functions but also those which do not have the advertised effect, the marketing of which may thus be prohibited in order to protect consumers. It cannot, however, encompass substances such as certain cosmetics which, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions.

It is for the national courts to determine on a case-by-case basis the classification of each product having regard to its pharmacological properties as they may be ascertained in the current state of scientific knowledge, to the way in which it is used, to the extent to which it is sold and to consumers' familiarity with it.

2. Even though it may fall within the definition of cosmetic products given in Article 1(1) of Directive 76/768, a product must nevertheless be treated as a medicinal product as referred to in Article 1(2) of Directive 65/65 relating to proprietary medicinal products and, if it is a proprietary medicinal product, subjected to the corresponding rules, to the exclusion of those governing cosmetic products, if it is presented for treating or preventing disease or if it is intended to be administered with a view to restoring, correcting or modifying physiological functions.

Such a classification is a necessary consequence of the aim, pursued by both directives, of protecting public health, since the rules governing proprietary medicinal products are stricter than those governing cosmetic products, in view of the particular risks to public health which the former may represent and which are generally not displayed by cosmetic products.

REPORT FOR THE HEARING
in Case C-112/89 *

I — Facts, legal background and development of the dispute

A — *Facts*

The Upjohn Company, a United States company, and its Belgian subsidiary Upjohn NV (hereinafter referred to jointly as 'Upjohn') manufacture and market 'Regaine' lotion, containing 'minoxidil', which is intended to counteract alopecia androgenetica, or natural baldness.

Upjohn markets that product in the Netherlands as a proprietary medicinal

* Language of the case: Dutch.

product and it has been registered as such since 27 May 1987. According to Upjohn, between 1986 and 1988 Regaine was registered as a medicinal product in some fifty countries, including eleven in the European Economic Community (registration as a proprietary medicinal product in the Federal Republic of Germany is currently under consideration).

The United States company Farzoo, represented in the Netherlands by Mr Kortmann, markets, under the name 'Minoxidil', a product identical to the Regaine sold by Upjohn, also containing minoxidil and used for the same purpose. However, Farzoo markets its Minoxidil as a cosmetic product and not as a proprietary medicinal product.

Upjohn, considering that Farzoo was infringing the Netherlands law on medicinal products and competing unfairly with Upjohn, applied to the President of the Arrondissementsrechtbank (District Court), 's-Hertogenbosch, for an order restraining Farzoo from marketing minoxidil in any manner whatever, requiring it to inform Upjohn within four days of service of the judgment of the identities and addresses of Farzoo's suppliers of minoxidil and of any persons to whom it had already sold or delivered the product and imposing penalties in the event of non-compliance.

Farzoo entered a cross-application for an order restraining Upjohn from preventing Farzoo from using minoxidil in any manner whatever.

By judgment of 19 May 1987, the President of the Arrondissementsrechtbank dismissed both applications. That judgment was confirmed on appeal by judgment of the Gerechtshof (Regional Court of Appeal), 's-Hertogenbosch, of 18 January 1988, whereupon Upjohn appealed to the Hoge Raad der Nederlanden (Supreme Court of the Netherlands).

B — *The applicable Community legislation*

1. *The Community definition of 'medicinal product'*

The Community definition of 'medicinal product' is given in Article 1(2) of 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 (Official Journal, English Special Edition 1965-1966, p. 20). That article provides that the term 'medicinal product' is to have the meaning:

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

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'.

The objective of Directive 65/65 is essentially to make it necessary to obtain author-

ization before placing on the market proprietary medicinal products, defined in Article 1(1) as 'any ready-prepared medicinal product placed on the market under a special name and in a special pack'. The directive lays down, *inter alia*, the circumstances in which such authorization may be granted and revoked.

2. *The Community definition of 'cosmetic product'*

Article 1(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 (Official Journal 1976 L 262, p. 169) defines a 'cosmetic product' as:

'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 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'.

Under Article 1(2), certain products listed in Annex I to the directive, including various hair care products, in particular hair tints and bleaches, products for waving, straightening and fixing, setting products, cleansing products (lotions, powders, shampoos), conditioning products (lotions, creams, oils) and hairdressing products (lotions, lacquers, brilliantines), are to be regarded as cosmetic products.

