OPINION OF ADVOCATE GENERAL VAN GERVEN
delivered on 13 March 1992 *

Mr President,
Members of the Court,

1. This case is concerned with an action brought by the Commission against the Federal Republic of Germany on the basis of Article 169 of the EEC Treaty. The central issue in this case is whether the eye lotions produced by the French firm Prevor [1] are medicinal products within the meaning of Article 1 of Directive 65/65/EEC. [2] The German Government considers that they are and further contends that — as Article 21 of the Arzneimittelgesetz (German Law on Medicinal Products) provides in accordance with Article 3 of the aforesaid directive — those products may be placed on the market in Germany only if a prior authorization has been issued by the competent German authority. However, the Commission takes the view that the products concerned do not constitute medicinal products and that the requirement of authorization constitutes a measure having equivalent effect which is prohibited by Article 30 of the EEC Treaty. The Commission further maintains — contrary to the German Government's alternative contention, put forward in the event that the eye lotions are deemed not to constitute medicinal products — that a requirement of authorization cannot be justified on grounds of the protection of health under Article 36 of the EEC Treaty.

The relevant Community legislation and case-law

2. Article 3 of Directive 65/65, in the version which was in force at the material time, [3] provides as follows:

'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.'

According to Article 1(1), 'proprietary medicinal product' for the purposes of the directive means:

'Any ready-prepared medicinal product placed on the market under a special name and in a special pack.'

* Original language: Dutch.

1 — The four eye lotions at issue are as follows: 'solution pour lavage oculaire au chlorure de sodium', 'solution fixatrice d'acides au bicarbonate de soude', 'solution fixatrice de bases à la glycine et au méthyle-4-hydroxybenzoate de sodium' and 'solution "Previn" fixatrice d'acides et de bases (glycine, acide éthyldiamintetra acétique, citrate trisodique, acide éthyldiamintetra acétique, sodium monosodique et méthyle-4-hydroxybenzoate de sodium)'.

2 — Directive 65/65/EEC of the Council of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 20), as most recently amended by Council Directive 89/341/EEC of 3 May 1989 (OJ 1989 L 142, p. 11). The latter directive had to be implemented only by 1 January 1992. Accordingly, it is not relevant to this case since the time limit set in the reasoned opinion delivered in this case expired on 8 March 1990 (see in that connection the Court's judgment in Case C-200/88 *Commission* v *Greece* [1990] ECR I-4299, paragraph 19).

3 — See footnote 2.

In this case it is a matter of dispute whether the eye lotions in question constitute proprietary medicinal products. [4]

The *first* subparagraph of Article 1(2) of the directive defines a medicinal product as:

'Any substance or combination of substances presented for treating or preventing disease in human beings or animals.'

The *second* subparagraph further adds:

'Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product.' [5]

As the Court has already stated on a number of occasions, Directive 65/65 thus contains two definitions of the term 'medicinal product': one relating to 'presentation' and the other to 'function', and a product constitutes a medicinal product if it is covered by one or other of those definitions. [6] Furthermore, it follows from the case-law of the Court that both definitions must be given a broad interpretation in order to ensure the protection of public health by means of a compulsory marketing authorization. [7]

3. With regard to the definition relating to 'presentation', the Court has already held in its judgment in Case 227/82 *Van Bennekom* that Directive 65/65, by basing itself 'on the criterion of the product's "presentation", is designed to cover not only medicinal products having a genuine therapeutic or medical effect but also those which are not sufficiently effective or which do not have the effect which consumers would be entitled to expect in view of their presentation'. [8] The directive seeks to protect consumers not only from the harmful effects of medicinal products with genuine therapeutic or prophylactic properties, but also from ineffective or insufficiently effective products presented as medicinal products and used by consumers instead of the proper remedies. Furthermore, products constitute medicinal products within the meaning of the first definition in Article 1 of Directive 65/65 if they are presented as having therapeutic (healing) or prophylactic (disease-preventing) properties, even if they do not actually possess those properties. [9] If they do possess those properties, then they constitute medicinal

4 — Apparently, it is not disputed that the eye lotions in question are 'ready prepared' and are placed on the market under a special name and in a special pack. As is clear from footnote 1, however, only one of the four eye lotions, namely the fourth, is referred to by name ('Previn'). The other three are referred to by reference to their composition.

