advertising) of one particular method of marketing products (distribution) (see *Leclerc-Siplec*, paragraph 22).

72 By contrast, the Court has accepted the relevance of the argument that a prohibition on television advertising deprived a trader of the only effective form of promotion which would have enabled it to penetrate a national market (see *De Agostini and TV-Shop*, paragraph 43). Furthermore, the Court has found that in the case of products such as alcoholic beverages, the consumption of which is linked to traditional social practices and to local habits and customs, prohibiting all advertising directed at consumers in the form of advertisements in the press, on the radio and on television, the direct mailing of unsolicited material or the placing of posters on the public highway is liable to impede access to the market for products from other Member States more than it impedes access for domestic products, with which consumers are instantly more familiar (see Case C-405/98 *Gourmet International Products* [2001] ECR I-1795, paragraphs 21 and 24).

73 As regards a prohibition such as that laid down in Paragraph 43(1) of the AMG, it is not disputed that the provision contains both a requirement that certain medicines be sold only in pharmacies and a prohibition on mail-order sales of medicines. It is true that such a prohibition on mail-order sales may be regarded

as merely the consequence of the requirement for sales to be made exclusively in pharmacies. However, the emergence of the internet as a method of cross-border sales means that the scope and, by the same token, the effect of the prohibition must be looked at on a broader scale than that suggested by the Apothekerverband, by the German, French and Austrian Governments and by the Commission (see paragraphs 56 to 59 of this judgment).

74 A prohibition such as that at issue in the main proceedings is more of an obstacle to pharmacies outside Germany than to those within it. Although there is little doubt that as a result of the prohibition, pharmacies in Germany cannot use the extra or alternative method of gaining access to the German market consisting of end consumers of medicinal products, they are still able to sell the products in their dispensaries. However, for pharmacies not established in Germany, the internet provides a more significant way to gain direct access to the German market. A prohibition which has a greater impact on pharmacies established outside German territory could impede access to the market for products from other Member States more than it impedes access for domestic products.

75 Accordingly, the prohibition does not affect the sale of domestic medicines in the same way as it affects the sale of those coming from other Member States.

76 The answer to Question 1(a) is therefore that a national prohibition on the sale by mail order of medicinal products the sale of which is restricted to pharmacies in the Member State concerned, such as the prohibition laid down in Paragraph 43(1) of the AMG, is a measure having an effect equivalent to a quantitative restriction for the purposes of Article 28 EC.

Whether there is any justification for the prohibition on mail-order sales (Question 1(b))

77 By its first question, under subparagraph (b), the national court is asking essentially whether the prohibition on the sale by mail order of medicines the sale of which is restricted to pharmacies can be justified under Article 30 EC where, before prescription medicines are supplied, a doctor's original prescription must have been produced to the pharmacy dispatching the medicines. On that point, the national court wonders what requirements should be placed on that pharmacy as regards control of orders, packaging and receipt.

Observations submitted to the Court

78 As regards the principles applicable in the case before the national court, the Apothekerverband and the defendants in the main proceedings, together with the French and German Governments, submit that Article 30 EC remains applicable as long as full harmonisation of national rules has not been achieved (see Case 215/87 *Schumacher* [1989] ECR 617, paragraph 15; Case C-369/88 *Delattre* [1991] ECR I-1487, paragraph 48; Case C-347/89 *Eurim-Pharm* [1991] ECR I-1747, paragraph 26; Case C-62/90 *Commission* v *Germany* [1992] ECR I-2575, paragraph 10; and *Ortscheit*, paragraph 14).

79 Both the parties in the main proceedings and the French and German Governments also agree on the fact that the health and life of humans rank foremost among the assets and interests protected by Article 30 EC and that it is for the Member States, within the confines imposed by the Treaty, to decide the degree of protection they wish to ensure and, in particular, the stringency of the checks to be carried out. Pursuant to the case-law in this area, any national legislation having a restrictive effect must be necessary and proportionate.

80 In that regard, the Apothekerverband and the German and Austrian Governments submit that the health of the population cannot be protected in any manner which is less restrictive of intra-Community trade than the manner applied in Germany, which provides for an outright prohibition on the sale by mail order of medicinal products the sale of which is restricted to pharmacies (see *Commission* v *Germany*, paragraph 11, and Case C-55/99 *Commission* v *France* [2000] ECR I-11499, paragraph 42).

