OPINION OF ADVOCATE GENERAL GULMANN
delivered on 16 June 1994 *

Mr President,
Members of the Court,

1. In this case the Landgericht (Regional Court) Saarbrücken has asked the Court for an interpretation of Articles 30 and 36 of the EEC Treaty with a view to determining the compatibility with those provisions of national legislation prohibiting the advertising of medicinal products which are not authorized in Germany even though there is an obligation to obtain such authorization but which, in pursuance of an exemption provision, may be imported from another Member State where it may be lawfully marketed, provided that in each individual case there is a medical prescription and an order from a pharmacist.

The facts

2. Paragraph 73(1) of the German Law on medicinal products (the Arzneimittelgesetz, hereinafter referred to as 'the AMG') provides that medicinal products for which authorization or registration is required may be imported into Germany only if they are authorized or registered in Germany. [1] Paragraph 73(3) contains a derogation according to which medicinal products for which authorization has not been granted may be imported on an individual order provided that they may be lawfully marketed in the Member State from which they are exported and provided that in each case there is a medical prescription and an order from a pharmacist. [2] Paragraph 8(2) of the Law on advertising of medicinal products (Heilmittelwerbegesetz, hereinafter referred to as 'the HWG') prohibits the advertising of medicinal products which may be lawfully imported on the basis of paragraph 73(3) of the AMG. [3]

3. Eurim-Pharm Arzneimittel GmbH (hereinafter referred to as 'Eurim-Pharm')

* Original language: Danish.

1 — The provision is worded as follows: 'Medicinal products for which authorization or registration is required may be introduced into the territory to which this Law applies, with the exception of customs-free areas other than the Island of Heligoland, only if they have been authorized or registered for marketing within the territory to which this Law applies, or exempted from such authorization or registration ...' It should be read in conjunction with paragraph 21(1) of the Law, which provides: 'Ready-prepared medicinal products which are medicinal products within the meaning of paragraphs 2(1) or 2(2)(1) may be marketed within the territory to which this Law applies only if they have been authorized by the competent Federal authorities'.

2 — The provision reads as follows: 'Notwithstanding the provisions of the subparagraph 1, ready-prepared medicinal products which are not authorized or registered for marketing in the territory to which this Law applies or are not exempt from authorization or registration may be introduced into the territory to which this Law applies if the marketing thereof is lawful in the country of origin and if they are ordered by pharmacists. Pharmacists may procure such medicinal products only in small quantities on a medical, dental or veterinary prescription and to the special order of individual persons and may supply them only in the course of the normal business of a pharmacist ...'

3 — The provision is worded as follows: 'Advertisements containing an offer to obtain given medicinal products by individual importation under paragraph 73(2)(6a) or paragraph 73(3) shall be prohibited'.

imports into Germany under paragraph 73(3) of the AMG medicinal products for which authorization has not been granted. Since April 1992 the company has been advertising these medicinal products in specialist journals which are purchased and read by interested specialist circles in the pharmaceutical industry, pharmacists and doctors.

On 14 October 1992 one of Eurim-Pharm's competitors, Lucien Ortscheit GmbH (hereinafter referred to as 'Ortscheit') brought an application before the Landgericht for an ordering requiring Eurim-Pharm to desist from advertising medicinal products not authorized in Germany.

4. The Landgericht takes the view that Eurim-Pharm's advertisements are contrary to paragraph 8(2) of the HWG in so far as that provision is compatible with Articles 30 and 36 of the Treaty and on that basis has referred the following questions to the Court:

'(1) Is the national prohibition of advertising for medicinal products which despite the requirement of authorization are not authorized in Germany, but may lawfully be imported from another Member State of the European Community in response to an individual order if they have already been lawfully put into circulation in that Member State, a measure having an effect equivalent to a quantitative restriction within the meaning of Article 30 of the EEC Treaty?

(2) If the prohibition of advertising described above is a measure having equivalent effect within the meaning of Article 30 of the EEC Treaty, in what circumstances can it be permitted by way of exception under Article 36 of the EEC Treaty for the protection of health and life of humans?'

The first question concerning the interpretation of Article 30 of the Treaty

5. Eurim-Pharm, the Commission and the French Government contend that a ban on advertising such as that laid down in paragraph 8(2) of the HWG is a measure having an effect equivalent to a quantitative restriction on imports within the meaning of Article 30. Ortscheit and the Greek Government on the other hand do not think that such a national provision is covered by the prohibition in Article 30. The Belgian Government merely states that the provision is compatible with Community law without specifying whether that is due to the fact that the provision is covered by Article 30 or that it is justified under Article 36.