Article 2 of the directive provides that cosmetic products must not be liable to cause damage to human health when they are applied under normal conditions of use, and the directive lays down rules to facilitate the free movement of such products.

The directive lists a number of substances and colouring agents the use of which is prohibited in cosmetic products; that list may be updated in accordance with the procedure laid down in Articles 9 and 10.

Finally, under Article 12, a Member State which notes that a cosmetic product represents a hazard to health may provisionally prohibit that product or subject it to special conditions, and the matter is then to be reviewed at a Community level.

3. *With regard to the respective scopes of Directive 65/65 and Directive 76/768, the fifth recital in the preamble to Directive 76/768 states that:*

'this directive relates only to cosmetic products and not to pharmaceutical specialities and medicinal products; whereas for this purpose it is necessary to define the scope of the directive by delimiting the field of cosmetics from that of pharmaceuticals; whereas this delimitation follows in particular from the detailed definition of cosmetic products, which refers both to their areas of application and to the purposes of their use; whereas this directive

is not applicable to the products that fall under the definition of cosmetic product but are exclusively intended to protect from disease; whereas, moreover, it is advisable to specify that certain products come under this definition, whilst products containing substances or preparations intended to be ingested, inhaled, injected or implanted in the human body do not come under the field of cosmetics'.

C — *The questions referred to the Court*

By judgment of 31 March 1989 the Hoge Raad der Nederlanden, considering that the dispute before it entailed the interpretation of Directives 65/65 and 76/768 as regards the definitions of 'medicinal product' and 'cosmetic product' respectively, sought a preliminary ruling from the Court of Justice on the following two questions:

'(1) May a product which is not "for treating or preventing disease in human beings or animals" within the meaning of the first sentence of the definition of a medicinal product in Article 1(2) of Directive 65/65/EEC nevertheless be regarded as a medicinal product if it may be administered to human beings with a view to restoring, correcting or modifying physiological functions?

(2) If so, how is the concept of "medicinal product" in Directive 65/65/EEC to be delimited from that of "cosmetic product" in Directive 76/768/EEC?'

D — *Procedure before the Court of Justice*

1. In accordance with Article 20 of the Protocol on the Statute of the Court of Justice of the EEC, written observations were submitted by Upjohn, represented by C. J. J. C. van Nispen, of the Hague Bar; by Farzoo, represented by I. G. F. Cath and M. J. Geus, of Buruma & Maris, of the Hague Bar; by the Spanish Government, represented by J. Conde de Saro, Director-General for Community Legal and Institutional Coordination, and R. Silva de Lapuerta, Abogado del Estado, of the Community Legal Affairs Department, acting as Agents; by the French Government, represented by E. Belliard, Deputy Director of the Legal Affairs Directorate in the Ministry of Foreign Affairs, and S. Grassi, Secretary for Foreign Affairs in the said ministry, acting as Agents; by the Italian Government, represented by O. Fiumara, Avvocato dello Stato, acting as Agent; by the United Kingdom, represented by J. A. Gensmantel, of the Treasury Solicitor's Department, acting as Agent, assisted by J. G. McK. Laws, Barrister; and by the Commission of the European Communities, represented by R. Barents, a member of its Legal Department, acting as Agent.

2. By decision of 7 November 1990, the Court assigned the case to the Fifth Chamber. Upon hearing the report of the Judge-Rapporteur and the views of the Advocate General, the Court further decided to open the oral procedure without any preparatory inquiry. However, it gave the Member States which had submitted observations and the Commission notice of questions which it requested them to be prepared to answer at the hearing.

II — Summary of the written observations

A — *The first question*

Upjohn, the Commission of the European Communities, the Spanish, French and Italian Governments and the United Kingdom consider that the national court's first question should be answered in the affirmative.

1. *Upjohn's position*

In *Upjohn's* view, the Hoge Raad wishes to ascertain whether the expression used in the first subparagraph of Article 1(2) of Directive 65/65 ('for treating or preventing disease in human beings') and that used in the second subparagraph ('with a view to . . . restoring, correcting or modifying physiological functions in human beings') are equivalent, or whether the import of the latter expression is wider.

