OPINION OF MR ADVOCATE GENERAL LENZ
delivered on 19 February 1991 *

Table of contents

* Original language: German.

Mr President,
Members of the Court,

A — The facts

1. In the present reference for a preliminary ruling by the Hoge Raad der Nederlanden, this Court is again asked to define the concept of medicinal product within the meaning of Council Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products [1] and to elucidate the relationship between that concept and the concept of cosmetic product within the meaning of Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products. [2]

2. The facts, for the details of which reference may be made to the Report for the Hearing, may be summarized as follows: the parties to the main proceedings (hereinafter referred to as 'the plaintiff' and 'the defendant') are in dispute as to whether the defendant may market a hair restorer as a cosmetic product. The plaintiff produces and markets under the name 'Regaine' a preparation to combat male baldness, containing as its active ingredient 2% of a substance the short name of which is 'minoxidil'. In the Netherlands — and also, according to the plaintiff, in other Member States of the Community and non-member countries — that product is registered as a medicinal product; it is marketed as a proprietary medicinal product. The defendant markets in the Netherlands under the name 'Minoxidil' a product whose composition is apparently the same as or similar to that of the plaintiff's product; the defendant's product, however, is marketed not as a (proprietary) medicinal product but as a cosmetic product for encouraging hair growth or counteracting male baldness.

3. The plaintiff took the view that the product marketed by the defendant constituted a medicinal product within the meaning of the Netherlands legislation and that by marketing it as a cosmetic product the defendant was infringing that legislation and thereby also acting unlawfully towards the plaintiff. The defendant considered that its product did not constitute a medicinal

1 — Council Directive 65/65/EEC of 26 January 1965 (OJ English Special Edition 1965-1966, p. 20). Directive 89/341/EEC (OJ 1989 L 142, p. 11) has replaced the term 'proprietary medicinal product' by 'medicinal product' in the title of Directive 65/65; it must be transposed before 1 January 1992.

2 — Council Directive 76/768/EEC of 27 July 1976 (OJ 1976 L 262, p. 169).

product, since male baldness was not a disease. The plaintiff called upon the defendant to refrain from its actions, and initiated proceedings for an interim order to that effect. The Hoge Raad, called upon to consider the matter in an appeal for cassation, took the view that the concept of medicinal product must have the same meaning in the Netherlands as in the Community legislation. It referred in that regard to Article 1(2) of Directive 65/65, which reads as follows:

'For the purposes of this Directive, the following shall have the meanings hereby assigned to them;

...

Medicinal product:

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.'

4. The national court's *first question* concerns that provision:

'(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?'

5. The *second question* concerns the delimitation between the concepts of 'medicinal product' and 'cosmetic product'. It reads:

'(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?'

6. The definition of the concept of a 'cosmetic product', to be compared here with that of a medicinal product, is given in Article 1(1) of Directive 76/768 in the following terms:

'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'.

B — Analysis

The first question

7. The first question concerns the relationship between the two parts of the abovementioned definition of the concept of a medicinal product. The Hoge Raad seeks, essentially, to ascertain whether the second part of that definition requires that the 'restoring, correcting or modifying [of] physiological functions in human beings' must be for one of the purposes stated in the first part of the definition, that is to say 'for treating or preventing disease in human beings'. Everything seems to point to the conclusion that such is not the case, and that the national court's *first question* must thus (in agreement with all those who have submitted observations, other than the defendant) be answered *in the affirmative.*

8. *I. 1.* That solution is in accordance, first of all, with the *wording* and *structure* of the definition. That definition comprises two mutually independent parts, which means that a product need meet the conditions of only one part — and not both — in order to be classified as a medicinal product.[3] The first part of the definition, which refers to the presentation of the product, establishes a link between the concepts of 'medicinal product' and 'disease': a product may be classified as a medicinal product under this part of the definition only if it is 'presented for treating or preventing *disease* in human beings or animals'.[4] The second part of the definition, which does not refer explicitly to the preparation of the product but to the fact that it 'may be administered' for one of the purposes listed, does not establish any such link between the concepts of 'medicinal product' and 'disease'. Had such a link been intended, the authors of the directive could have simply copied the first part word for word and couched the second part in, for instance, the following terms:

'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 treating or preventing disease in human beings or animals.'

9. The fact that such an obvious alternative was not seized upon supports the view that in that respect an independent meaning should be assigned to the second part of the definition, which means that the use of the phrase 'restoring, correcting or modifying physiological functions in human beings or in animals' does not presuppose an intention to treat or prevent disease.

10. *2.* That conclusion based on formal considerations — the wording and structure of the provision — is firmly supported by the *meaning and purpose* of the regulation. It is clear from its preamble that Directive 65/65 pursues two aims. First — and foremost — it seeks to ensure the protection of public health (but the means employed to that end must be devised in such a way as not to hinder trade in medicinal products within the Community) (first and second recitals). Secondly, disparities between national provisions which hinder the trade

3 — See the judgment in Case 227/82 *van Bennekom* [1983] ECR 3883, paragraphs 22 and 23.

4 — Emphasis added.

in proprietary medicinal products within the Community and thus directly affect the establishment and functioning of the common market must be removed through the approximation of laws (third to fifth recitals).

11. In its judgment in *Tissier*,[5] which concerned the concept of 'making a medical diagnosis', the Court of Justice concluded from those two objectives that

'the definition of medicinal product given in Article 1 of Directive 65/65 may not be interpreted restrictively'.[6]

12. A teleological approach, in complete consistency with that general finding, also leads in the actual circumstances of the present case to the *broad* interpretation advocated by the plaintiff, the Commission and the Member States which have submitted observations.

13. *(a)* I shall first consider the aspect of the protection of public health.