6. As the Commission stated during the oral procedure, it must first be considered whether a national provision such as that in this case is a provision 'restricting or prohibiting certain selling arrangements', which applies 'to all relevant traders operating within the national territory' and which affects 'in the same manner, in law and in fact, the marketing of domestic products and those from other Member States', with the result that the provision falls outside the scope of Article 30, such as is defined in the Court's judgment in Joined Cases C-267/91 and 268/91, *Keck and Mithouard*, in particular at paragraph 16. [4]

7. A ban on advertisements such as that in paragraph 8(2) of the HWG must be regarded as a provision prohibiting certain selling arrangements within the meaning of the judgment in *Keck and Mithouard*. That is confirmed by the Court's judgment in Case C-292/92 *Hünermund*, in which the Court decided that that condition was met as far as concerned a rule of professional ethics adopted by a professional organization in a Member State according to which pharmacists within the sphere of responsibility of the organization were prohibited from advertising outside their pharmacies products normally dealt with by pharmacists and for which authorization was required. [5]

8. Paragraph 8(2) of the HWG, however, is applicable only to imported goods and, as the Commission contends, the provision can therefore scarcely be regarded as fulfilling the condition in the *Keck and Mithouard* judgment that it affects in the same manner, in law and in fact, the marketing of domestic products and of those from other Member States.

It is obvious that the unequal treatment of domestic products and products from other Member States arises where stricter rules are applied to domestic goods. Thus domestic products may in all circumstances be marketed only if they have received authorization. On those grounds it may be claimed that a provision such as paragraph 8(2) of the HWG cannot, for products from another Member State, 'prevent their access to the market or ... impede access any more than it impedes the access of domestic products' (cf. paragraph 17 of the *Keck and Mithouard* judgment).

But in my view the decisive point must be that — irrespective of the rules applicable to domestic products — it is a provision

4 — [1993] ECR I-6097.

5 — [1993] ECR I-6787 at paragraph 22.

designed to regulate trade in goods between Member States by limiting the importation of unauthorized medicinal products (cf. paragraph 12 of the *Keck and Mithouard* judgment), [6] and which is expressly aimed at products from other Member States (cf. paragraph 14 of the *Keck and Mithouard* judgment). Provisions of that kind should in my view not be regarded as falling outside the scope of Article 30 but should be appraised according to whether they are based on those considerations which, according to the case-law of the Court, may justify restrictions on trade.

9. That result is not affected by any of the views put to the Court.

10. The Greek Government and Ortscheit contend that the German provision at issue prohibits only advertisements for medicinal products which may be imported on an individual order so that it cannot therefore prevent the importation of the medicinal products in question.

That argument cannot be upheld. There can be no doubt that a ban on advertising such as that at issue may potentially restrict the extent of importation of unauthorized medicinal products and that must suffice for a decision that this is a measure having an effect equivalent to a quantitative restriction on imports within the meaning of Article 30. [7]

11. The Greek Government contends that since importation is permitted only if there is a medical prescription or an order, marketing and advertising as regards consumers are already ensured beforehand and that the German legislation does not therefore obstruct the marketing in Germany of the medicinal products in question.

That view cannot be accepted since the relevant advertisements are aimed at doctors and

6 — Later, in relation to my view with regard to the second question from the court of reference, I shall go further into the purpose of the contested German provision.

7 — As Eurim-Pharm, the Commission and the French Government have stated, the Court has declared that 'national legislation which restricts or prohibits certain forms of advertising and certain means of sales promotion may ... be such as to restrict the volume of trade because it affects marketing opportunities' for imported products and that such legislation therefore represents a measure having equivalent effect to quantitative restrictions on imports within the meaning of Article 30 of the EEC Treaty. It is clear further that Article 30 does not distinguish between measures which are to be described as measures having an effect equivalent to quantitative restrictions according to the extent of their effect on trade within the Community. See the judgment in Case C-126/91 *Yves Rocher* [1993] I-2361 at paragraphs 10 and 21. See also *inter alia* the judgments in Case 286/81 *Oosthoek's Uitgeversmaatschappij* [1982] ECR 4575 at paragraph 15, in Case 382/87 *Buet* [1989] ECR 1235 at paragraph 7, in Case C-362/88 *GB-INNO-BM* [1990] ECR I-667 at paragraph 7, in Case C-241/89 *SARPP* [1990] ECR 4695 at paragraph 29, in Case C-369/88 *Delattre* [1991] ECR I-1487 at paragraph 50 and in Joined Cases C-1/90 and C-176/90 *Aragonesa de Publicidad Exterior* and *Publivía* [1991] ECR I-4151 at paragraph 10). That case-law is in my view still decisive for an appraisal of provisions prohibiting certain forms of sale when it may be determined, as in this case, that moreover the conditions set out in the *Keck and Mithouard* judgment are not met.

