place in order to remove from the eyes dust and dangerous chemical substances by neutralizing them by chemical reaction and eliminating them mechanically by rinsing are not exceeding the bounds of their discretion, where it is not disputed that the lotions in question are intended to be used, after a substance has accidentally come into contact with the eye, in order to prevent potentially serious consequences, that if they are ineffective the consequences may be harmful and that they are classified as medicinal products by the European Pharmacopoeia Commission of the Council of Europe.

REPORT FOR THE HEARING
in Case C-290/90 *

I — Summary of the facts

A — *Legislative background*

(a) Community law

1. Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relation to proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 20) has as its aim, according to the third recital in its preamble, to remove hindrances to trade in proprietary medicinal products within the Community arising from disparities between national provisions in the subject-matter. According to the first recital in the preamble to the directive, the efforts of harmonisation of the Community are guided, in this regard, by the principle according to which the primary purpose of any rules concerning the production and distribution of proprietary medicinal products must be to safeguard public health.

Article 1 gives the following definitions of 'proprietary medicinal product' and 'medicinal product':

'1. Proprietary medicinal product:

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

2. Medicinal product:

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

* Language of the case: German.

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 animals is likewise considered a medicinal product.'

The procedure for authorization of proprietary medicinal products is laid down in Chapter II of the directive (under the title: 'Authorization to place proprietary medicinal products on the market') by Articles 3 to 10.

Article 3 provides that 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.

The particulars and documents which must accompany the application for authorization made by a manufacturer are specified in Article 4 of the directive. They are in particular the name of the product (paragraph 2), its constituents (paragraph 3) and its posology (paragraph 6), its therapeutic indications and contra-indications (paragraph 5), control methods employed by the manufacturer and the results of tests and trials (paragraphs 7 and 8), specimens and package leaflet (paragraph 9), as well as the submission, where applicable, of any authorization obtained in another Member State (paragraph 11).

Article 2(1) of Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (OJ L 262, p. 169), gives the following definition of 'cosmetic product':

'A "cosmetic product" means any substance or preparation intended for placing in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours.'

(b) National law

2. The German Law on Medicinal Products (Arzneimittelgesetz), as amended by the Law of 24 August 1976 reforming the legislation relating to medicinal products (BGBl. I, p.2445), transposed Directive 65/65 into German law. Paragraph 2(1) of that Law gives the following definition of 'medicinal product':

'Medicinal products are to be understood as meaning substances and preparations of substances intended, by use on or in the bodies of human beings and animals, to:

(1) cure, attenuate, prevent or detect diseases, ailments, physical injury or pathological disorders;

(2) assess the state, condition or functions of the body or mental states;

(3) replace substances or fluids secreted by the bodies of humans or animals;

(4) repel, eliminate or neutralize pathogenic agents, parasites or foreign bodies, or

(5) modify the state, condition or functions of the body or mental states.'

By virtue of Paragraph 21 of that Law the medicinal products described in Paragraph 2(1) may not be placed on the market in the Federal Republic of Germany 'unless they have been authorized by the competent federal authority'.

B — *Background to the dispute*

3. A complaint from a French manufacturer (the Prevor company, whose registered office is at Valmondois) brought to the Commission's attention the fact that certain lotions produced by that manufacturer, which may be employed, by way of first aid in the context of the safety at the workplace, in undertakings and workshops to remove from the skin and eyes dust and dangerous chemical substances, are, in so far as they are used a an eyewash, regarded by the German authorities as medical products within the meaning of Directive 65/65 and provisions of the German Law of 1976 on medicinal products.

The German authorities make the sale of the products in question on the German market subject to obtaining authorization to market them as medicinal products, in so far as they are intended to be marketed as eye-lotions ('eye-baths') supplied with special equipment. On the other hand, where it is proposed to market lotions for use on the human skin, the German authorities do not require that the whole of the procedure for prior authorization be applied, but allow the lotions to be placed on the market without any specific controls.

These eye-baths may be used when a harmful substance (acid or alkaline) has come into contact with the eye or where the eye has been infected. They absorb the harmful agent (by means of acid-alkaline reaction) and eliminate it mechanically — through rinsing.