14. *(aa)* Proprietary medicinal products for human use intended to be placed on the market in Member States require an authorization under Chapter II of the directive, which specifies the relevant conditions and detailed rules; Chapter III deals with the suspension and revocation of such authorization in general. Chapter IV contains provisions concerning labelling, non-compliance with which may lead to the suspension or revocation of the authorization. Article 21 provides that the authorization may not be suspended or revoked on grounds other than those set out in the directive. The requirement of an authorization thus forms the hub and the linchpin of the whole system of rules.

15. The definition of the concept of 'medicinal product' (as a component element in the concept of proprietary medicinal product) is decisive in determining whether that requirement applies to a specific product. The possibility that authorization may be refused from the outset[7] and the product thus kept from the consumer acquires crucial significance in that context. That possibility of refusing the mandatory authorization is intended to keep products which may be harmful to public health off the market. The definition must therefore ensure that that machinery comes into operation whenever the placing of a product on the market may — at least potentially — bring about one of the dangers which the specified grounds for refusal are designed to avert. In other words, it must ensure that the protection afforded by the grounds for refusing authorization is not ineffectual.

16. Three different categories may be discerned among the grounds for refusal set out in Article 5.

17. The first category seeks to protect public health against actual, material dangers. It covers the cases of actual harmfulness and inadequate therapeutic efficacy. Authorization is to be refused 'if, after verification of the particulars and documents listed in Article 4, it proves that the proprietary medicinal product is harmful in the normal conditions of use, or that its

5 — Case 33/85 *Procureur de la Republique* v *Tissier* [1986] FCR 1207

6 — Paragraph 26

7 — The grounds for the suspension or revocation of the authorization set out in Article 11 of the directive are closely modelled on the grounds for refusal in Article 5

therapeutic efficacy is lacking'. In that case, the presence of one of the two grounds for refusal is established on the basis of the properties of the product as they appear from the documents submitted.

18. The second category also refers to the established properties of the product, namely to the fact 'that its qualitative and quantitative composition is not as declared'. This is what the plaintiff termed the 'quality' criterion at the hearing. In my opinion, however, inadequate quality in that sense is, as a ground for refusing authorization, closely related to the abovementioned grounds of harmfulness and inadequate therapeutic efficacy. The fact that the composition of a product differs from that declared is not in itself prejudicial to public health. However, there is an undeniable danger in such cases that, having regard to the intended mode of administration, the product may, on account of its actual composition, have properties other than those which it would have had if the composition had been as declared.[8] That detracts from the value of the particulars concerning composition which, together with other particulars and documents, form the basis of the authorities' assessment of the harmfulness and therapeutic efficacy of the product. In particular, it casts doubt on the reliability of the results of the tests to be provided under Article 4(8). It thus appears that this ground for refusal, in comparison with the grounds of harmfulness and inadequate therapeutic efficacy, represents a safety net in the sense that it prevents products from reaching the market when it cannot be properly established whether either of the previously mentioned grounds for refusing authorization exists.

8 — Cf. Article 4(5) and (6) of Directive 65/65.

19. The same is true, in my opinion, for the third category of grounds for refusing authorization listed in Article 5, which refers to certain formal irregularities. This includes cases where the therapeutic efficacy of the product 'is insufficiently substantiated by the applicant' and where the particulars and documents submitted in support of the application do not comply with Article 4. In the former case, the therapeutic efficacy is in doubt for want of sufficient substantiation, leaving open the possibility that the product has no such efficacy. In the latter case, it is impossible to reach a decision on either the question of harmfulness or that of therapeutic efficacy, since the required documents are not all available.

20. In the light of that consideration of the various categories of grounds for refusing authorization, their common aim may be summed up as follows: proprietary medicinal products are to be prevented from reaching the consumer when it is clear, or in any event cannot be ruled out, that:

(i) they are harmful in the normal conditions of use, or

(ii) they have no therapeutic efficacy.

21. Both of those aspects are directly linked to the definition of a medicinal product. Mrs Advocate General Rozès was right in pointing out, in her Opinion in *van Bennekom*,[9] that the first part of the definition in Article 1(2) of Directive 65/65 is

9 — Opinion in Case 227/82 *van Bennekom* [1983] ECR 3883, at pp. 3908-3910.

intended to prevent the marketing, under the title of medicinal product, of products to which the manufacturer or seller attributes properties for treating or preventing disease when they are devoid of such properties. Authorization to place such a product on the market must logically be refused under Article 5 of the directive because it lacks any therapeutic efficacy.

22. The first part of the definition in Directive 65/65 is also connected, however, to the aspect of harmfulness. As I have said, the conditions of only one of the two parts of the definition need be met for a product to be classed as medicinal. It follows that the consideration of the harmfulness of a product starts with the very way in which it is 'presented' within the meaning of the first part of the definition. That is indeed obvious, since it may generally be assumed that the manufacturer's 'presentation' is essentially truthful — he has nothing to gain from an unsuccessful authorization procedure. Moreover, experience shows that products having physiological effects which enable them to treat or prevent disease cannot be assumed without testing to have no harmful effects, so they too must from that point of view be subject to the authorization requirement. [10]

23. *(bb)* We now come to the second part of the definition, which is of interest in the present case, and its relationship with the characteristics of harmfulness and therapeutic efficacy, to which I have referred above.

10 — Cf. the Opinion of Mrs Advocate General Rozes, cited above, p 3911

24. (1) Turning first to the aspect of harmfulness, it must in the light of my previous observations, be asked whether it is only the properties of such products as may be used for treating or preventing disease which make it necessary, in view of their potential harmfulness, to subject the products to the authorization requirement, or whether the same may be true of other products 'which may be administered to human beings ... with a view to ... restoring, correcting or modifying physiological functions in human beings'. In my view, the latter alternative must clearly be confirmed. In that connection, a clear distinction must be drawn between two things: on the one hand, any deviation from a normal physiological condition (which itself generally allows of a wide range of possibilities) and, on the other, the importance of the undesirable consequences which the administration of a medicinal product may entail. The relationship between the two is not always constant. For example, a normal case of 'ordinary' influenza will certainly be regarded as a disease within the meaning of the first part of the definition in Directive 65/65, whereas temporary sleeplessness triggered by transient factors such as overeating, objective worries or overexertion will not.