81 The Apothekerverband states that the purpose of the prohibition on the sale by mail order of such medicinal products is to ensure that the customer receives individual information and advice from the pharmacist when the product is purchased and to ensure the safety of medicines and pharmacovigilance.

82 In that regard, the Apothekerverband, supported on this point by the Greek and Austrian Governments, maintains that, so far as questions linked to a particular medicine are concerned, even if the mail-order buyer is able to obtain advice on the internet or by telephone, that is no substitute for advice given in a pharmacy in a direct face-to-face conversation with the customer. The customer's physical and psychological state, his bearing, his life-style and his current medication are factors which must be taken into account during such a consultation.

83 The Austrian Government points out that many medicinal products ordered over the internet reach the addressee in damaged or inadequate packaging, often without a label or without any information in the addressee's own language.

84 Furthermore, the Apothekerverband maintains that, unlike traditional pharmacies, wholly virtual pharmacies can be set up by anybody, without any major

investment and with minimal capital. Given that the activities of virtual pharmacies are currently not subject to adequate supervision, the necessary protection of the health and life of human requires preventive control.

85 Mail-order sales of medicinal products also jeopardise the continued existence of traditional pharmacies. Whilst pharmacies marketing their products by internet can 'cherry-pick', concentrating on certain economically attractive market segments, traditional pharmacies, bound by the ABO, are subject to a set of costly obligations, including maintaining a full range of products, stocking a minimum quantity of medicines and providing a duty service. That entails distortion of the conditions of competition.

86 More specifically, the Apothekerverband submits that, as regards prescription medicines, all German pharmacies are obliged by law to charge the prices set by the ABO, reached by applying increases to the manufacturers' prices, which the latter are free to set. By contrast, undertakings selling medicinal products by mail order from abroad are not subject to the requirements of the ABO and take advantage of that to offer a limited range of products, essentially composed of expensive medicines, which they offer at prices that are competitive in comparison with those in traditional pharmacies.

87 Consequently, in the Apothekerverband's submission, the prohibition on selling medicines by mail order forms an integral part of the social security system, the aim of which is to ensure that a reliable and balanced supply of medicines is available to the general public at any time. The prohibition cannot be modified or abolished in isolation unless the system as a whole is reviewed. In that regard, the

Apothekerverband mentions the considerations developed by the Court in Case C-368/98 *Vanbraekel and Others* [2001] ECR I-5363, paragraphs 47 to 49, and Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, paragraphs 72 to 74, relating to safeguarding the social security system and a balanced hospital and medical service.

88 The Greek Government supports that view, pointing out the importance placed on the method of distributing medicines in pharmacies and the role of the pharmacist both by the Court's case-law and by certain Community law provisions (see *Commission* v *Germany*, paragraph 20, and Council Directive 85/432/EEC of 16 September 1985 concerning the coordination of provisions laid down by law, regulation or administrative action in respect of certain activities in the field of pharmacy (OJ 1985 L 253, p. 34) and Council Directive 85/433/EEC of 16 September 1985 concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy, including measures to facilitate the effective exercise of the right of establishment relating to certain activities in the field of pharmacy (OJ 1985 L 253, p. 37)).

89 The Irish Government favours an outright prohibition on the sale of prescription medicines over the internet. It recognises that checking the authenticity of prescriptions is facilitated by the local knowledge and experience of pharmacists who are in close and daily contact with patients and doctors in their region. Allowing prescription medicines to be supplied following receipt of a prescription and without any other control would greatly increase the risk of prescription fraud or misuse. Furthermore, doctors usually only prescribe medicines which are available to their patients and therefore prescribe medicines which are authorised in the Member State in which they practise. However, a doctor may prescribe a medicine not authorised in the Member State in which he practises if he is aware that the medicine may be obtained from an internet pharmacy. In that way, prescription medicines unauthorised in a Member State may be marketed in that Member State without the authorities being informed that that is the case.

90 The defendants in the main proceedings put forward a number of arguments against the dangers allegedly posed by the sale of medicinal products by mail order. First, the guarantee that the customer will receive expert advice from the pharmacist when the medicine is supplied does not provide justification for an all-out prohibition on mail-order sales, on the basis of Article 30 EC. The pharmacist can also advise and monitor when he is not in the presence of the customer but sends the customer the medicines after having given him thorough advice and carefully checked the order.

91 The defendants in the main proceedings add that in the case of an internet order the customer has the opportunity to contact the pharmacist by telephone or in writing (for example, by e-mail). The quality of the advice given in that way may even be superior to that of normal pharmaceutical advice given directly to the customer in the pharmacy.