5 — The meaning of 'substance' is more closely defined in Article 1(3) of the directive.

6 — See, for instance, the judgment in Case C-112/89 *The Upjohn Company and NV Upjohn* v *Farzoo and Kortmann* [1991] ECR I-1703, paragraph 15, the judgment in Case C-369/88 *Delattre* [1991] ECR I-1487, paragraph 15, and the judgment in Case C-60/89 *Monteil and Samanni* [1991] ECR I-1547, paragraph 11.

7 — See, for instance, the aforesaid judgment in *Upjohn*, paragraph 16 (with regard to the definition relating to 'presentation') and paragraph 21 (with regard to the 'functional' definition) and the judgment in Case 35/85 *Procureur de la République* v *Tissier* [1986] ECR 1207, paragraph 26.

8 — See the judgment in Case 227/82 *Van Bennekom* [1983] ECR 3883, paragraph 17. See also the judgment in *Upjohn*, cited above, paragraph 16.

9 — See the judgment in *Monteil and Samanni*, cited in footnote 6, paragraph 30.

products within the meaning of the second (functional) definition. [10]

A product is presented as having therapeutic or prophylactic properties where it is expressly 'described' or 'recommended' as such, possibly on the label or in the accompanying leaflet. In its aforesaid judgment in *Van Bennekom*, the Court stated that this is the case, however, 'whenever any averagely well-informed consumer gains the impression, which, provided it is definite, may even result from implication, that the product in question should, regard being had to its presentation, have an effect such as is described by the first part of the Community definition'. [11] In that judgment, the Court also stated that '... the external form given to the product in question — such as that of a tablet, pill or capsule — may in this connection serve as strong evidence of the seller's or manufacturer's intention to market that product as a medicinal product', although such evidence 'cannot ... be the sole or conclusive evidence'. [12] In its aforesaid judgments in *Delattre* and *Monteil and Samanni*, the Court added that the external form must be taken to refer not only to the form of the product itself but also to the packaging, which may resemble that of a medicinal product, [13] and to the accompanying leaflet in which, for instance, reference is made to research carried out in pharmaceutical laboratories or to the application of medical practices aimed at reinforcing the remedial properties of the product. [14] Naturally, as the Court states, the external form of a product cannot be the sole or conclusive premise 'since otherwise certain food products which are traditionally presented in a similar form to pharmaceutical products would also be covered'. [15]

4. With regard to the so-called 'functional' definition, the Court has stated that it applies to 'all products which are intended to restore, correct or modify physiological functions and which may thus have an effect on health in general'. [16] The Court went on to explain that 'it is clear from the aim of health protection pursued by the Community legislature that the phrase "restore, correct or modify physiological functions" must be given a sufficiently broad interpretation to cover all substances capable of having an effect on the actual functioning of the body'. [17] Substances such as certain cosmetic products which have an effect on the human body but do not significantly affect the metabolism and therefore do not actually modify the way in which the body functions, cannot be regarded as medicinal products. [18]

According to the case-law of the Court, the question whether a product is capable of affecting the actual functioning of the organism must be assessed on a case-by-case basis having regard to the pharmacological properties of the product as they may be ascertained in the present state of scientific

10 — See, for instance, the judgment in *Van Bennekom*, cited in footnote 8, paragraph 22.

11 — Ibid., paragraph 18.

12 — Ibid., paragraph 19.

13 — See the judgments in *Monteil and Samanni* and *Delattre*, cited in footnote 6, paragraphs 24 and 40 respectively.

14 — See the judgment in *Delattre*, cited in footnote 6, paragraph 41.