25. However, it does not necessarily follow that the composition of a medicinal product to combat influenza is potentially more harmful than that of a product to relieve sleep disturbances of the kind described. That reveals, as far as the potential harmfulness aspect is concerned, one reason for separating the concept of 'medicinal product' from that of disease: consumers desire, and manufacturers produce, preparations which make it possible to be 'more' than 'just' healthy. If we assume, as the

national court obviously does, that male baldness is not a disease,[11] then the parties' products are preparations of that kind. Contraceptive preparations constitute a further example of a similar kind. Article 6 of Directive 65/65 specifically mentions, as the plaintiff rightly points out, proprietary medicinal products intended for use as contraceptives. That means that contraceptives are, or at least may be, medicinal products (incontrovertibly so in the case of the pill). The condition which such products are intended to avert — pregnancy — is not a disease (unless human reproduction is taken to be only the result of recurring illness).

26. A second reason, linked with the foregoing considerations, for holding that, as regards the harmfulness aspect, the concept of medicinal product should be separated from that of disease, is to be found in the many difficulties which may be encountered in defining the limits of the latter concept. The type of case which immediately springs to mind is one in which physiological functions or manifestations present in all human beings (among others, heartbeat, blood pressure, blood supply to organs and glandular function) may be at any point on the scale between the healthy and the pathological.[12] The boundary between (still) 'healthy' and (already) 'diseased' is not always obvious. It is often not immediately possible to determine whether a product capable in such cases of correcting an impairment up to a certain degree but not covering the whole range of the disease, including the most serious forms, is a product for treating disease. That no doubt also explains why the second part of the Community definition refers, *inter alia*, to 'correcting' physiological functions.

27. This all goes to show that protection against potentially harmful medicinal products would be subject to considerable uncertainty if the defendant's view were followed. That interpretation could, moreover, also be applied to phenomena, such as pain, whose relationship with the concept of disease is unclear.[13]

28. A third reason for separating the two concepts is to be found, in my view, in a group of products which perform certain ancillary functions in a medical context, although they are not of direct use for treating or preventing disease. They include, *inter alia*, narcotics, mentioned in Article 16 of the directive as proprietary medicinal products, which may also be regarded as potentially harmful.

29. To recapitulate, it may be concluded that having regard to the harmfulness aspect in Article 5 of Directive 65/65 a product cannot justifiably be excluded from the concept of medicinal product merely because it is not for treating or preventing disease, since the fact that a product is for treating or preventing disease does not rule out the necessity of testing its physiological effects in the interests of public health before it is placed on the market.

11 — It is not for the Court of Justice to examine the correctness of that assumption or, therefore, the relevance of the national court's question to the settlement of the case.

12 — Or between two pathological states, such as hypertonia and hypotonia.

13 — With regard to the classification of pain relievers, just two questions may be cited here. Can pain itself constitute a disease or is it no more than a symptom of a disease? And if the former is true, what and how great a part of the body must be affected and how intense must the pain be in order to speak of a disease?

30. The Court of Justice appears also to have taken that approach in its judgment in *van Bennekom*, where it had to elaborate criteria for drawing a distinction between foodstuffs and medicinal products within the meaning of the second part of the Community definition. Although that case concerned vitamin preparations which could be classified either as foodstuffs or as medicinal products used 'for therapeutic purposes in combating certain *diseases*',[14] the Court did not choose to base the distinction on that latter concept, but ruled:

'The classification of a vitamin as a medicinal product within the meaning of the second part of the definition in Directive 65/65 must be carried out case by case, having regard to the pharmacological properties of each of them, to the extent to which they have been established in the present state of scientific knowledge.'

31. The concept of 'pharmacology' is defined as relating to the nature and composition of chemical substances and their effect on the body.[15] That is consistent with the above considerations, concentrating for the interpretation of the second part of the definition on the (potentially harmful) effects of a product rather than on an assessment of the physical condition constituting the cause for the medication.

32. (2) Those considerations are sufficient for it to be concluded that the primary aim of Directive 65/65 — the protection of public health — provides support for an affirmative answer to the national court's first question. The aspect of therapeutic efficacy, the second component of that protection, need not therefore be dealt with in any greater detail for the purposes of the first question. I shall return to it in my discussion of the second question.

33. *(b)* As regards the second objective of Directive 65/65, namely the facilitation of trade in proprietary medicinal products, it may be seen from the *van Bennekom* judgment that recourse to Article 36 of the EEC Treaty is not ruled out by the existence of directives on pharmaceutical products, since the harmonization for which they provide is not complete.[16] That fact is relevant especially where a product which is not a medicinal product (or, therefore, a proprietary medicinal product) within the meaning of Community law none the less constitutes such a product under national law and is thus subject (under national law) to an authorization requirement.[17] It is clear that any dilution of the Community law concept of medicinal product such as would be entailed by the defendant's arguments, calling into question — as we have seen — the essential interests of the protection of health, would encourage the development of differences between national rules. The resulting obstacles — in so far as they are not precluded by Articles 30 and 36 of the EEC Treaty — run contrary to the directive's aim of facilitating inter-State trade in medicinal products.

34. That is unreservedly true, in any event, where the category in which the product falls if it is held not to be a medicinal product is not itself subject to complete harmonization. I am thinking here of the one major category bordering on that of

14 — Paragraph 27; emphasis added.

15 — Meyers Enzyklopädisches Lexikon, 1978, sub 'Pharmakologie'.

16 — See the judgment in *van Bennekom*, cited above, paragraph 35.