The lotions produced by the French manufacturer have been marketed for approximately 15 years in France as well as in other Member States (Belgium, Luxembourg, The Netherlands, Italy and Spain), without having been made subject there to the issue of an authorization to place them on the market as medicinal products.

In Germany, they had also been marketed since 1986 and employed in particular in the chemical industry without having been made subject to authorization or tests under the legislation on medicinal products. Nevertheless, after the attention of the President of the District (Bezirk) of Cologne had apparently been drawn by a third party to the lotions, a control procedure was initiated, in 1987, by this authority within the area under its jurisdiction. The sole object of this control was to determine whether the lotions

were medicinal products within the meaning of Paragraph 2 of the German Law of 1976 on medicinal products and whether, therefore, the issue of a prior authorization to place them on the market should then be granted, pursuant to Paragraph 21 of the aforementioned Law, by the Federal Health Office in Berlin, which is competent in the matter, was required.

The President of the District of Cologne, referring to the opinion of the Federal Health Office, informed Prevor, by letters of 26 June 1987 and 21 September 1988, that, in so far as the lotions were to be applied to the eye, they were intended to 'prevent physical damage (corrosion)' and were therefore medicinal products subject to authorization within the meaning of Paragraph 2(1) of the German Law on Medicinal Products, since this did not constitute 'external use'. On the other hand, in so far as the lotions were 'intended to eliminate, by application to the surface of the body, chemical substances such as alkalis or acids', they were to be regarded as 'body-toilet preparations' within the meaning of Paragraph 4(1) of the Law of 15 August 1974 on Foodstuffs and Necessaries (Lebensmittel-und Bedarfsgegenständegesetz, BGBl. I, p. 1945).

Following the opinion delivered by the German authorities and set out in the abovementioned letters, the French manufacturer ceased marketing the lotions as 'eye-baths' and has been selling them since then, in the Federal Republic of Germany, solely as 'body showers'.

4. Since numerous bilateral contacts between the German Government and the French Government had proved fruitless, the Commission, by letter of 20 April 1988, requested the German Government, pursuant to Article 169 of the EEC Treaty, to submit its observations with respect to the specific requirement of an authorization to place the lotions in question on the market as medicinal products.

In its reply of 14 February 1989, the German Government stated that, according to the French manufacturer's description of the products, the lotions constituted medicinal products within the meaning of Directive 65/65, regard being had to the fact that they were used on, and indeed in, the human body, specifically in the eye, in order to cure, relieve or prevent disease or physical injury, specifically inflammation and corrosion. The lotions had, according to the German Government, the property of being able to restore or correct use of a human physiological function, namely the mobility of the eye or, indeed, eyesight. The lotions were not only intended to eliminate from the eye foreign bodies or substances, but to modify an organic function by stimulating the secretion of lachrymal fluid. Therefore, in its opinion, on the grounds of their medicinal properties, the lotions had to be submitted, with a view to an authorization to place them on the market, to appropriate efficacy, safety and quality testing pursuant to Article 3 et seq. of the directive, at the request of the Federal Health Office.

In response to the wishes of the German Government, the Commission arranged on 8 September 1989 a meeting of experts in

Brussels, at which representatives of the French Government and the French manufacturer also participated. Since the discussions did not lead to a convergence of views regarding the conditions of access to the market for the lotions, the Commission proposed to those concerned a compromise solution which sought, in particular, to satisfy the German requirements for a prior test of the safety of the products from the point of view of human health.

However, by letter of 7 December 1989, the Government of the Federal Republic of Germany communicated to the Commission the result, which it described as provisional, of that test, on the basis of which an authorization to place the lotions at issue on the market was still considered as indispensable. According to the German Government, it was impossible, for want of sufficient medical data, to make a definitive statement on the safety of the lotions.

The German Government's response led the Commission to send to it, on 8 February 1990, a reasoned opinion in which it again set out in detail its position, which was that the lotions in question were not medicinal products within the meaning of Directive 65/65 and that the marketing of those products was consequently unjustifiably hindered.

In its reply of 30 April 1990 the Government of the Federal Republic of Germany essentially repeated and supplemented the arguments which it had already developed.