92 The argument that the 'virtual pharmacist' is not in a position to take the initiative in giving advice is not justified. The necessary information about taking the medicine, or using it appropriately, is provided in writing by the pharmacist when the medicine is dispatched. That initiative may be backed up, should the need arise, by a telephone call from the pharmacy to the customer.

93 As to the alleged need for the physical presence of the customer when a medicine is purchased, the defendants in the main proceedings also observe that a great many consumers do not come to the pharmacy in person to collect their medicines.

94 Second, as regards the alleged lack of control of 'virtual pharmacies', the defendants in the main proceedings submit that such pharmacies are subject to State supervision and to requirements that orders be checked internally. First,

DocMorris is subject to supervision by the competent authorities in the Member State of origin, namely the State inspector of Netherlands pharmacies. That supervision covers all procedures and operations carried out in the course of operating the pharmacy and selling medicines by mail order. Second, under Netherlands law, all pharmacies must record their internal security rules and operational procedures in a quality manual. DocMorris complies with the rules of the European Association of Mail Service Pharmacies of which it is a member, which contain more detailed provisions on the question of checking orders, packaging and receipt.

95 The internal security measures imposed by DocMorris ensure that the processing of orders and the provision of advice are solely within the purview of authorised pharmacists and qualified pharmaceutical technicians and comply with certain quality requirements. The fact that the purchase of a medicinal product takes place in a pharmacy in another Member State is not relevant given that the conditions for access to the profession of pharmacist and those relating to the exercise of the profession are harmonised at Community level (see, in relation to Directive 85/432, *Schumacher*, paragraph 20, and *Commission* v *Germany*, paragraph 19).

96 Third, concerning the risks linked to prescription medicines, the pharmacist, in accordance with the requirements of the European Association of Mail Service Pharmacies, must ensure that medicines are sent only where the pharmacy concerned has received the original prescription, issued by a doctor or a dentist, and only where the person who will receive the product is actually the prescription holder.

97 Since the conditions in which a medicinal product must be subject to a doctor's prescription have been harmonised (see Directive 92/26, as replaced by Title VI of the Community Code), there is a uniform level of protection throughout the Community. Where, exceptionally, the classification of the medicine in the

Member State of origin differs from that in the importing Member State, DocMorris always proceeds on the basis of the most stringent national legislation, so that national rules concerning the need for a prescription are never evaded.

98 Fourth, given the advanced stage of harmonisation of provisions concerning the authorisation of medicinal products within the Community and the system of mutual recognition laid down thereby (see Regulation No 2309/93, and Directive 93/39 and Commission Directive 2000/38/EC of 5 June 2000 amending Chapter Va (Pharmacovigilance) of Council Directive 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (OJ 2000 L 139, p. 28)), it is appropriate to start from the principle that a medicinal product which is authorised in one Member State cannot give rise to health risks which are so serious that they warrant an absolute ban on any cross-border mail-order trade in medicines.

99 Fifth, nor does the use of the internet give rise to any additional health risks, which can be avoided only by an absolute prohibition on mail-order business in medicinal products. However, the technical potential of the internet, in particular the ability to prepare customised interactive pages, can be used in order to ensure optimum health protection.

100 Finally, the prohibition at issue in the main proceedings is not justified on the ground that it ensures, from an economic point of view, that the population at large is supplied with medicinal products commensurate with its needs. In that regard, the defendants in the main proceedings maintain that, since any 'virtual pharmacy' must be approved in the same way as a pharmacy to which the public has access in the Member State in which it is established, the ability to sell medicinal products by mail order must not be perceived as an alternative in competition with pharmacies open to the public but as an offer complementing

sales by the latter. Since they are bound by national requirements applicable in the Member State of origin, 'virtual pharmacists' are precluded from confining themselves to selling a range of expensive products.

101 The defendants in the main proceedings conclude that neither the German Government nor the Apothekerverband has shown that cross-border mail-order trade in medicinal products constitutes a danger to health, which can be avoided only by an absolute prohibition on that type of business. In reality, health may be protected just as effectively by appropriate rules, in particular by requirements relating to the control of orders, packaging and receipt, as imposed by the Member State from which the medicinal products come.