17 — See paragraph 41 of the *van Bennekom* judgment; see also Case 35/85 *Procureur de la République* v *Tissier* [1986] ECR 1207, paragraph 22, and point 5 of the Opinion of Mr Advocate General Tesauro in Case C-369/88 *Delattre* [1991] ECR I-1487 at p. I-1511.

medicinal products, namely foodstuffs (within the meaning of Community law). Where, however, the product in question, if not classified as a medicinal product, falls within the scope of the aforementioned directive on cosmetic products, as is conceivable in the present case, then the means of excluding free movement of goods available to Member States are subject to even stricter provisions than under Article 36 (see Articles 12 and 13 of the directive). We must not, however, lose sight of the fact that Directives 65/65 and 76/768 each seek, in areas of divergent sensitivity, to reconcile the requirements of health protection and the free movement of goods. Where the properties of a product require, on grounds connected with health protection, that it should be made subject to the authorization requirement under the rules on medicinal products and that the principle of free movement of goods should thus necessarily be curtailed, it is in my view unwarrantable, in pursuance of that principle, to subject the product to another set of rules (namely those applicable to cosmetic products) the essence and purpose of which emphasize other aspects.

35. *II.* While I thus propose that the Court should follow in principle the plaintiff, the Commission and the Member States which have submitted observations when answering the Hoge Raad's first question, there can be no question of extending indefinitely the concept of medicinal product. The defendant rightly points out that the second part of the definition in Directive 65/65 is couched in extremely broad terms, particularly in its reference to 'modifying physiological function in human beings'. That wording obviously covers foodstuffs and perhaps also cosmetic products (which Directive 65/65 describes, in the possibly somewhat too narrow language of the day, as 'toilet preparations'), although both those groups of products are specifically to be excluded, in accordance with the third recital in the preamble to the directive, from the concept of medicinal product. However, the question of the delimiting criteria to be taken into consideration here extends beyond the framework of the national court's first question, which concerns only the specific problem of whether the concept of disease is an appropriate delimiting criterion. The fact that it is not does not mean, contrary to the defendant's view, that the concept of medicinal product is extended unreasonably but merely that the delimiting criteria must be established in another way — which is the subject-matter of the second question.

36. *III.* All the above considerations lead me to propose that the Hoge Raad's first question should be answered as follows:

'The fact that a product is not for treating or preventing disease in human beings or animals within the meaning of the first part of the definition set out in Article 1(2) of Directive 65/65 does not preclude its administration to human beings with a view to restoring, correcting or modifying physiological functions and, therefore, its being a medicinal product within the meaning of that directive.'

The second question

37. *I.1* In referring to delimiting the concepts of 'medicinal product' and 'cosmetic product', the national court is obviously assuming that the conditions set out in the terms of each definition are met.

If a specific product is covered by the wording of only one definition and not the other, then there can be no question of classifying it other than under the first definition, and vice versa. In such a case there is no need for any specific delimitation.

38. The hypothesis on which the national court's second question is based, namely that the two definitions can be (and in the present case do) overlap, is at first sight surprising. A definition should, by its very nature, clearly and unambiguously indicate the boundaries of a concept — and thus the scope of the rules attaching to it. The fifth recital in the preamble to Directive 76/768 explicitly acknowledges, however, just such a possibility of overlapping. The recital begins, in its first and second clauses, by emphasizing that it is necessary to exclude medicinal products and proprietary medicinal products [18] from the scope of the directive by separating cosmetic products from medicinal products, and indicates in its third clause that such a delimitation follows 'in particular' (and thus not exclusively) from the definition of cosmetic products. The fourth clause immediately goes on to state:

'this directive is not applicable to the products that fall under the definition of cosmetic product but are exclusively intended to protect from disease'.

18 — Like the German text, the English text of Directive 76/768 differs from that of Directive 65/65 in that it refers to 'pharmaceuticals' rather than 'medicinal products' and to 'pharmaceutical specialities' rather than 'proprietary medicinal products' But that is to be regarded as a mere terminological variation, I consider the content of the concepts to be identical in both cases

39. *2.* An examination of the two definitions demonstrates that an overlap is indeed possible.

40. *(a)* The question whether such overlapping is conceivable between the first part of the definition of a medicinal product (the 'presentation criterion') and the definition of a cosmetic product and, if so, what consequences that might entail may be left open, since the Hoge Raad is manifestly concerned only with the delimitation of the second part of the definition of a medicinal product, as may be seen from the way in which its two questions relate to each other.

41. *(b)* It is obvious, in my view, that the second part of the definition in Directive 65/65 (leaving aside the alternative of 'making a medical diagnosis', which is not relevant here) may overlap with the definition of a cosmetic product. The definition of a cosmetic product refers only to the application of the product to certain — external — *parts* of the body. Here, the delimitation between cosmetic and medicinal products is relatively clear, and there can be no question of overlapping if the product is for application to other parts of the body — broadly speaking, for internal use. [19] If, however, as in the present case, it is for external application (application 'on the body', in a literal translation of the German version of Article 1(2) of Directive 65/65), then the two definitions may overlap as regards that point, so the delimitation must be derived from the *purpose* of the application.

19 — See also the clarifications in the fifth clause in the fifth recital in the preamble to Directive 76/768

42. As regards that purpose, however, it must be noted that the concepts of 'restoring, correcting or modifying physiological functions in human beings or in animals' are not inherently limited, and that the definition of cosmetic products does not refer to those concepts to distinguish them from medicinal products, but introduces its own concepts, which are not compared with those of Directive 65/65 ('cleaning' the specified parts of the body, 'perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours'). It is apparent that the definition of a medicinal product is based on the effect of the product — which in certain circumstances may be considerable from a medical point of view — on physiological functions, whereas the definition in Directive 76/768 is based on specified cosmetic objectives. Both definitions apply if a product serves one of the purposes listed in Directive 76/768 and *in order to do so* produces certain — intended or inevitable — effects on physiological functions. Those effects constitute one of the aims of the product, inseparable from its cosmetic purpose.