15 — See the judgment in *Van Bennekom*, cited in footnote 8, paragraph 19, and the judgment in *Delattre*, cited in footnote 6, paragraph 38.

16 — See the judgment in *Upjohn*, cited in footnote 6, paragraph 17.

17 — Ibid., paragraph 21.

18 — Ibid., paragraph 22.

knowledge, the manner in which it is used, the extent for which it is sold, its familiarity to consumers and the risks which its use may entail. [19]

5. It is apparent from the recent case-law of the Court that in the first stage of the harmonization of national legislation as provided for in Directive 65/65, a not inconsiderable discretion is left to the Member States, with the result that differences may continue to exist as between Member States with regard to the classification of products. Hence it is conceivable that a product classified as a foodstuff in one Member State, may be treated as a medicinal product in another. [20]

Let me point out, moreover, that as the Court has consistently held, in proceedings under Article 169 of the EEC Treaty it is for the Commission to prove an alleged infringement of Community law. [21] In this case, therefore, it is primarily for the Commission to establish that the German Government misapplied Directive 65/65, notwithstanding the wide discretion left to it, by wrongly treating the eye lotions in question as medicinal products. Of course, this does not preclude the Member State concerned from having to cooperate in the production of evidence by plausibly demonstrating, as the Court has stated in its case-law, [22] on the basis of the results of international scientific research and, in particular, the findings of specialized committees operating at Community level, that a given product is a medicinal product for the purposes of Directive 65/65. If the Commission wishes to contest the data furnished by the Member State, it must do so on the basis of equally reliable data.

6. Finally, let me also point out that this case is concerned only with eye lotions which are intended to be used where by mischance a harmful substance (acid or alkaline) finds its way into the eye. The lotions must then be applied as quickly as possible, in which case they absorb the substance (by means of an acid/alkaline reaction) and remove it by rinsing. However, the parties disagree on the extent to which the capacity to absorb the lotion is restricted to the surface of the eye (see paragraph 8 below).

According to the German Government, the eye lotions in question constitute medicinal products within the meaning of both definitions in Article 1 of Directive 65/65. The Commission disputes that. I shall now consider whether the eye lotions come within the 'functional' definition, and only thereafter whether they come within the definition relating to 'presentation'. This order strikes me as more logical than that followed in Article 1(2) of the directive: in order to ascertain whether a product is presented as a medicinal product, it is necessary to establish what is meant by medicinal product first.

19 — Ibid., paragraph 23, and the judgment in *Monteil and Samanni*, cited in footnote 6, paragraph 30.

20 — See the judgments in *Delattre* and *Monteil and Samanni*, cited in footnote 6, paragraphs 26 to 29.

21 — See, for instance, the judgment in Case 97/81 *Commission* v *Netherlands* [1982] ECR 1819, paragraph 6, the judgment in Case 323/87 *Commission* v *Italy* [1989] ECR 2275, paragraph 19, and the judgment in Case 290/87 in *Commission* v *Netherlands* [1989] ECR 3083, paragraph 11.

22 — See the judgment in *Delattre*, cited in footnote 6, paragraph 32.

The 'functional' definition

7. As stated earlier, the German Government takes the view that the eye lotions produced by Prevor constitute medicinal products for the purposes of the second, that is to say 'functional', Community definition. It submits that the European Pharmacopoeia Commission of the Council of Europe regards eye lotions as medicinal products, [23] which is significant since, according to the case-law of the Court, the Member States are required in connection with the classification of a product as a medicinal product to take account of the results of international scientific research and, in particular, the findings of specialized committees operating at a Community (or comparable) level. [24]

In its application the Commission acknowledges that if the definition in question is construed literally, it is hard to deny that eye lotions serve to restore, correct or modify a physiological function, namely eyesight. In its view, such a literal interpretation is incorrect, however, because it disregards the fact that the concept of medicinal product, notwithstanding the need acknowledged by the Court for a wide interpretation, must be restricted in the light of the aim of protecting public health. Products which have no effect as medicinal products must therefore be excluded, even though they have a medical or even a clinical purpose. So far as concerns the 'functional' Community definition, the decisive criterion is the way in which the substance works. If the action of a product is purely mechanical (as is the case of plaster or a splint), or is very diffuse and feeble (as is the case of salts for foot baths or herbal sweets), then it is not a medicinal product.