The Commission then decided to bring the present action.

II — Written procedure and forms of order sought by the parties

5. The Commission's application was lodged at the Court Registry on 20 September 1990.

The normal written procedure followed the usual course. Upon hearing the report of the Judge-Rapporteur and the views of the Advocate General, the Court decided to open the oral procedure without any preparatory inquiry.

The *Commission* claims that the Court should:

(i) declare that, by making the sale of eye-lotions imported from a Member State dependent upon authorization to place them on the market as medicinal products under 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 and the Law on medicinal products adopted in implementation of the directive, the Federal Republic of Germany has failed to fulfil its obligations under Article 30 of the EEC Treaty;

(ii) order the Federal Republic of Germany to pay the costs.

The *Federal Republic of Germany* contends that the Court should:

(i) dismiss the application;

(ii) order the applicant to pay the costs.

III — Pleas in law and arguments of the parties

6. The *Commission* considers, as a preliminary point, that there is no justification for regarding as medicinal products the lotions in question, whether they are intended for the human eye or skin, since these products have no therapeutic effect, which places them outside the provisions of Article 1 of Directive 65/65. Consequently, the fact that the German authorities refuse access to their market to products coming from other Member States constitutes a measure having equivalent effect to a quantitative restriction, which is incompatible with Article 30 of the EEC Treaty, and which cannot be justified on grounds of protection of health under Article 36 of the Treaty or other mandatory requirements.

In so far as concerns the possible application of Article 1 of Directive 65/65 to eye-lotions is concerned, the Commission maintains that if eye-lotions were to come under the directive, they would be 'proprietary medicinal products', since the lotions are 'ready-prepared' and 'placed on the market under a special name and in a special pack'. Furthermore, the concept of proprietary medicinal product is based on that of medicinal product.

As regards the definition of medicinal product, it is clear, according to the Commission, that the first part of this definition cannot apply in the present case. The eye-lotions are not for the treatment or prevention of disease in human beings. The question whether corrosion of the eye resulting from chemical action must be considered a 'disease' within the meaning of this provision may in this respect be left open. Treatment and prevention of disease are mentioned together in the first part of the definition. They must therefore be interpreted in the same way. As regards treatment of disease, it is, however, undeniable that the product in question must have a therapeutic effect. Thus it is that plasters and bandages, although they evidently contribute to the healing of wounds, cannot be classified as medicinal products, precisely because they have no therapeutic effect. They merely serve to allow and accelerate, by affording external protection, the body's self-healing process, without otherwise encouraging it. That which is undeniable as regards treatment must also be true as regards prophylactic properties, mentioned in the same context. The latter must be founded on a therapeutic effect of the substance.

Consequently, the Commission considers that there can be no question of bringing simple eye-cleansing product which is not presented for treatment and which cannot prevent injury except by a purely mechanical action within the first part of the definition of medicinal product.

According to the Commission, the same holds true as regards the second part of the definition of medicinal product. It cannot, admittedly, be denied that, by their use in and on the human body, the eye-lotions serve to restore, correct or modify a human physiological function, namely eyesight, if the letter of the definition is taken, in purely conceptual terms, as a basis. Since that part of the definition of medicinal product represents the second branch of the alternative vis-à-vis the first part, it may also be argued that the definition is, in this case, interpreted more widely. On closer inspection, however, it will be found, continues the Commission, also as regards this part, that an interpretation based on the letter of the definition would be mistaken because it leads to indefensible results. Admittedly the concept of medicinal product has deliberately been given a broad definition in order to encompass all substances which in some way come into consideration. This broad view, nevertheless, requires a 'corrective', by reason of the objective of protection, in the sense that substances which do not behave as medicinal products must be excluded, even where their intended medical, indeed clinical, use is beyond question.

In the Commission's opinion, the determining criterion in the second part of the definition of medicinal product is the manner in which the substance acts. It is not a medicinal product if its action is purely mechanical (plaster, splints, for example) or if it is very general and feeble in nature (salts for footbaths, herbal sweets). To subject these products to the obligation of authorization would be totally disproportionate.

According to the Commission, there is no doubt that eye-lotions merely have a cleansing effect. Furthermore, they do not have the power to stimulate the secretion of lachrymal fluid nor are they analgesic.