The Court's reply

102 As is maintained by the parties to the main action, the Member States which have submitted observations to the Court and the Commission, Article 30 EC continues to apply in relation to the manufacture and marketing of specialised pharmaceutical products as long as harmonisation of national rules has not been fully achieved in those areas (see *Schumacher*, paragraph 15; *Delattre*, paragraph 48; *Eurim-Pharm*, paragraph 26; *Commission* v *Germany*, paragraph 10; and *Ortscheit*, paragraph 14). In that regard, it should be noted that the sale of medicinal products to end consumers has not been subject to full Community harmonisation.

103 It is settled case-law that the health and life of humans rank foremost among the assets or interests protected by Article 30 EC and it is for the Member States, within the limits imposed by the Treaty, to decide what degree of protection they wish to assure (see *Schumacher*, paragraph 17; *Eurim-Pharm*, paragraph 26; and *Ortscheit*, paragraph 16).

104 However, national rules or practices likely to have a restrictive effect, or having such an effect, on the importation of pharmaceutical products are compatible with the Treaty only to the extent that they are necessary for the effective protection of health and life of humans. A national rule or practice cannot benefit from the derogation provided for in Article 30 EC if the health and life of humans may be protected just as effectively by measures which are less restrictive of intra-Community trade (*Schumacher*, paragraphs 17 and 18; *Delattre*, paragraph 53; *Eurim-Pharm*, paragraph 27; *Commission* v *Germany*, paragraphs 10 and 11; and *Ortscheit*, paragraph 17).

105 In the case before the national court, no doubt is cast on the fact that the 'virtual pharmacy' is subject to supervision by the Netherlands authorities, with the result that the arguments put forward by the Apothekerverband to assert generally that the supervision to which such a pharmacy is subject is inadequate, in comparison with that to which a traditional pharmacy is subject, cannot be accepted.

106 The only arguments which are capable of providing adequate reasons for prohibiting the mail-order trade in medicinal products are those relating to the need to provide individual advice to the customer and to ensure his protection when he is supplied with medicines and to the need to check that prescriptions are genuine and to guarantee that medicinal products are widely available and sufficient to meet requirements.

107 Looked at generally, most of those reasons are based on the possible dangers posed by medicinal products and, accordingly, on the care which must be taken with all aspects of the marketing of those products, objectives which are also those of the Community legislation in the pharmaceuticals field. Thus, and in any event, consideration of the reasons put forward to justify the prohibition on the sale by mail order of medicinal products must take into account the various provisions of Community law which may affect that issue.

108 First, the Community Code provides, in Title VI, 'Classification of Medicinal Products', that when the competent authorities of the Member States grant a marketing authorisation for a medicinal product they must specify its classification, namely whether or not it is subject to prescription. Although it is for those authorities to determine the classification of medicinal products, they must none the less take as their basis the criteria set out in Article 71(1) of the Code, namely those concerning the potential dangers connected with use of the relevant product (see paragraphs 5 and 6 of this judgment).

109 Second, the distinction between medicinal products which are subject to prescription and those which are not, which is based on those criteria and which thus concerns the potential danger of the product concerned, is applied in the Community rules concerning advertising for medicinal products. As pointed out in paragraphs 7 to 13 of this judgment, advertising of prescription medicines is prohibited (Article 88(1) of the Community Code), whilst, in general, advertising of medicinal products intended and designed for use without the intervention of a medical practitioner is permitted, provided that certain conditions are complied with (see Article 88(2) of the Community Code).

110 In addition to the distinction mentioned in the preceding paragraph, Article 14 of Directive 97/7, which regulates distance selling for the purpose of consumer protection, allows the Member States to adopt, with due regard for the provisions of the Treaty, measures which prohibit, on grounds of general interest, the marketing of certain goods or services, 'particularly medicinal products', within their territory by means of distance contracts. That provision indicates that the Community legislature did not intend to prevent Member States from prohibiting the sale by mail order of medicinal products merely because the provisions relating to authorisations to market such products within the Community have been harmonised and merely because of the existence of a system of mutual recognition and of provisions intended to coordinate the rules relating to certain activities in the field of pharmacy and the mutual recognition of diplomas in pharmacy.

111 In the light of the foregoing, the reasons advanced by the Apothekerverband by way of justification must be examined in relation to non-prescription medicines, on the one hand, and prescription medicines, on the other hand.

Non-prescription medicines

112 None of the reasons which the Apothekerverband advances by way of justification can provide a valid basis for the absolute prohibition on the sale by mail order of non-prescription medicines.