pharmacists and the prohibition of advertising can therefore only mean that doctors and pharmacists are less well acquainted with the possibility of importing the medicinal products concerned.

12. Finally Ortscheit claims that paragraph 73(3) of the AMG and paragraph 8(2) of the HWG are to be read together and to be regarded as a whole, that is, as a limited derogation from an import ban which is permissible under Community law. There is therefore no question of a measure having an effect equivalent to restrictions on imports but on the contrary of a measure representing a step in the direction of the implementation of the internal market in the medicinal products sector.

That view must be rejected, even though at first sight it may seem attractive. The correct approach must, I think, be to regard the prohibition of advertising as capable of hindering directly or indirectly, actually or potentially an import which may lawfully be made in pursuance of paragraph 73(3) of the AMG. A provision cannot be regarded as permissible under Community law simply because it may be stated that the Member States are entitled to lay down stricter rules in the sector concerned. It is not impossible for the less strict rule to pursue purposes different from those of the stricter rule and for those different purposes to be incompatible with Community law. In the case also of a provision of the type before us therefore, we must enquire whether it is justified by the considerations referred to in Article 36 of the Treaty.

13. My view therefore is that the answer to the first question should be that a national provision prohibiting the advertising of medicinal products which are not authorized for use in the Member State in question but which, under a derogation, may be imported from another Member State upon individual order, is a measure having an effect equivalent to a quantitative restriction on imports within the meaning of Article 30 of the Treaty.

The second question on the interpretation of Article 36 of the Treaty

14. In the medicinal products sector there has not yet been a complete harmonization of all the measures necessary for the protec-

tion of health and life of humans, [8] and it is therefore still permissible to rely on Article 36 to justify national measures restricting trade in this sector. [9] In this connection the Commission and the French Government have stressed in particular that Council Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use [10] was not due to be transposed by the Member States until 1 January 1993 and could not therefore *ratione temporis* apply in this case, in which the advertising at issue occurred from April 1992 onwards and the action was brought before the Landgericht Saarbrücken on 14 October 1992.

15. The Court has consistently held that 'the health and life of humans rank foremost among the property or interests protected by Article 36 of the Treaty and it is for the Member States, within the limits imposed by the Treaty, to decide what degree of protection they intend to ensure'. However, the Court points out at the same time that 'it follows from Article 36 that national rules or practices having, or likely to have, a restrictive effect on the importation of pharmaceutical products are compatible with the Treaty only to the extent to which they are necessary for the effective protection of health and life of humans. National rules or practices cannot benefit from the derogation provided for in Article 36 if the health and life of humans may be protected just as effectively by measures which are less restrictive of intra-Community trade'. [11]

16. It is common ground in this case that the Member States are entitled under Community law to prohibit entirely the marketing of medicinal products which have not received national authorization. A system of national authorizations is thus generally speaking justified and necessary for the protection of life and health of humans. It was stated during the proceedings that that is expressly provided in Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, [12] amended by Council

8 — The Council has approved a long series of measures intended to achieve a harmonization in the medicinal products sector. See in particular Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization 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) which, with effect from 1 January 1995, introduces a centralized Community authorization procedure for technologically advanced medicinal products and Council Directive 93/39/EEC of 14 June 1993 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products (OJ 1993 L 214, p. 22) laying down for other medicinal products rules regarding a decentralized Community authorization procedure, according to which the marketing of a medicinal product in a Member State continues to be subject to the competent authorities of that Member State having granted authorization therefor, but under which authorization to place a medicinal product on the market in one Member State is in principle to be recognized by the authorities of the other Member States unless there are serious grounds for supposing that authorization may present a risk to public health and in which a disagreement between the Member States about the quality, the safety or the efficacy of a medicinal product is to be settled by a decision having binding effect throughout the Community by means of a scientific evaluation by the European Agency for the Evaluation of Medicinal Products. The directive is to be transposed by the Member States before 1 January 1995.