Upjohn points out, first, that if two different expressions are used then their import should normally be different. Secondly, it submits that the same conclusion is reached by considering the objectives of the authors of the directive when defining medicinal products: the 'presentation' criterion is intended as a safeguard against quackery, whereas the 'administration' or 'function' criterion is aimed at catching all products which may affect public health.

Upjohn also bases an argument on the fourth indent of Article 1(2) of Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products (Official Journal 1981 L 317, p. 1), which defines 'medicated feedingstuffs' as those which are intended to be fed to animals without further processing, because of [their] curative or preventive properties or other properties as a medicinal product covered by Article 1(2) of Directive 65/65/EEC'. In Upjohn's view, such 'other properties as a medicinal product' necessarily relate to the effect of the medicinal product on physiological functions, thereby distinguishing them from the concept of 'curative or preventive properties' ('for treating or preventing disease'). The Court's judgment in Case 227/82 *van Bennekom* [1983] ECR 3883 is consistent with that view. A product is therefore to be regarded as medicinal whenever it affects a physiological function, whether or not it is also for treating or preventing disease.

2. *The position of the Commission of the European Communities, the Spanish, French and Italian Governments and the United Kingdom*

In the *Commission's* view, it is clear from Directive 65/65 and from the judgment in *van Bennekom* that it is sufficient for a product to meet any one of the criteria laid down in Article 1(2) of Directive 65/65 for it to be regarded as a medicinal product. Consequently, if a product has the effect of modifying physiological functions it must be classified as a 'medicinal product' whether or not it is also for treating or preventing disease in human beings. Since the Hoge Raad based its reasoning on the fact that

minoxidil was administered in order to restore, correct or modify physiological functions, it thus has the characteristics of a medicinal product.

The *Spanish, French and Italian Governments* also consider that if a product has the effect of modifying physiological functions it must be classified as a 'medicinal product', regardless of whether it is also for treating or preventing disease. All three governments consider that minoxidil does have the characteristics of a medicinal product.

The *United Kingdom* considers that a product which is endowed with pharmacological properties has the characteristics of a medicinal product and the question whether or not it is endowed with such properties is a question of fact for the national court to determine. A product which is not for preventing disease is therefore none the less a medicinal product if it modifies physiological functions.

3. *Farzoo considers that the first question raised by the Hoge Raad der Nederlanden should be answered in the negative*

Farzoo submits that minoxidil has no effect other than on natural baldness, which is not a disease. The Netherlands authorities treat the product, moreover, as a cosmetic product.

Farzoo considers that it is clear from the wording of the first part of the national court's first question that the Hoge Raad considers that minoxidil is not for treating or preventing disease. While, according to the Court's case-law, the 'presentation' criterion is to be given a broad interpretation with a view to combatting quackery, it is none the less clear from that case-law, and in particular from paragraphs 22 and 23 of the *van Bennekom* judgment, that a product which is not presented for treating or preventing disease and which, moreover, is not endowed with the necessary properties for that purpose may not be classified as a 'medicinal product'. Farzoo submits that it is not possible for the expressions 'for treating or preventing disease in human beings' and 'with a view to . . . restoring, correcting or modifying physiological functions' to have different meanings.

Farzoo examines the concepts of 'pharmacological properties', 'disease' and 'physiological functions', and concludes that the various ways in which physiological functions may be modified are covered by the concept of 'treating or preventing disease'. A product is, therefore, to be regarded as 'medicinal' not because physiological functions are restored, corrected or modified, but because of the relationship between the product and the condition of a patient, viewed as a diseased person whose physiological functions must be treated. A different interpretation entailing the separation of those two concepts would lead, in Farzoo's submission, to absurd conclusions. Farzoo therefore considers that where a product is not covered by the first part of the Community definition of a medicinal product (in the first subparagraph of Article 1(2) of Directive 65/65), then the expression 'with a view to . . . restoring, correcting or modifying physiological

functions in human beings or in animals' should be understood as involving 'treating or preventing disease in human beings or animals'.

on an ordinary consumer, and decisions of the competent authorities of the Member State concerned or of other Member States with regard to identical or similar products should be taken into consideration.