113 First, as regards the need to provide the customer with advice and information when a medicinal product is purchased, it is not impossible that adequate advice and information may be provided. Furthermore, as the defendants in the main proceedings point out, internet buying may have certain advantages, such as the ability to place the order from home or the office, without the need to go out, and to have time to think about the questions to ask the pharmacists, and these advantages must be taken into account.

114 As to the argument that 'virtual pharmacists' are less able to react than pharmacists in dispensaries, the disadvantages which have been mentioned in this regard concern, first, the fact that the medicine concerned may be incorrectly used and, second, the possibility that it may be abused. As regards incorrect use of the medicine, the risk thereof can be reduced through an increase in the number of on-line interactive features, which the customer must use before being able to proceed to a purchase. As regards possible abuse, it is not apparent that for persons who wish to acquire non-prescription medicines unlawfully, purchase in a traditional pharmacy is more difficult than an internet purchase.

115 Second, as regards non-prescription medicines, considerations relating to their delivery do not justify an absolute prohibition on their sale by mail order.

116 Third, as regards the reasons based on the need to guarantee that medicinal products are widely available and sufficient to meet requirements, the Court notes that, in the submission of the defendants in the main proceedings (see paragraph 100 of this judgment), the Netherlands 'virtual pharmacy' is subject to public-service obligations such as those mentioned by the Apothekerverband, with the result that it is not, in that respect, in a better position than German pharmacies. Furthermore, the APO, which sets the ultimate selling price of medicinal products, applies solely to prescription-only medicines and thus is not a reason for prohibiting mail-order sales of non-prescription medicines, the prices of which may be set freely by German pharmacies.

Prescription medicines

117 The supply to the general public of prescription medicines needs to be more strictly controlled. Such control could be justified in view of, first, the greater risks which those medicines may present (see Article 71(1) of the Community Code) and, second, the system of fixed prices which applies to them and which forms part of the German health system.

118 As regards the first consideration, the fact that there might be differences in the way those medicines are classified by the Member States, so that a particular medicinal product may be subject to prescription in one Member State but not in

another, does not mean that the first Member State forfeits the right to take more stringent action with regard to that type of medicinal product.

119 Given that there may be risks attaching to the use of these medicinal products, the need to be able to check effectively and responsibly the authenticity of doctors' prescriptions and to ensure that the medicine is handed over either to the customer himself, or to a person to whom its collection has been entrusted by the customer, is such as to justify a prohibition on mail-order sales. As the Irish Government has observed, allowing prescription medicines to be supplied on receipt of a prescription and without any other control could increase the risk of prescriptions being abused or inappropriately used. Furthermore, the real possibility of the labelling of a medicinal product bought in a Member State other than the one in which the buyer resides being in a language other than the buyer's may have more harmful consequences in the case of prescription medicines.

120 The Apothekerverband has also put forward arguments concerning the integrity of the German health system, arguing that, since German pharmacies are obliged by the APO to sell prescription medicines at fixed prices, allowing the cross-border sale of those medicines at uncontrolled prices would jeopardise the existence of those pharmacies and thus the integrity of the German health system.

121 That argument requires an examination of the rationale for the system set up by the APO, which sets the selling price of prescription medicines.

122 Although aims of a purely economic nature cannot justify restricting the fundamental freedom to provide services, it is not impossible that the risk of seriously undermining the financial balance of the social security system may constitute an overriding general-interest reason capable of justifying a restriction of that kind (see *Kohll*, paragraph 41; *Vanbraekel*, paragraph 47; *Smits and Peerbooms*, paragraph 72; and Case C-358/99 *Müller-Fauré and Van Riet* [2003] ECR I-4509, paragraphs 72 and 73). Moreover, a national market for prescription medicines could be characterised by non-commercial factors, with the result that national legislation fixing the prices at which certain medicinal products are sold should, in so far as it forms an integral part of the national health system, be maintained.

123 However, neither the Apothekerverband nor the Member States which have submitted observations to the Court have put forward any arguments as to the necessity of the APO. Therefore, in the absence of any such arguments, the Court cannot find that, as regards prescription medicines, the prohibition on mail-order sales in Germany may be justified on grounds of the financial balance of the social security system or the integrity of the national health system.