43. Examples of cases where the definitions overlap are to be found in Annex I to Directive 76/768. For instance, depilatories, the eighth item on that list, may modify not only hair stability by their chemical effects on body hair but also skin function. They thus fall both within the second part of the definition of medicinal product and under Article 1(2) read in conjunction with Article 1(1) ('change their appearance') of Directive 76/768.

44. Anti-perspirants (the ninth item on the list) modify the function of the sweat glands by constricting them, which is relevant for the purposes of the definition in Directive 65/65, but they also have an effect on body odours, thus meeting the criteria of Article 1 of Directive 76/768.

45. *II.* Since there is nothing in Annex I to Directive 76/768 which classifies the product in issue as a cosmetic product, as hair restorer is not amongst the examples cited, it is necessary to clarify the interrelationship of the two definitions in the event of overlapping in cases where there is no indication as to the proper classification. Such clarification is necessary whenever there would otherwise be a clash between the rules on proprietary medicinal products (Directive 65/65) and those on cosmetic products (Directive 76/768), since those two sets of rules are, as the Commission and the Spanish Government have rightly pointed out, mutually incompatible. Directive 65/65 is based on the principle that proprietary medicinal products must be made subject to a special authorization before they are placed on the market (Article 3 et seq.). Under Directive 76/768, products which meet the requirements laid down therein may in principle be sold freely (Article 7(1)).

46. *1.* The parties to the main proceedings and those who have submitted observations have proposed two alternative solutions to this problem. In the defendant's view, when the definitions overlap, it is generally to be assumed that the product is a cosmetic product. There might be an exception only in the two cases specified in the fifth recital in the preamble to Directive 76/768, namely where the product is exclusively intended to protect from disease or intended to be ingested, inhaled, injected or implanted in the human body. The plaintiff and the other

parties which have submitted observations propose, essentially, the opposite course, taking the definition of a medicinal product rather than that of a cosmetic product as the basis for establishing the delimitation. They take the view that the concept of medicinal product prevails in the event of overlapping. The plaintiff, the United Kingdom and the Italian Government thus all — albeit with differences in detail — seek the limits of the second part of the definition (which is broadly expressed, as has been said) in a criterion based on the effects of the product in question rather than in the definition of a cosmetic product. I endorse that view. [20]

47. The basis for the considerations is the practical effect of the two directives in issue. That can best be taken into account by defining the scope of each measure in accordance with its respective objectives. I have already pointed out that both directives are intended to reconcile the aspects of free movement of goods and protection of health in areas of divergent sensitivity. Protection of health is the *primary* objective pursued. [21] The directive on medicinal products concerns products which may be comparatively more negative in their effects on public health. For that reason, it lays down a prohibition on marketing unless authorization has been obtained, whereas Directive 76/768 lays down certain conditions which cosmetic products must meet (Articles 2 to 6) but which, if met, mean that the products are in principle freely marketable (Article 7(1)).

48. Consequently, as has been said, a product whose properties make it clear that the verification by national medical authorities provided for in Directive 65/65 is, in the light of the objectives of that directive, necessary may on no account fall within the scope of the arrangements under Directive 76/768. To take any other approach would be to disregard not only those objectives but also the demarcation of the roles played by the two directives with regard to the protection of public health. The delimitation between medicinal products and cosmetic products may therefore take the definition of a cosmetic product as its starting point only if such an approach will ensure that all products which must, in view of the objectives of Directive 65/65, be governed by that directive do actually fall within its scope. If not, the starting point for that delimitation must be the definition in Directive 65/65, the precise meaning of which must be ascertained by interpretation where appropriate.

49. I am of the opinion that the definition of a cosmetic product (in Article 1(1) of Directive 76/768) does not provide such assurance. That is indicated by the fifth recital in the preamble to that directive, according to which it 'is not applicable to the products that fall under the definition of cosmetic product but are exclusively intended to protect from disease'. That indication links up with the consideration already mentioned that overlapping of the two definitions concerned is possible precisely because the terms of Directive 76/768, which outline the purpose of the product, do not make it possible to draw any definitive conclusion as to the effects

20 — As has already been stressed, the following considerations, in accordance with the facts of the case, concern only the relationship between Article 1*(1)* of Directive 76/768 and the second part of the definition of a medicinal product. Other considerations apply to the products listed in Annex I to the directive, to which Article 1*(2)* refers. If a product corresponds to one of the alternatives listed, it is established as being a cosmetic product. That annex is, however, also relevant to the delimitation where the product in issue does not correspond to any of the alternatives listed in it, thus limiting the primacy of the definition of medicinal product to a certain extent in that respect. I shall return to this question (point 77).

21 — See the first recital in the preamble to Directive 65/65 and the third recital in the preamble to Directive 76/768.

produced by the product in the fulfilment of its cosmetic purpose. It is clear that a product for 'protecting' the skin, for example, in order to keep it 'in good condition' is not a cosmetic product if it is 'exclusively intended to protect from disease'. One point is thus established, namely that at least in this specific case the definition of a medicinal product prevails over the definition of a cosmetic product — in other words, in this case of overlapping, the definition of a cosmetic product is not sufficient to ensure that all products which should in accordance with the meaning and purpose of Directive 65/65 be classified as medicinal products are in fact so classified.

50. Unlike the United Kingdom, I do not believe that the phrase cited from the fifth recital refers to the first part of the definition of a medicinal product. It relates not to the presentation [22] but to the purpose [23] of the product. That is also — with all the differences between the various language versions — the basis for the second part of the definition of a medicinal product. It is known from the *van Bennekom* judgment that a product for preventing disease (that is to say, a product which actually possesses such properties) is to be classified, regardless of its presentation, as a medicinal product within the meaning of the second part of Article 1(2) of Directive 65/65. [24]

51. However, the defendant considers that the abovementioned indication derived from the fifth recital is relevant only to the case referred to therein and cannot be generalized. At the hearing, the further question arose whether the word 'exclusively' used in that indication militated against such a generalization.