The Commission considers that the declared objective of the strict control of medicinal products is to protect the unwary consumer against the possible damaging consequences for the body of powerful chemical or biological preparations. This system of protection would lead, however, to absurd results if one were simply to bring within it all products solely on the ground that they bear some relation to the prevention of consequences harmful to health.

Moreover, according to the Commission, the position of the German authorities as regards the 'body showers' shows that it is not so much the specific pharmacological effect of the product as its method of use which constitutes their criterion of assessment. Although the composition and the manner of action of the solutions contained in the 'body showers' of the manufacturer correspond to those of the eye-lotions, the lotions for the body have been classified by the German authorities as 'cosmetic products' within the meaning of the Law on foodstuffs and basic necessaries. The Commission considers that classification as appropriate, but considers that, precisely because of their similarity, the eye-lotions should not be treated differently, otherwise the application of the criteria of the definition of medicinal products by the German authorities will remain inconsistent.

The Commission is therefore of the opinion that the eye-lotions produced by the French manufacturer do not possess any therapeutic effect and do not therefore come under the Community definition of medicinal product.

The Commission adds that application of the German Law on medicinal products cannot be justified either on the ground that, even if the products have no therapeutic effect, such an effect is nevertheless asserted in their description and their presentation. The Commission notes that it is true that, in Case 227/82 (*Van Bennekom* [1983] ECR 3883) the Court observed that, by basing itself, in the first Community definition of a medicinal product, on the criterion of the product's 'presentation', Directive 65/65 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. In this context, the Court further pointed out that a product is presented for treating or preventing disease within the meaning of Directive 65/65 not only when it is expressly indicated or recommended as such, possibly by means of labels, leaflets or oral representation, but also 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.

In the Commission's opinion there is, however, nothing in the presentation of the products or in the publicity documents of the manufacturer to allow the inference to be drawn that the eye-lotions are medicinal products or have a therapeutic effect. The advertising leaflets merely describe the cleansing function of the eye-lotions in question and their application by means of body showers and the eye-baths provided.

Furthermore, according to the Commission, it must not be supposed that the 'average consumer' sees the eye-lotions as medicinal products or that he is entitled to expect that they are. In the Federal Republic of Germany as in the other Member States of the Community, consumers as a rule start from the premise that medicinal products, where these are not prescribed by a doctor, must at least be sold by dispensing chemists. Neither of these conditions applies to the eye-lotions. Both the 'body showers' and the 'eye-baths' are intended to be available on the plant or in the factory, close to centres of potential risk, in order to enable them to be used as quickly as possible by the workers concerned for the purposes of irrigation in the event of contact with a corrosive agent. The first-aid nature of the lotions which, like bandaging material, may be used by anyone in case of need, clearly militates against their being regarded as medicinal products.

Consequently, according to the Commission, since, by an erroneous application of Directive 65/65, the German Government has hindered or needlessly complicated the placing of eye-lotions imported from another Member State on the market, there has been an infringement of Article 30 of the EEC Treaty, which is not justified by the provisions of Article 36 of the Treaty.

Referring to the judgment in *Van Bennekom*, above, the Commission observes that the Court, interpreting Article 36 of the EEC Treaty, held that the national authorities of a Member State which oppose the import of such preparations by invoking the mandatory requirements of public-health protection must, having regard to the principle of proportionality, demonstrate, in each case, that their rules are necessary to give effective protection to the interests referred to in Article 36 of the Treaty and, in particular, that the marketing of the product in question poses a serious risk to public health (see paragraphs 39 and 40 of the judgment). In the Commission's opinion, the German Government has not provided substantiated proof of this in the case of the eye-lotions in question.

The Commission goes on to add that in the present case, as well as an infringement of Article 30 of the EEC Treaty as a result of an incorrect application of Directive 65/65, there has been an infringement of the second sentence of Article 36 of the EEC Treaty. The Commission criticizes the German Government for the fact that a certain number of older preparations which, by reason of an authorization deemed to have been obtained under the German Law of 1976 on medicinal products, have not been made subject to any substantive control with a view to obtaining authorization under the Community provisions in force, may still be sold on the German market after the expiry of the transitional period from 1978 to the end of 1990 prescribed in that Law. Requests for a posteriori authorization have moreover been submitted before 30 April 1990 for these preparations, although the competent Federal Health Office has still not tested them.