Moreover, according to the Commission, products whose composition is identical to that of eye lotions but which are used on the skin instead of the eyes are cosmetic not medicinal products. Why then should eye lotions with the same composition constitute medicinal products? The German Government, however, disagrees with that argument. According to the case-law of the Court, account must also be taken of the manner in which the product is used and it is therefore justified to draw a distinction between a product used on the skin and one used on the eyes, even though there is no difference in composition.

8. The arguments regarding the 'functional' definition revolve essentially around the question whether the eye lotions in question are merely cleansing agents, or are more far reaching in their effects. According to the Commission, the lotions concerned merely cleanse the eyes simply by the mechanical process of rinsing them. However, they lack the property of restoring or correcting the mobility of the eye or eyesight where it is affected by a harmful substance which has found its way into the eye. Eye lotions have only a superficial effect, that is to say during

23 — See the definitive version (January 1991) of the heading 'Solutiones Ophthalmicae' in the European Pharmacopoeia, Annex II attached to the rejoinder.

24 — See the judgment in *Delattre*, cited in footnote 6, paragraph 32. See also paragraph 5 above.

the few minutes in which a harmful substance is in contact with the eye but has not yet penetrated it. If the object is to neutralize harmful substances which have already penetrated the eye and have affected mobility and eyesight, the Commission maintains that special medical intervention is called for.

The German Government does not deny that an eye attacked by an acid or alkaline calls for specialized medical treatment. However, it does dispute the view that a harmful substance which comes into contact with the eye penetrates inside the eye after only a few minutes and it maintains, moreover, that treatment already begins with the application of the eye lotions which, owing to their special chemical composition and in contrast to water for instance, are capable — as the Commission also acknowledges — of absorbing the harmful substance. According to the German Government, absorption (or neutralization) occurs not only on the surface of the eye but also through the upper layers of the cornea and the connective tissue, as well as through the epithelium and the corneal stroma. In support of that assertion, it refers to a scientific study concerning the prevention of corneal ulcers, [25] which states that an eye lotion containing EDTA, the substance of which 'Previn' is also largely composed, has therapeutic properties and, more specifically, prevents the development of corneal ulcers.

25 — Slansky H. et al, 'Prevention of Corneal Ulcers', *Tr. Am. Acad. Ophth. Otol.* Vol. 75, (Nov-Dec 1971) p. 1208.

9. I do not believe it is necessary to go into the matter in more detail or to devote further consideration to the parties' arguments as to whether the eye lotions in question are suitable for treating pain and spasms in the eyelid. It is striking that the Commission is unable, or at least finds it unnecessary, to support its assertions with scientific data, [26] even in order to invalidate a scientific study relied upon by the German Government in connection with one of the eye lotions.

Admittedly, the Commission is right in claiming that the discretion left to the Member States must be exercised within reasonable limits and that compliance with those limits must be subject to some measure of judicial review. In order to enable such a review to be carried out, however, the Commission, which bears the onus of proof (see paragraph 5 above), must, albeit on the basis of the internationally recognized results of scientific research, plausibly demonstrate that the Member State's decision to treat a product as a medicinal product cannot be justified. A mere reference to the attitude of the competent authorities of other Member States with regard to the product concerned [27] is not decisive in itself since the Court accepts (see paragraph 5 above) that, at the present stage of harmonization, differences in classification may continue to exist as between the Member States.

26 — At the hearing the Commission belatedly referred to a study carried out by a French institution, which postdates the Court's judgment in *Upjohn* and consequently the expiry of the period material to this case (see footnote 2).