124 In the light of the foregoing, the answer to Question 1(b) must be that Article 30 EC may be relied on to justify a national prohibition on the sale by mail order of medicinal products the sale of which is restricted to pharmacies in the Member State concerned in so far as the prohibition covers medicinal products subject to prescription. However, Article 30 EC cannot be relied on to justify an absolute prohibition on the sale by mail order of medicinal products which are not subject to prescription in the Member State concerned.

Reimportation of medicinal products (Question 1(c))

125 By Question 1(c), the national court is asking whether Questions 1(a) and 1(b) concerning, first, whether Paragraph 43(1) of the AMG amounts to a measure

having an effect equivalent to a quantitative restriction and, second, whether there is any possible justification for it, should be assessed differently, in the light of Articles 28 EC and 30 EC, where medicinal products are imported into a Member State in which they are authorised, having been previously obtained by a pharmacy in another Member State from a wholesaler in the importing Member State.

Observations submitted to the Court

126 The defendants in the main proceedings observe that Article 28 EC prohibits all obstacles to imports regardless of where the goods were manufactured. The Court has expressly accepted that the protection of the free movement of goods covers reimportation of goods (see Case C-240/95 *Schmit* [1996] ECR I-3179, paragraph 10; Case C-201/94 *Smith & Nephew and Primecrown* [1996] ECR I-5819, paragraphs 18 to 22; Joined Cases C-267/95 and C-268/95 *Merck and Beecham* [1996] ECR I-6285, and Case C-379/97 *Upjohn* [1999] ECR I-6927, paragraphs 13 and 14). They submit that, contrary to the view expressed by the Court in Case 33/74 *Van Binsbergen* [1974] ECR 1299 and Case 229/83 *Leclerc and Others* [1985] ECR 1, the reimportation of authorised medicinal products from a pharmacy established in another Member State does not constitute unlawful circumvention of mandatory national provisions. The defendants in the main action state that the cross-border commercial transaction at issue before the national court was carried out in two distinct marketing stages and, in addition, at different levels of the market (first, the medicinal products were exported by German wholesalers to pharmacies established in another Member State and second, they were reimported by way of retail sale to private customers). The defendants conclude that the transaction merits protection under Article 28 EC, given that it is conducive precisely to the attainment of the objectives of that article. Nor is there any abuse of the free movement of goods, for the simple reason that sale by mail order pursues precisely the objective at the heart of the free movement of goods (see, as regards freedom of establishment, Case C-212/97 *Centros* [1999] ECR I-1459).

The Court's reply

Whether Paragraph 43(1) of the AMG is a measure having an effect equivalent to a quantitative restriction

127 The place of manufacture of a product is of no significance as regards the question whether Paragraph 43(1) of the AMG is a measure having an effect equivalent to a quantitative restriction for the purposes of Article 28 EC. Accordingly, a product manufactured in the territory of a Member State which is then exported and reimported into the first Member State constitutes an imported product in the same way as a product manufactured in another Member State which is then directly introduced into the national territory (see, to that effect, *Leclerc*, paragraph 26, and *Schmit*, paragraph 10).

128 That analysis holds good even if the law governing the sale of the products at issue in the main proceedings, namely medicinal products, is not harmonised at Community level, with the result that a product which comes from the importing State may, in principle, by virtue of its movement across borders, enjoy the protection of Community law.

129 However, the Court has accepted, in relation to the free movement of goods, that that finding does not apply where, on the basis of objective factors, it is established that the products concerned were exported for the sole purpose of reimportation in order to circumvent legislation such as that in the main proceedings (see *Leclerc*, paragraph 27).

130 In the case before the referring court, since the trader which exported the medicinal products was not involved in their reimportation, the reimportation of the products by the defendants in the main action cannot be found to be an abuse of the free movement of goods.

131 Consequently, since a provision such as Paragraph 43(1) of the AMG could restrict the marketing of medicinal products from other Member States, the finding that such a provision constitutes a measure having an effect equivalent to a quantitative restriction cannot be confined to medicinal products originating in Member States other than the importing Member State but also relates to medicinal products which were purchased from wholesalers established in the importing Member State.

Whether there is justification

132 In answering the question whether the prohibition on the sale by mail order of medicinal products is justified, it is appropriate again to draw a distinction between prescription and non-prescription medicines. In relation to the first category, the considerations underpinning the finding, in paragraphs 112 to 116 of this judgment, that the prohibition is not warranted apply in the same way to reimported products. There is thus no need to modify the answer to Question 1(b) in the light of Article 28 EC.