The Commission therefore considers that the fact that the German Government wishes to make the marketing of these medicinal products — assuming that they are medicinal products — subject to prior authorization by the Federal Health Office is discriminatory with respect to eye-lotions. If it were accepted that authorization for eye-lotions is necessary, objective equal treatment of these lotions and the older preparations requiring renewed authorization would require, in the Commission's opinion, that the sale of the lotions be authorized as from the submission of the request for authorization.

Finally, the Commission concludes, if the German Government claims that there exists, in the case of eye-lotions, a legitimate interest in verifying, within the framework of the control relating to the request for authorization as a medicinal product, whether the medicinal product in question corresponds to the present state of scientific knowledge, the same should essentially apply to the older German preparations.

7. The *German Government* states first that the capacity to absorb the products in question is not restricted, contrary to the Commission's contention, to the surface of the eye. They may also be absorbed through the upper layers of the cornea and the conjunctiva as well as through the epithelium and the stroma of the cornea. It goes on to state that the lotions should therefore be regarded as being used inside the eye and, consequently, inside the body.

The German Government further observes that Directive 65/65 gives a broad definition of the concept of medicinal product. It adds that it follows from the case-law of the

Court that the definition of medicinal product given in Article 1 of that directive may not be interpreted too restrictively (the judgment in Case 35/85 *Tissier* [1986] ECR 1207, paragraph 26) regard being had to the first recital in the preamble to the directive according to which the primary purpose of the directive is the safeguarding of public health. According to the German Government, this wide definition was deliberately chosen in order to avoid uncertainties in the area of proprietary medicinal products, foodstuffs and cosmetics. In order to protect patients and consumers, no substance or composition presented for treatment or intended, more generally, for medical use, may be placed on the market without having been tested by the administration.

In the German Government's opinion, the eye-lotions manufactured by the Prevor company are covered by both Community definitions of the concept of medicinal products.

The German Government maintains that the first Community definition is applicable in the present case because the eye-lotions are combinations of substances 'for treating or preventing disease in human beings' and are presented as such.

The German Government criticizes in particular the Commission's assertion that it is undeniable that the lotions in question merely have a cleansing power. It considers, on the contrary, that these lotions are not cleansing products but — according to the indication provided by the manufacturer himself — products to treat burns in the eye, and therefore medicinal products.

According to the German Government, the manufacturer himself presents the eye-lotions as possessing therapeutic properties.

It adds that neither is it possible to deny that the lotions in question are medicinal products by stating that the lotions produced by the Prevor company are totally harmless, since, on the one hand, such an observation can only be made after an authorization procedure provided for in the legislation on medicinal products and cannot constitute a criterion for determining the need for it, and, on the other hand, the harmless nature of a product is not a factor suggesting that it is not a medicinal product but constitutes rather one of the conditions for its authorization.

The German Government maintains that, in accordance with the recognized general rules for the testing of medicinal products as laid down in Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products (OJ L 147, p. 1), medicinal products must be examined according to criteria of efficacy, safety and quality. Knowing whether a substance or a preparation is effective with regard to the declared therapeutic objective and whether the quality of the product is faultless are questions which are at least as important as the testing of a product's safety. Efficacy

tests are particularly important for eye-lotions because the use of ineffective lotions could lead to loss of the eye. One of the primary purposes of the authorization procedure provided for in the legislation on medicinal products is, continues the German Government, to identify the products devoid of therapeutic efficacy and which therefore only appear to be offering protection, as provided for in Article 3 of Directive 65/65 for all substances or combination of substances which are to be placed on the market and presented as possessing therapeutic properties.

Furthermore, according to the German Government, eye-lotions must be treated as medicinal products because they are 'presented' as possessing the properties described in the first definition. It refers to the judgment in *Van Bennekom*, above, as authority for maintaining that the concept of 'presentation' of a product must not be interpreted restrictively, but must include products which are not actually effective (see paragraph 18).