9 — See in particular the judgments in Case 215/87 *Schumacher* [1989] ECR 617 at paragraph 15, in Case C-369/88 *Delattre* [1991] ECR I-1487 at paragraph 48, in Case C-347/89 *Eurim-Pharm* [1991] ECR I-1747 at paragraph 26, in Case C-62/90 *Commission* v *Germany* [1992] ECR I-2575 at paragraph 10 and, most recently, in Case C-317/92 *Commission* v *Germany* [1994] ECR I-2039 at paragraph 14.

10 — OJ 1992 L 113, p. 13.

11 — See for example the judgments in Case 62/90 *Commission* v *Germany* at paragraphs 10 and 11, in the *Schumacher* case at paragraphs 17 and 18, in the *Delattre* case at paragraph 53 and in the *Eurim-Pharm* case at paragraphs 26 and 27, all already cited in footnote 9.

12 — OJ, English Special Edition 1965-1966, p. 20.

Directive 89/341/EEC of 3 May 1989, [13] Article 3 of which provides:

'No proprietary medicinal product may be placed on the market in a Member State unless an authorization has been issued by the competent authority of that Member State'. [14]

17. It is therefore also common ground in the case that paragraph 73(3) of the AMG is a derogation permitting an import which, under Community law, Germany is under no obligation to permit and that the prohibition of advertising the relevant medicinal products, in paragraph 8(2) of the HWG, aims to limit the extent of such imports.

18. There are two basic views in this case as to how such a rule limiting the scope of a derogation from a provision restricting trade, which under Community law is regarded as necessary for the protection of the life and health of humans, is to be appraised in relation to Article 36.

19. Ortscheit, the Commission and the French Government contend that a provision such as that in paragraph 8(2) of the HWG must be regarded as justified and necessary for the protection of the life and health of humans in accordance with Article 36 *simply because* it may be stated that its purpose is to restrict a derogation from a principal rule which is regarded under Community law as necessary for the protection of life and health of humans. As far as can be seen the Belgian Government essentially shares that view.

The fact that the ban on advertising in paragraph 8(2) of the HWG has that purpose is confirmed by the explanatory memorandum to the draft of the provision, which states:

'The individual importation of medicinal products which have not been authorized under the legislation on medicinal products constitutes a derogation. Individual imports must not be expanded by advertising measures to such an extent as to constitute an evasion of the provisions on authorization.' [15]

13 — OJ 1989 L 142, p. 11.

14 — See in this respect also the first recital in the preamble to the directive, which states: '... the primary purpose of any rules concerning the production and distribution of proprietary medicinal products must be to safeguard public health'.

15 — Bundestagsdrucksache No 11/5373 regarding Article 6 of the draft Law.

On these grounds it is claimed that a ban on advertising is necessary to avoid doctors and pharmacists being encouraged to prescribe and order unauthorized medicinal products which may be imported on individual order under paragraph 73(3) of the AMG. A systematic application of that derogation would mean the derogation becoming a principal rule, which would undermine the system of authorization for marketing of medicinal products. Ortscheit states that the producers of medicinal products would then have the opportunity to circumvent the requirement for national authorization, since they could obtain authorization in the Member State which imposes the fewest requirements and subsequently, by means of advertising campaigns and the rules on importation on individual order, market the medicinal products in question in Germany. [16]

20. Eurim-Pharm and, as far as can be seen, the Greek Government think that there should be an independent inquiry as to whether the advertising ban in paragraph 8(2) of the HWG, regarded in isolation, is necessary for the protection of the life and health of humans.