133 Given that considerations relating to the reimportation of prescription medicines — in particular the fact that any such reimported medicines will not be

subject to the APO since they have been purchased over the internet — have already been taken into account in the context of the answer to Question 1(b), there is no need to modify that answer either.

134 The answer to Question 1(c) must therefore be that Questions 1(a) and 1(b) do not need to be assessed differently where medicinal products are imported into a Member State in which they are authorised, having been previously obtained by a pharmacy in another Member State from a wholesaler in the importing Member State.

The second question

135 By the first part of its second question, the national court is asking essentially whether, in the context of a national prohibition on advertising the sale by mail order of medicinal products, Articles 28 EC and 30 EC preclude a broad interpretation of 'advertising', whereby a number of features of the internet portal of a pharmacy established in a Member State are classed as 'prohibited advertising', making cross-border ordering of medicines over the internet appreciably more difficult.

136 The question presupposes the co-existence of a lawful internet sale of medicinal products with a lawful prohibition on the advertising of those products, which might adversely affect the sale. Accordingly, it should be made clear that two distinct questions are being raised: first, whether national prohibitions on

advertising the sale by mail order of medicinal products are compatible with Articles 28 EC and 30 EC, and second whether, in so far as those prohibitions (or some of them) are found compatible, a broad interpretation of 'advertising', which would make internet selling more difficult, would also be compatible with Articles 28 EC and 30 EC.

137 It is only when a prohibition on advertising which is compatible with Community law coincides with an internet sale which is also compatible with Community law that it will be necessary to consider how broadly the concept of 'advertising' should be interpreted, as well as Questions 2(a) and 2(b).

Whether the prohibitions on advertising are compatible with Community law

138 As explained in paragraphs 31 to 33 of this judgment, the German legislation provides for three kinds of prohibition on the advertising of medicinal products. It is necessary to ascertain whether each of those prohibitions complies with Community law. First, as regards Paragraph 3 of the HWG, which in essence lays down a prohibition on advertising medicinal products which require authorisation but have not been authorised, it is sufficient to note that such a prohibition is in conformity with the prohibition referred to in Article 2(1) of Directive 92/28, replaced by Article 87(1) of the Community Code. Thus there is no reason to examine the compatibility of such a prohibition with the Treaty.

139 Second, Paragraph 10(1) of the HWG provides, in general, for a prohibition on advertising prescription medicines. As was stated in connection with Paragraph 3 of the HWG, a prohibition of the kind in Paragraph 10(1) of that law is compatible, as the Commission has observed, with Article 3(1) of Directive

92/28, replaced by Article 88(1) of the Community Code, which lays down a corresponding prohibition at Community level. Accordingly, since a domestic prohibition of that kind constitutes a national measure implementing a Community harmonising measure, its compatibility with the Treaty cannot be called in question either.

140 Third, Paragraph 8(1) of the HWG lays down a prohibition on advertising the sale by mail order of medicinal products which may be supplied exclusively in pharmacies. Paragraph 8(2) also prohibits advertising in connection with the sale of medicinal products by way of individual import as described in Paragraph 73(2), point 6a, and Paragraph 73(3) of the AMG. According to the observations of the German Government, that prohibition, read with Paragraph 73(1) of the AMG, seeks to prevent individual imports of unauthorised medicinal products becoming so extensive, as a result of advertising, as to undermine the system of authorisation, whereas under the AMG individual imports are possible only in exceptional cases. In any event, as the Advocate General has noted in point 171 of her Opinion, according to the documents provided to the Court by the national court, the latter considers that only the prohibition laid down in Paragraph 8(1) of the HWG applies in relation to the sale by mail order of medicinal products. Thus, the provisions of Paragraph 8(2) of the HWG do not form part of the legal and factual framework of the dispute in the main proceedings.

141 The prohibition in Paragraph 8(1) of the HWG has no precise corollary at Community-law level. Article 88(1) of the Community Code prohibits advertising of prescription medicines, whilst Article 88(2) permits, as a general rule, advertising for medicines intended and designed for use without the intervention of a medical practitioner, but with the advice of the pharmacist, if necessary.

142 The Austrian Government relies on that provision to observe that even if that type of advertising is permissible in principle, and given that Article 88 of the Code does not state to what extent the pharmacist's advice is deemed necessary, it must be assumed that the Member States have some latitude in this sphere. The Austrian Government concludes that a prohibition on internet advertising is also justified for medicinal products which may be sold only in pharmacies and for which a prescription is not required.