The German Government states that the packaging cannot, as was held in the case just mentioned, be the sole evidence. Account should also be taken of the indicated use. It is undeniable, in its opinion, that eye-lotions must be used when the eye has already been infected. The 'average consumer' can immediately infer from the directions for use that this is not a cosmetic product but a product for preventing or treating disease. Use of an eye-lotion stops the process of deterioration in the eye. Consequently, only the authorization prescribed for medicinal products can ensure that the user has the necessary information as to the limits of the therapeutic properties of the product.

The German Government maintains that the lotions in question also correspond to the second Community definition of the concept of medicinal product given by Directive 65/65.

According to the German Government, substances which 'behave as medicinal products' are products 'for treating or preventing disease in human beings or animals' and are therefore medicinal products in the sense of the first definition. The second definition would be devoid of purpose if it only concerned remedies already falling within the scope of the first definition by virtue of their properties. Contrary to the concept defended by the Commission, the German Government believes that the second definition cannot have as its sole criterion the therapeutic efficacy of the product. If such were the case, the concept of medicinal product would not cover *inter alia* products used for making a medical diagnosis.

According to the German Government, regard being had to the objective of 'safeguarding public health' referred to in the first recital in the preamble to Directive 65/65, the Court, applying a broad definition to the concept of medicinal product, referred in its judgment in *Tissier*, above, to the principle according to which 'users [must] be able to rely on the quality of the substance without having to carry out checks when ...

administering to human beings or animals' (paragraph 27). In the German Government's opinion, this reasoning can also be applied in the present case.

It adds that, in the case of medicinal products, labelling, a package leaflet and specialized information, for example, is prescribed, while in the case of cosmetic products directions are required only for certain substances. Therefore only the authorization procedure laid down in the legislation on medicinal products can ensure the necessary protection for the user.

In the German Government's opinion, Article 5 of Directive 65/65 accords the same importance to the protection of the user against medicinal products which claim to have a therapeutic efficacy that they do not have or composition of which is not indicated, or is indicated but only incompletely or inaccurately. To inform the user correctly about the manner in which the product acts, the limits of its efficacy, its compatibility, possible side effects and its composition is at least as important an objective.

The German Government contends that, contrary to what the Commission says, the properties of a medicinal product cannot be inferred solely from its composition. On the contrary, the composition must always be taken into account according to the intended use. Even lay persons can easily understand that a single product is subjected to different requirements according to the use intended to be made of it. Consequently, similar compositions may be treated differently according to their use and the way in which they are to be used. The same lotion may therefore have to satisfy different requirements according to whether it is to be used as a body-wash or eye-wash solution.

The German Government further notes that the 'average consumer' is not alone in considering that the eye-lotions are medicinal products. In its opinion, experts of the Council of Europe's European Pharmacopoeia Commission share this view. Indeed, the January 1991 version of the document headed 'Solutiones Ophthalmicæ' drawn up by Group of Experts No 3 of this commission (PA/PH/Exp. 3/T (89) 38, DEF) states that eye-lotions used in surgical procedures or in first-aid treatment do not contain a preservative and are to be supplied exclusively in containers intended for use on one occasion only. Provisions concerning labelling require the label to state that the contents are to be used on one occasion only. In the German Government's view, it is for these reasons that the lotions manufactured by the Prevor company containing preservatives intended for application on the eye are not marketable at European level.

The German Government goes on to state that another unacceptable risk incurred on application of the lotions in question lies in the lack of a use-by date. It alleges that the notice provided by the Prevor company merely mentions that the manufacturer replaces its products annually. This is incompatible with medical rules and requirements and is an unacceptable risk.

The German Government also accuses the Commission of wishing to include eye-

lotions in the category of 'cosmetic products', on account of their similarity with products intended as body showers. The German Government considers that the Commission is thereby mistaken in its understanding of the concept of 'cosmetic product'.

In the German Government's opinion, according to the recitals in the preamble to Directive 76/768, cosmetics differ in two ways from medicinal products: first, in the areas of application on the body and, secondly, in the purposes of their use. Eye-lotions do not come under either of these two headings in the definition given in Article 1 of the directive.