21. Eurim-Pharm claims that an advertising ban such as is at issue here is not necessary or appropriate for the protection of the life and health of humans, since it is the use of the medicinal product and not the advertising as such which may represent a danger to human life and health. What is decisive, according to Eurim-Pharm, is that it is a question of advertising for medicinal products which the German legislature authorizes for marketing in pursuance of paragraph 73(3) of the AMG and so does not regard as harmful to health. The company further emphasizes that these are medicinal products which are authorized in other Member States and therefore cannot be regarded, either, as dangerous for the health of German consumers. According to Eurim-Pharm concern for the protection of the life and health of humans is already sufficiently safeguarded by the conditions laid down in paragraph 73(3) of the AMG for the import of unauthorized medicinal products and by the requirements imposed on pharmacists by the Verordnung über den Betrieb von Apotheken (regulation on pharmacists) with a view to making it possible for the competent authorities to control imports of medicinal products. Finally the company adds that the possibility of advertising on the other hand is necessary to ensure that doctors and pharmacists are appropriately informed as to the possibility of obtaining medicinal products which are available in other Member States. [17]

16 — The Commission adds that the opportunity to import unauthorized medicinal products on an individual order was intended to apply to cases in which a foreigner is in Germany and continues to need medicine which is authorized in his own country and that that type of importation does not apply to new medicinal products. The French Government adds that advertisements for unauthorized medicinal products cause the public to exert pressure on the authorities for authorization to be given, which distorts the authorization procedure.

17 — It was stated during the proceedings that Eurim-Pharm's advertisement had indeed the sole purpose of informing interested circles where they might obtain the medicinal products in question. As an example of the advertising at issue it is stated in the order for reference that on 6 August 1992 the company had an advertisement in the 'Pharmazeutische Zeitung', a specialist journal purchased and read exclusively by the specialist circles concerned, worded as follows: 'Individual imports in accordance with 73(3) AMG obtained at short notice and at low prices, *inter alia*, Dysport, Imigran, Jumex, Paludrine, Regaine, Eurim-Pharm GmbH 8235 Piding, Am Gänselehen 4-5'.

22. The Greek Government contends on the contrary that the ban on advertising is naturally necessary to protect the life and health of humans, since advertising risks encouraging doctors and pharmacists to promote the sale of medicinal products which the competent national authorities either regard as dangerous to health and have refused to authorize or have not had the opportunity to check, and the effects of which are therefore unknown. The Greek Government points out that it follows from the Court's case-law that 'advertising acts as an encouragement to consumption' and rules which prohibit or restrict advertising 'are not therefore a matter of indifference from the point of view of the requirements of public health recognized by Article 36 of the Treaty'. [18]

23. The first of the two basic views expressed is, in my opinion, correct.

Even though at first sight it may seem hard to understand that a requirement for national authorization of medicinal products which are approved in other Member States should be necessary for the protection of the life and health of humans, the legal position nevertheless is under Community law that such a requirement is, generally speaking, regarded as justified and necessary for safeguarding that concern.

18 — Judgment in Case 152/78 *Commission* v *France* [1980] ECR 2299 at paragraph 17.

In the same way it may be hard to see that, regarded in isolation, a ban on the advertising of unauthorized medicinal products which may be marketed in one Member State should be necessary for the protection of the life and health of humans.

It would however be wrong to appraise in isolation a provision such as that at issue here.

If the basic rule prohibiting the marketing of unauthorized medicinal products is in general regarded as necessary to protect the life and health of humans, a provision which aims at restricting as far as possible derogations from that rule must in the same way be regarded in general as necessary to protect that interest.

It is naturally a condition that such a restriction of the derogation in fact pursues the same aim as the principal rule. As already stated, there are no pre-conditions as regards subjecting any derogation from a major rule to an independent appraisal under Article 36 of the Treaty, and in particular it is necessary to consider in that respect whether the provision in question constitutes a means of arbitrary discrimination or a disguised restriction on trade between Member States contrary to the second sentence of Article 36. However, it is not contested in this case that the provision at issue aims at restricting the derogation from the require-

ment of authorization and hence has the same purpose as the principal rule, namely the protection of the life and health of humans.

24. Contrary to what Eurim-Pharm claims, the judgments in Case 215/87 *Schumacher* [19] and in Case C-62/90 *Commission* v *Germany* [20] cannot be quoted as support for the company's claim that the ban on advertising is incompatible with Articles 30 and 36. Those judgments concerned provisions of paragraph 73 of the AMG involving essentially the fact that the legality of the importation of medicinal products from other Member States was conditional upon not only a national authorization but also on the fact that the consignee must either be a pharmaceutical undertaking, a wholesaler or a veterinary surgeon or must run a pharmacy. The Court decided that the provisions in question were incompatible with Articles 30 and 36 of the Treaty in so far as they prohibited individuals from importing for their own use medicinal products purchased in other Member States which in the State of importation were available without or with a medical prescription respectively. Those cases did not therefore raise the question of the importation of unauthorized medicinal products but only of who could effect the importation of medicinal products which had received authorization in the State of importation. As the Commission and the French Government state, those cases are therefore essentially different from this case and have no decisive significance for it.