B — *The second question*

1. Upjohn, the Commission, the Spanish and French Governments and the United Kingdom consider that a product administered 'with a view to . . . restoring, correcting or modifying physiological functions' must be classified as a 'medicinal product' and thus cannot constitute a 'cosmetic product'.

Article 1 of Directive 76/768 defines cosmetic products by reference to the area and purpose of application, excluding all products intended to have an active effect on the human body. It is therefore always necessary first to enquire whether or not a product falls within the legal definition of a medicinal product; if so, that is enough to exclude it from the category of cosmetic products. As regards the product in issue in the main proceedings, whether or not natural baldness is a disease, the fact that minoxidil has the effect of modifying physiological functions since it encourages hair growth is a sufficient reason for concluding that it is a medicinal product. That conclusion is consistent with the position adopted by the other Member States. Furthermore, Commission Directive 87/137/EEC of 2 February 1987 adapting to technical progress Annexes II, III, IV, V and VI to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Official Journal 1987 L 56, p. 20) prohibited the use of minoxidil in cosmetic products. That constitutes evidence that it is a pharmacologically active substance.

(a) In *Upjohn's* submission, it is generally accepted that the two concepts of 'medicinal product' and 'cosmetic product' are mutually exclusive. The contrary opinion prevails in the Federal Republic of Germany and the United Kingdom, but in those States the rules governing the two types of product are applied cumulatively. Upjohn claims that the concept of 'medicinal product' must take precedence over that of 'cosmetic product', since medicinal products are more strictly regulated, thus ensuring greater protection of public health. Medicinal products are clearly distinguished from foodstuffs and cosmetics by the specific effect which they may have on physiological functions, that is to say by their pharmacological properties, a criterion which the Court has used in past decisions.

In cases where it is difficult to determine whether a product is to be classified as a 'medicinal product' or as a 'cosmetic product', account should be taken of its presentation, of the manufacturer's intention and of the impression made by the product

(b) The *Commission* points out that a single product may meet the two definitions of 'medicinal product' and 'cosmetic product', but that overlapping of the two sets of rules is inconceivable.

The Community legislation concerning medicinal products allows of no derogations, and the scheme of Directives 65/65 and 76/768 shows that the two sets of rules governing medicinal products and cosmetic products are mutually exclusive. That fact is clear, moreover, from the fifth recital in the preamble to Directive 76/768 and from Article 7 thereof.

The *French Government* observes that minoxidil may not be used in cosmetic products; the *Spanish Government* points out that, in the definition given in Article 1 of Directive 76/768, cosmetic products do not have the effects of medicinal products; and, finally, the *United Kingdom* considers that the product must be classified as a 'medicinal product' and that the fifth recital in the preamble to Directive 76/768, the only provision which gives a clear indication of the delimitation of the scopes of the two directives concerned, shows clearly that the two sets of rules which they introduce are mutually exclusive.

(c) The *Italian Government* observes that the definitions given by the two directives are not harmonized, and accepts that a cosmetic product may have the effect of modifying certain physiological functions subject to the dual proviso that such modification must be envisaged in Directive 76/768 — as is the case, for example, for anti-perspirant products and products for tanning without sun — and that it must be unconnected with any pathological condition. Since the restoration of the hair growth function is not provided for in Directive 76/768, a product intended for that purpose should therefore be classified as a medicinal product.

2. *Farzoo* considers that, on the contrary, the criteria for delimitation given in the fifth recital in the preamble to Directive 76/768 lead to the conclusion that a product such as minoxidil is a cosmetic product.

That recital refers to positive criteria — the area and purpose of application of the product concerned — and to negative criteria — the product must not be exclusively intended to protect from disease or intended to be ingested, inhaled, injected or implanted in the human body. On the one hand, products containing minoxidil are not intended to protect from disease or to be ingested, inhaled, injected or implanted in the human body. They cannot therefore be excluded from the scope of Directive 76/768 on those criteria. On the other hand, they do meet the two criteria of area and purpose of application. That reasoning is all the more powerful in so far as Directive 76/768, which is more recent than Directive 65/65, considered in detail the problem of the delimitation between the concepts of 'medicinal product' and 'cosmetic product'.

F. Grévisse
Judge-Rapporteur