27 — It is not clear from the documents before the Court precisely what requirements other Member States impose for the marketing of eye lotions. The scant data provided by the Commission in that regard were contested by the German Government at the hearing.

I have therefore come to the conclusion that the Commission has failed to demonstrate to a sufficient extent that, by treating the eye lotions in question as medicinal products, the German Government has misapplied the second subparagraph of Article 1(2) of Directive 65/65.

The definition relating to 'presentation'

10. Having come to the conclusion that the Commission has failed to demonstrate that Germany was wrong to regard the eye lotions in question as medicinal products for the purposes of the 'functional' definition and since, as stated earlier, a product constitutes a medicinal product if it is covered by one or other of the two definitions, I need not dwell on the question whether those lotions constitute medicinal products for the purposes of the definition relating to 'presentation'. In that connection, the German Government maintains that, in its publicity leaflets, Prevor describes the eye lotions as products for treating burns in the eye. According to the Commission, that is incorrect and the publicity leaflets describe only the cleansing effect of the lotion.

The publicity leaflet constituting Annex 3 to the German Government's defence states as follows:

'Those lotions mitigate the corrosiveness of foreign substances and restrict the extent to which they penetrate the eye ... Those lotions serve to rinse the eye and remove corrosive products.'

I share the Commission's view that in that passage Prevor does not expressly state that the eye lotions in question have therapeutic or prophylactic properties. The same must be said, in my view, of the document from Prevor, constituting Annex 2 to the German Government's rejoinder, which gives a graphic description of the pharmacological effect of 'Previn' eye lotion (and which, according to the German Government, forms part of a publicity leaflet for 'Previn').

11. Nor, it seems to me after inspecting the eye lotions in question at the hearing, can it be said that they convey to the average consumer the impression 'which, provided it is definite, may even result from implication' [28] that they have a therapeutic or prophylactic effect. The external form and packaging of the eye lotions in question, and the *publicity* leaflets distributed by Prevor, certainly do not convey that impression. Besides, that criterion must be applied with care, otherwise it would be only too easy for a producer to present a product as a medicinal product, resulting in its withdrawal (unless authorization is granted) from the free movement of goods.

Even the fact that the eye lotions are incontrovertibly presented, according to the Ger-

28 — See the judgment in *Van Bennekom*, cited in footnote 8, paragraph 18.

man Government, as being for use *on an injured eye* is insufficient, in my view, to give the average consumer the impression that they have therapeutic and/or prophylactic properties. Nor is it sufficient for the purpose of conveying that impression, in the case of products the use of which does not have to be prescribed by a physician, which are not sold in pharmacies only and which, in addition, can be administered by anyone in the event of an accident, that the eye lotions are applied *on* an injured eye. To that end, it is necessary to convey the definite impression that they are capable of healing injuries *to* the eye.

The Commission was therefore right in concluding that the eye lotions in question could not be treated by the Federal Republic of Germany as medicinal products within the meaning of the first subparagraph of Article 1(2) of the directive.

The alternative contention: Article 36 of the EEC Treaty

12. Should the Court consider that, contrary to the view which I have taken, the Commission has successfully demonstrated that the eye lotions in question do *not* constitute medicinal products for the purposes of the 'functional' definition and that, in keeping with my view, those lotions do not constitute medicinal products for the purposes of the definition relating to 'presentation' either, then the requirement of a marketing authorization laid down by German law would undoubtedly constitute a measure having equivalent effect which is prohibited by Article 30 of the EEC Treaty. The question then arises whether, as the German Government contends in the alternative, that requirement could still be justified on grounds of the protection of public health under Article 36 of the EEC Treaty. In its judgments in *Tissier* and *Monteil and Samanni*, the Court held that the fact that a product does not meet the Community definitions of the concept of 'medicinal product' does not preclude the Member States from nevertheless subjecting such a product, on grounds of public health, to a requirement of authorization or a restrictive measure concerning marketing or distribution. [29]