19 — [1989] ECR 617.
20 — [1992] ECR I-2575.

25. Ortscheit, the Commission and the French Government finally mention that the legality of an advertising ban such as that at issue here may be confirmed by Council Directive 92/28 on the advertising of medicinal products for human use, Article 2(1) of which provides:

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

26. Eurim-Pharm contends that the provision should be interpreted as meaning that the Member States are only to prohibit the advertising of medicinal products which are not authorized in any Member State, since that interpretation harmonizes best with the future legal position in which authorization of medicinal products is to be a Community matter. The company thinks therefore that the provision may be regarded as supporting its viewpoint, according to which it must be permissible in a Member State to advertise medicinal products which are authorized in another Member State.

27. My view is that the Commission must be regarded as correct in stating that the provi-

sion is to be interpreted as meaning that the Member States are to prohibit the advertising of medicinal products which are not authorized in the Member State in question, even if such authorization has been received in another Member State. [21]

28. But it seems to me doubtful in any case whether it is possible to deduce from the provision in question a duty for the Member States to prohibit the advertising of medicinal products which are not authorized in the relevant Member State even when such medicinal products may be marketed under a provision such as that laid down in paragraph 73(3) of the HWG, which *inter alia* pre-supposes that authorization has been received in another Member State. And conversely it similarly seems doubtful to me whether the Member States can be compelled to permit advertising in such a case simply because a duty to prohibit such advertising cannot be deduced from the provision.

29. On the present basis and for the purposes of an opinion on this case I therefore think that the Court should simply declare that the directive, particularly Article 2(1) thereof, as stated by the Commission, represents a statement that advertising cannot be regarded as the most appropriate source of information with regard to medicinal products and that in any case there is a need on grounds of public health to subject advertisements for medicinal products to strict conditions and effective control. It may be noted in that respect, moreover, that the French, Greek and Belgian Governments have all stated that their legislation prohibits advertising for unauthorized medicinal products. [22]

30. I therefore think that the second question should be answered to the effect that a national rule prohibiting advertising for unauthorized medicinal products which, in pursuance of a derogation, may be imported from other Member States on an individual

21 — As stated by the Commission, the provision must be interpreted in its context, in particular in the light of the principle of national authorization of medicinal products as laid down in Article 3 of Directive 65/65. In addition it seems to me convincing when the Commission contends that the slightly equivocal reference to 'marketing authorization ... in accordance with Community law' results from the fact that the provision was drafted with a view to the future Community system in the medicinal products sector, according to which authorization of medicinal products may take place under a centralized Community procedure or a decentralized one by which it continues to be in principle the Member States which grant marketing authorization within their respective territories; see footnote 8 above.

22 — The French Government and Ortscheit have finally referred to Article 2(4) of Directive 65/65 as amended by Directive 89/341, which gives Member States the opportunity to derogate from the requirement for national authorization in Article 3. The paragraph reads as follows: 'A Member State may, in accordance with legislation in force and to fulfil special needs, exclude from Chapters II to V medicinal products supplied in response to a *bona fide* unsolicited order, formulated in accordance with the specifications of an authorized health care professional and for use by his individual patients on his direct personal responsibility.' The French Government claims that permission to advertise for unauthorized medicinal products would be incompatible with the restrictions laid down in that provision, in particular in so far as concerns unsolicited orders. However, I think it is doubtful whether Article 2(4) covers derogations of the kind with which we are concerned, where it is not a question of medicinal products prepared according to instructions from a recognized practising doctor for his own patients. But the provision shows at any rate that the marketing of unauthorized medicinal products must be an exception.

order is justified and necessary for the protection of the life and health of humans within the meaning of Article 36, in so far as it is designed to restrict the extent of the importations which may be effected in pursuance of the said derogation.

Opinion

31. I shall accordingly recommend the Court to answer the questions referred to it as follows:

'Articles 30 and 36 of the EC Treaty are to be interpreted as meaning that they do not preclude a national rule prohibiting the advertising of medicinal products which are not authorized in the Member State concerned, even where there is a duty to obtain such authorization, but which, under a derogation, may be imported from another Member State where they may be lawfully marketed, on condition that in every individual case there is a medical prescription and an order from a pharmacist.'