143 In that regard, it is appropriate to bear in mind the answer to Question 1(b), in paragraphs 112 to 116 of this judgment, concerning justification for the prohibition on the sale by mail order of non-prescription medicines. In its reply, the Court held that the prohibition cannot be justified, in relation to those medicines, by the alleged need for a pharmacist to be physically present when medicines of that type are purchased.

144 It follows that Article 88(2) of the Community Code, which allows medicinal products not subject to prescription to be advertised to the general public, cannot be interpreted as precluding advertising for the sale by mail order of medicines on the basis of the alleged need for a pharmacist to be physically present. Accordingly, Article 88(1) of the Community Code, which prohibits advertising for prescription medicines, precludes a prohibition such as that laid down in Paragraph 8(1) of the HWG in so far as that prohibition covers non-prescription medicines.

Scope of the concept of 'advertising to the general public' under Article 1(3), first indent, and Article 3(1) of Directive 92/28

145 It is apparent from the foregoing that only prohibitions on advertising such as those in Paragraphs 3a and 10 of the HWG, namely those concerning unauthorised medicinal products and prescription medicines respectively, are compatible with Community law. Accordingly, the Court must consider whether the scope of either of those prohibitions is such as may prevent internet sales of medicinal products, in order to ascertain whether it is necessary to give an interpretation of the term 'advertising to the general public' and, in particular, to state how broadly that term should be interpreted.

146 As regards a prohibition of the kind referred to in Paragraph 3a of the HWG, it suffices to observe that the very placing on the market of medicinal products within the territory of a Member State in which they are subject to authorisation but have not been authorised is prohibited at Community level. Accordingly, it cannot be maintained that a prohibition of that kind prevents the lawful sale of medicines over the internet.

147 Community law does not preclude a prohibition on mail-order selling of prescription medicines, which means that a prohibition on advertising the sale by mail order sale of that class of medicinal products cannot be found to prevent a lawful method of selling medicinal products.

148 In light of the foregoing, the answer to the first part of the second question must be that Article 88(1) of the Community Code precludes a national prohibition on

advertising the sale by mail order of medicinal products which may be supplied only in pharmacies in the Member State concerned, such as the prohibition laid down in Paragraph 8(1) of the HWG, in so far as the prohibition covers medicinal products which are not subject to prescription.

149 Consequently, and in light of the answer to Question 1(b), the Court finds that in the main case there is no prohibition on advertising compatible with Community law which is such as may prevent the lawful sale of medicinal products over the internet. Accordingly, there is no need to answer Question 2(a) and (b).

The third question

150 Given the answer to the second question, there is no need to reply to the third question.

Costs

151 The costs incurred by the German, Greek, French, Irish and Austrian Governments and by the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT,

in answer to the questions referred to it by the Landgericht Frankfurt am Main by order of 10 August 2001, hereby rules:

1 (a) **A national prohibition on the sale by mail order of medicinal products the sale of which is restricted to pharmacies in the Member State concerned, such as the prohibition laid down in Paragraph 43(1) of the Arzneimittelgesetz (Law on medicinal products) in the version of 7 September 1998, is a measure having an effect equivalent to a quantitative restriction for the purposes of Article 28 EC.**

(b) **Article 30 EC may be relied on to justify a national prohibition on the sale by mail order of medicinal products which may be sold only in pharmacies in the Member State concerned in so far as the prohibition covers medicinal products subject to prescription. However, Article 30 EC cannot be relied on to justify an absolute prohibition on the sale by mail order of medicinal products which are not subject to prescription in the Member State concerned.**

(c) Questions 1(a) and 1(b) do not need to be assessed differently where medicinal products are imported into a Member State in which they are authorised, having been previously obtained by a pharmacy in another Member State from a wholesaler in the importing Member State.

2. Article 88(1) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use precludes a national prohibition on advertising the sale by mail order of medicinal products which may be supplied only in pharmacies in the Member State concerned, such as the prohibition laid down in Paragraph 8(1) of the Heilmittelwerbegesetz (Law on the advertising of medicinal products), in so far as the prohibition covers medicinal products which are not subject to prescription.

Skouris	Jann	Timmermans
Gulmann	Cunha Rodrigues	Rosas
Edward	La Pergola	Puissochet
Schintgen	Macken	Colneric
	von Bahr	

Delivered in open court in Luxembourg on 11 December 2003.

R. Grass

Registrar

V. Skouris

President