According to the German Government, the eye lotions in question may constitute a danger for public health, for instance if they are insufficiently effective or of inferior quality, and thereby fail to prevent serious injury to the eye or even cause the loss of an eye. Furthermore, all the eye lotions at issue in this case are placed on the market in multi-dose bottles, which means that a preservative has to be added to the product and if the latter is used on an injured eye, the healing process may be delayed or even hindered. For that reason, the German (and also the European) Pharmacopoeia provides that eye lotions which are used in surgical procedures or by way of first aid in the event of an accident may be supplied in single-dose bottles. Moreover, none of the eye lotions in question seems to carry a use-by date, even though the German Pharmacopoeia restricts

29 — See the judgment in *Tissier*, cited in footnote 7, paragraph 22, and the judgment in *Monteil and Samanni*, cited in footnote 6, paragraph 36.

that date in the case of eye lotion in multi-dose bottles to six weeks after the product has been opened and the European Pharmacopoeia Commission lays down even stricter rules. Indeed, notwithstanding the addition of a preservative, the danger of contamination grows appreciably with the passage of time.

13. It is not incorrect, in my view, to consider that the eye lotions in question — which, in the hypothetical situation now under consideration, are assumed not to constitute medicinal products — may in certain circumstances be a danger to public health. However, the question is whether that danger can be overcome by a measure which is less restrictive of intra-Community trade than the requirement of a marketing authorization. In my view, it can. A less restrictive measure could, for instance, consist in an obligation to notify the competent authorities (with supporting documents attached) who would be able to withdraw the product from the market in specified circumstances — according to the Commission, France has a system of that kind for the eye lotions in question — and/or in an obligation to provide appropriate information, or even in the imposition of single-dose bottles to be used for certain purposes (for instance in surgical operations or by way of first aid in the event of an accident).

Accordingly, it seems to me, the German Government has failed to demonstrate that the protection of public health could not be ensured just as well by a measure less restrictive of trade.

14. Since I consider that the requirement of a marketing authorization is too restrictive a measure in every respect, I need not devote too much time to the Commission's argument that such a requirement must in any event be regarded as constituting arbitrary discrimination within the meaning of the second sentence of Article 36 of the EEC Treaty. In the first place, it maintains, that requirement is not applied to certain eye lotions produced in Germany. Secondly, a less restrictive measure is applied in the case of older eye lotions, that is to say lotions sold before 1 January 1978. 'Old' products of that kind can be openly bought and sold if a marketing authorization was sought before 30 April 1990.

In my view those arguments are unfounded. So far as the first argument is concerned, the German Government states that in the case of the aforesaid domestically-produced lotions, either an authorization was actually sought and obtained, or the administrative procedure laid down was set in motion as soon as the competent national authority was notified that the products had been placed on the market without authorization, an assertion which, so far as I have been able to ascertain, is not gainsaid by the docu-

ments in the file. As regards the second argument, I consider that differential treatment of old eye lotions and lotions newly placed on the market can be justified in the light of the experience already acquired with regard to the former (always on the assumption that a marketing authorization as such is a justifiable measure, which it is not).

Conclusion

15. It follows from the foregoing that the Commission has not, in my view, convincingly demonstrated that the German Government is wrong to regard the eye lotions produced by Prevor as medicinal products within the meaning of the second subparagraph of Article 1(2) of Directive 65/65. I therefore suggest that the Court dismiss the Commission's application under Article 169 of the EEC Treaty as unfounded and order it to pay the costs.

Alternatively — should the Court consider that the German Government ought not to have regarded the eye lotions in question as medicinal products within the meaning of Article 1(2) of the directive — I am of the opinion that the German Government may not justify the requirement of a marketing authorization on grounds of the protection of public health under Article 36 of the EEC Treaty. In that case, I propose that the Court declare that the Federal Republic of Germany has failed to fulfil its obligations under Article 30 of the EEC Treaty, and order it to pay the costs.