52. As far as that question is concerned, first of all, I consider that the word 'exclusively' relates, in the context of the wording chosen, only to the purpose of the product ('exclusively intended to protect from disease') and has nothing to do with the problem of whether the definition of a medicinal product is to prevail only in such a case. Because of that more general problem, it is significant that, apparently quite consciously, the authors of the directive did not take the opportunity of introducing conclusive criteria for the delimitation of the products which it concerned from medicinal products — criteria which could have taken account of the requirements of Directive 65/65. Had that been intended, such criteria would have had their place not in the preamble but in the text of the directive itself; however, as I have said, it may be seen from the third and fourth clauses in the fifth recital that they are not contained in the text.

53. A preamble, however, may not and cannot replace a Community legislative text; its role is merely to clarify an existing text. Such clarification (cf. Article 190 of the EEC Treaty) need not be exhaustive but may confine itself to the basic features of the measure. [25] The fact that no attempt was to be made in the fifth recital in the preamble to Directive 76/768 to make a conclusive delimitation is also clear from the arrangement of the third, fourth and fifth clauses in that recital. The third clause, by its use of the term 'in particular', shows that the definition of a cosmetic product does

22 — 'Presented'.

23 — 'With a view to'.

24 — Paragraph 22 of the judgment.

25 — See Case 250/84 *Eridania* v *Cassa Conguaglio Zucchero* [1986] ECR 117, paragraph 38; consistent case-law since that date.

not contain all the details required for the delimitation. The fourth and fifth clauses are not, however, logically devoted to the details still lacking, but deal with two borderline cases. In the opinion of the authors of the directive, the first of those cases[26] cannot be resolved on the basis of the definition contained in the directive. As regards the second case (fifth clause), on the other hand, it is merely specified that it does not meet the conditions of Article 1(1) of the directive.[27] The wording of the preamble here returns to the area in which the definition contained in the directive makes the delimitation possible without adding any further details and where it does not overlap with that in Directive 65/65.

54. Evidence is also to be found in Annex I to Directive 76/768 to support the conclusion that the fourth clause in the fifth recital does not necessarily constitute the sole case of overlapping in which the definition of a medicinal product prevails over that of a cosmetic product. The second item on the list contained in that annex gives as an example the following type of cosmetic product: 'Face masks (*with the exception of peeling products*)'.[28] Peeling products are not intended to protect from disease. Their purpose is rather to soften the horny layer in order to enable the outermost layer to be dissolved and the layer below to be revealed, thus improving (freshening) the appearance. Because they act in that way, such products fall within the definition of a medicinal product — inasmuch as they influence a skin function (the repeated desquamation of the outermost layer) — but also within the definition of a cosmetic product — inasmuch as they are intended to change the appearance of the skin. Because they are excluded from the concept of a cosmetic product, they fall automatically (and solely) within that of a medicinal product.[29]

55. I conclude from all the foregoing that the authors of Directive 76/768 did not intend to undertake, within either the text or the preamble of that directive, an exhaustive delimitation covering the present problem and taking into account the requirements of Directive 65/65. Notwithstanding the arguments which the defendant seeks to draw from the fifth recital in the preamble to Directive 76/768, the conclusion must be maintained that the definition in that directive does not, in the event of overlapping, provide sufficient criteria to ensure that all products which must, in accordance with the meaning and purpose of Directive 65/65, be classified as medicinal products are actually so classified. In that case, the delimitation is to be operated in such a way that the definition of a medicinal product prevails over that of a cosmetic product.

56. In the answer to the Hoge Raad's second question, that fundamental option might be expressed as follows:

26 — Fourth clause: 'this directive is not applicable to the products that fall under the definition of cosmetic product but are exclusively intended to protect from disease'

27 — It is established that application to 'the various external parts of the human body . . . or with the teeth and mucous membranes of the oral cavity' (Article 1) does not cover cases where the products in question are intended to be 'ingested, inhaled, injected or implanted in the human body'

28 — Emphasis added

29 — The explanation for that classification seems to be afforded by the substances dissolving hard skin, which are also contained in products for the treatment of corns or acne; for peeling products, the possible harmful effects of contact with the eyes, which is difficult to prevent even when correctly applied, must apparently also be taken into consideration.

'A product which is not presented for treating or preventing disease in human beings or animals and which, although not mentioned as being a cosmetic product in Annex I to Directive 76/768, would constitute a cosmetic product under Article 1(1) of Directive 76/768 must nevertheless not be classed as such a product but as a medicinal product within the meaning of Directive 65/65 if it may be administered to human beings with a view to restoring, correcting or modifying physiological functions.'

57. 2. That decision raises, as has rightly been pointed out by the plaintiff, the United Kingdom and the Italian Government, the question of a more precise delimitation of the concept of medicinal product derived from the second part of the definition in Directive 65/65 (leaving aside the question of 'making a medical diagnosis', with which we are not concerned here). By that interpretation, the part of the definition of medicinal product which is applicable here must be confined to what is necessary in view of the objectives of the directive. All products which on the basis of that interpretation do not, or no longer, fall within the definition of a medicinal product but do meet the conditions of the definition of a cosmetic product, are to be classified as cosmetic products. Products which are, in the light of that interpretation, medicinal products within the meaning of the definition in Directive 65/65, on the other hand, can be classified only as medicinal products and not as cosmetic products.

58. I should again like to compare, as I did in my considerations concerning the Hoge Raad's first question, the objectives of the directive with the part of the definition in issue here.