The German Government observes that, in accordance with the first part of the definition given in Article 1(1) of the directive, a cosmetic product is 'intended for placing in contact with the various external parts of the human body (epidermis, hair system, nail, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity'. In its opinion, while this limitative enumeration mentions the mucous membranes of the oral cavity, it does not refer to the surface layers of the eye. It can be inferred a contrario — regard being had to the clear delimitation called for in the recitals — that the eye and its surface layers are expressly excluded. Furthermore, eye-lotions are not intended for external use.

The German Government further notes that the second part of the definition lays down that cosmetic products are used 'with a view exclusively or principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours.' The German Government maintains that cleaning does not constitute one of the effects of eye-lotions. Moreover, it may be inferred, in its view, from the context that the legislature here understood cleaning as referring to the normal care of the body and not to use of the product where there is a serious threat to health.

The German Government stresses, solely in the alternative, that in its opinion, even if the products manufactured by the Prevor company could not be regarded as medicinal products within the meaning of Directive 65/65, the obligation of authorization would not be open to criticism in Community law on the basis of Article 36 of the Treaty because it answers to the mandatory requirements of the protection of public health. The German Government refers in this regard to the judgment in *Tissier*, above, in which the Court held that the fact that certain pharmaceutical substances or compositions are not medicinal products within the meaning of Community law does not affect the right of Member States to subject such substances to controls or to require prior authorization in accordance with their own national law on medicinal products (see paragraph 22).

It goes on to state that German law on medicinal products rests on the principle of affording extensive protection of human health and that there is no room for doubt that the eye-lotions in question come under the concept of medicinal product.

The German Government also contends that the arguments which the Commission has

based on the judgment in *Van Bennekom*, above, as regards the burden of proof where imports have been made subject to restrictions, rest on an incomplete citation of the judgment which distorts not only what that judgment said, but also the facts giving rise to the action.

The German Government then refers to the judgments In Case C-60/89 *Monteil et Samanni* [1991] ECR I-1547 and C-369/88 *Delattre* [1991] ECR I-1487 as authority for maintaining that it is for the Member States do decide the level at which they intend to ensure the protection of health and life of persons.

Finally, in answer to the Commission's arguments based on an alleged arbitrary discrimination within the meaning of the second sentence of Article 36 of the Treaty, the German Government contends that for the eye-lotions which were placed on the market as medicinal products deemed to have been authorized, no request for a posteriori authorization had been submitted before 30 April 1990, so that such medicinal products deemed to have been authorized may no longer be placed on the market, in view of their sell-by date. There cannot therefore be said to be discrimination in relation to these lotions.

According to the German Government, it cannot be required that an authorization to place on the market be issued before a decision has been taken on the request for authorization. A request for a posteriori authorization for the medicinal products deemed to have been authorized may not be treated in the same way as a request for a new authorization. It is a question of requesting an extension of authorization which does not prevent the medicinal product deemed to have been authorized from continuing to be marketed up to the date of the decision granting the extension.

In its opinion, a right to equal treatment with older medicinal products for which an extension of authorization had to be requested by virtue of the transitional provisions by 30 April 1990 at the latest, may moreover, be invoked only if a request for authorization had been submitted for the product by the Prevor company. The German Government goes on to say that the company has refused on several occasions to submit such a request. By letter from its German subsidiary of 25 April 1991, the Prevor company has once again expressly pointed out that it had not submitted a request for authorization.

The German Government concludes by stating that its legislation in the field of medicinal products law, in the same way as the corresponding provisions of Community law, must prevent the existence of an unregulated grey area between cosmetic products and medicinal products. This would, however, be the case if the products were to be regarded neither as medicinal products nor as cosmetic products. It refers in this regard to the judgments in *Delattre*, above, and in Case C-112/89 (*Upjohn* [1991] ECR I-1703), which were concerned with the fifth recital in the preamble to Directive 76/768, as authority for maintaining that products which may be regarded both as medicinal products and as cosmetic products are subject exclusively to the provisions of Directive 65/65 on medicinal products, because only in this way can the objective of the protection of public health be taken into account.

G. C. Rodríguez Iglesias

Judge-Rapporteur