59. *(a)* Once again, we should begin with the protection of public health, which is the primary objective, covering protection against harmful and therapeutically ineffective products.

60. *(aa)* As far as the aspect of harmfulness is concerned, it is possible to draw, as the plaintiff and the Italian Government do, a parallel with the judgment in the *van Bennekom* case, cited above. In that judgment, having regard to the fact that overconsumption of vitamins may be harmful to human health, the Court made the classification of such vitamins under the second part of the definition of a medicinal product dependent on the 'pharmacological properties' of the product, 'to the extent to which they have been established in the present state of scientific knowledge', thus, as I have stated, basing its reasoning on the physiological effects of the product. That approach is correct, as may be seen, in the first place, from my considerations regarding the first question. Furthermore, it constitutes the link between the terms used in the second part of the definition of a medicinal product (restoring, correcting or modifying physiological functions) and the concept of harmfulness. All refer to the physiological effects of the product in question. However, whereas the terms used in the definition cover all effects — however minimal — the concept of 'harmfulness' refers only to certain specifically negative effects.

61. The answer to the Hoge Raad's second question should therefore establish the following principle:

'It should be determined on a case-by-case basis whether such a product is intended for the purpose of "restoring, correcting or

modifying physiological functions" in human beings or animals in the light of its pharmacological properties as they are established in the present state of scientific knowledge.'

62. *(bb)* The present case prompts us now to clarify in a number of regards the criterion thus laid down by the Court.

63. *(1)* First of all, it is necessary to reply to an argument of the French Government, which wishes to classify the product in issue as a medicinal product on the ground, *inter alia*, that if it is ingested (a possibility which cannot be ruled out, in particular in the case of children) untoward effects on health might ensue. As the defendant rightly points out, the only effects to be considered are those which the product has when applied to the part of the body to which, in the judgment of the average user, it is to be administered (which may be clear from the manufacturer's instructions) (hereinafter referred to as 'the proper place' of administration). That limitation is clear, in the first place, from the wording of the second part of the definition in Directive 65/65, which focuses on the administration of the product, that is to say an act whereby its specific properties are to be intentionally rendered operative. There can, however, be no question that a product is administered if, contrary to its intended purpose — accidentally, for example — it is applied to a part of the human body other than that for which it is destined. That approach is borne out by Article 5 of the directive, under which authorization to market the product is to be refused if it is harmful 'in the normal conditions of use'.[30] Effects which may arise when a product is applied to a part of the body other than the proper place should therefore not be taken into consideration. Otherwise, many products which are manifestly not medicinal products would have to be classified as such (nail varnishes, for example, which contain solvents).

64. On the basis of those reflections, it should be made clear in the answer to the Hoge Raad that the pharmacological properties concerned are only those

'observed when the product is administered to the proper part of the human body'.

65. *(2)* Furthermore, it is also necessary in my opinion to specify the quality which those properties must possess to enable the product in question to be regarded as a medicinal product within the meaning of the part of the definition under consideration.

66. In the view of the Italian Government, in the relationship between medicinal products and cosmetic products all products which modify physiological functions are medicinal products unless, despite that effect, the directive on cosmetic products explicitly (in Annex I) classifies the product in question as a cosmetic product. It cites the examples of anti-perspirants and products for tanning without sun. I do not believe, however, that such an approach makes it possible to reach an adequate solution in the present case. Generally speaking, Annex I to Directive 76/768, which contains an 'illustrative list', has the sole function of specifying that the items on that list are cosmetic products. It is not, however, intended to establish that products

30 — That expression has, however, a rather wider meaning than the criterion of the proper place of application to be borne in mind here. It also covers, in particular, the frequency and duration of the administration.

not listed do not possess that quality.[31] The significance for the problem raised in the present case is that if a product modifies physiological functions and corresponds to one of the possibilities listed in Annex I, then it is a cosmetic product. If, however, it does not correspond to any of those alternatives, the converse may not be concluded. That consequence, drawn from general considerations on the nature of the annex, seems to me to be particularly justified by the fact that the authors of the directive listed the products in the annex 'by category', in order to convey the clearest possible impression of the possibilities. They were not concerned, as may be seen from the mention of creams and powders, with designating specifically the difficult cases. Moreover, I would not wish to rule out the possibility that many products listed in Annex I but not mentioned by the Italian Government can modify — even to a totally insignificant extent — physiological functions. All the above should lend support to the 'case-by-case' approach decided upon by the Court in the *van Bennekom* case.

67. The United Kingdom proposal, with which I wish to concur, derives from the same consideration. In the United Kingdom's view, the conditions of the part of the definition of a medicinal product with which we are concerned here are fulfilled whenever the product interferes with physiological functions in an exceptional manner and thus constitutes a sufficient risk to public health to justify the application of the authorization system under Directive 65/65.

31 — The peeling products mentioned in the second item on the list constitute an exception.

68. Two grounds support that criterion. First, it is manifestly in harmony with the meaning and purpose of the directive, in so far as the latter serves to protect public health and in that respect contains rules to prevent harmful medicinal products from reaching the consumer. Secondly, it is consistent with the wording of the relevant part of the definition of medicinal product, which concentrates on the effects of the product; those effects are more precisely defined — from the point of view of harmfulness — without laying down any further conditions.

69. In the same context, I should like to reject the plaintiff's view that in the absence of pharmacological properties (as thus defined) the product in question nevertheless constitutes a medicinal product if the authorities of other Member States have classified it as such. In the first place, the directive does not provide that the authorities of Member States must be guided by the decisions of the authorities of other Member States. Each authority makes its own independent appraisal, which cannot thus be replaced by a decision of another authority. Furthermore, as I have already pointed out, according to the Court's case-law the concept of a medicinal product in national law may encompass more products than the Community law concept without thereby infringing Community law.[32]

70. It thus follows that the answer to the second question must include the following statement, clarifying the ruling in *van Bennekom*:

32 — See footnote 17.

'Consequently, a product is a medicinal product if it has an exceptional effect on physiological functions and therefore constitutes a risk to public health sufficient to justify the application of the authorization system laid down in Directive 65/65.'

71. (3) For the sake of completeness, I should like to make a few observations on the question of the concrete factors which national authorities may take into consideration when determining whether, in the light of the criterion elaborated above, the properties of a product qualify it as a medicinal product.

72. (a) The parties disputed before the Court the significance in that connection of an adapting directive of the Commission, Directive 87/137/EEC.[33] Under that directive, the use of minoxidil or its salts or derivatives in cosmetic products is prohibited and products containing such substances may no longer be placed on the market after 1 January 1989 or sold or disposed of to the final consumer after 31 December 1990 (see Article 1(1) in conjunction with Article 2 of the adapting directive). The plaintiff would conclude from that prohibition — introduced into Annex II to Directive 76/768 — of minoxidil in cosmetic products that the product under consideration is a medicinal product; the defendant would draw the opposite conclusion. Neither is right.

33 — Ninth Commission Directive 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 (OJ 1987 L 56, p. 20)

73. In the first place, as the United Kingdom rightly pointed out, the inclusion of prohibited substances in the relevant annexes to the directive on cosmetic products is a measure adopted by the Commission, unrelated to the course of action taken by Member States with regard to the authorization of medicinal products. Secondly, in addition to that formal distinction, there is also a substantive difference. The measure adopted by the Commission is relevant only to cosmetic products, and thus presupposes that a product is classified as a cosmetic product. It has the effect of preventing a cosmetic product from being marketed as such if it contains the prohibited substance. It relates, moreover, only to a specified *substance*, whereas classification as a medicinal product, a matter to be determined by the Member States, concerns the *product as a whole* and in particular the place of its application to the human body.

74. (b) Thus, the fact that the prohibition of specific substances under the directive on cosmetic products gives no indication as regards the classification of a product does not mean that such indications are completely lacking. If it is doubtful whether the properties of a product qualify it as a medicinal product in the light of the criterion elaborated above, it may be helpful for national authorities or national courts to compare those properties with the properties of other products whose classification as medicinal products or as cosmetic products is clear from that criterion. Here again, it is necessary to proceed on a 'case-by-case' basis.

75. (aa) First of all, as regards the utility of such an indication, I consider it important to bear in mind that any criterion based on an assessment of the effects of a product

raises a question of *proportion*. For the criterion selected in this case, it might thus be asked: how is it possible to assess whether the effect of a product (already) possesses that quality which makes it exceptional and requires the application of the authorization procedure under Directive 65/65 or whether it (still) does not reach that limit? Such an assessment requires, especially in borderline cases, a point of reference the determination of which is thus no mere academic exercise.

76. (bb) For that purpose it is possible, first of all, to make a comparison with other products whose classification as medicinal products is established because of their pharmacological properties. As is suggested by the broad terms of the part of the definition of a medicinal product under consideration, the authors thereof apparently assumed that the pharmacological properties of individual products self-evidently qualified them as medicinal products without any need for further explanation because they are *generally accepted* as such.[34] That is expressed, for instance, in Articles 6 and 16 of Directive 65/65, in which contraceptives and narcotics are classed, without further explanation, as medicinal products. Even if that central core of products whose status as medicinal products is in no doubt cannot always be helpful as a standard of comparison where preparations with completely new effects are concerned, such a comparison should nevertheless at least facilitate classification for most products.

77. (cc) The same consideration applies, basically, with regard to products whose status as cosmetic products is established. If matters are regarded solely from the point of view of Directive 65/65, it might be concluded from the third recital in the preamble that the Community legislator is assuming a central core of cosmetic products[35] established as such by general acceptance and that such products — alongside those whose status as medicinal products is clear from the considerations expounded above — may be used as further standards of comparison. Such a premiss is correct in principle. Superimposed upon it, however, is the legislative decision set out in Annex I to Directive 76/768 a list of examples of products whose status as cosmetic products is established. That annex covers a large proportion of the products to which the abovementioned general acceptance applies, and thus provides a codification in their regard; however, in so far as that codification extends beyond that general acceptance, the fact that a product is listed therein establishes its status as a cosmetic product. Thus, the first products to be taken as standards of comparison are those in Annex I to Directive 76/768. However, reference should also be made to products which are not listed in that directive but are by general acceptance classed as cosmetic products on account of their properties.

78. (dd) In the light of all of those considerations, I propose that the answer to the second question should include the following clarification:

'For the purpose of this assessment, as far as possible the pharmacological properties of

34 — See also the third recital in the preamble to Directive 65/65.

35 — See point 35 above.

the product in question should be compared with those of products classed as medicinal products because they are generally accepted as such on account of their properties; they should also be compared with the properties of cosmetic products which are classed as such in Annex I to Directive 76/769 or, failing such classification, are generally accepted as such.'

79. (cc) So far, the considerations relating to delimiting medicinal products from cosmetic products have concerned, in so far as Directive 65/65 seeks the protection of public health, protection against potentially harmful proprietary medicinal products. It may therefore justifiably be asked whether, from the point of view of therapeutic efficacy, other considerations must also be taken into account when choosing the criterion for delimitation. The view might be taken that protection against ineffective proprietary medicinal products is ensured only if it is enough that pharmacological properties which classify a product, in accordance with the abovementioned criterion, as a medicinal product are merely claimed by the manufacturer (but are not actually present). Under that interpretation, the part of the definition of a medicinal product at present under consideration would be not only a criterion of application (which it must in any event be in the light of the above considerations concerning protection against harmful proprietary medicinal products) but also a criterion of description, like the first part of the definition of a medicinal product.

80. The plaintiff appears to be advocating such a solution. It would indeed also be consistent with the wording of the second part of the definition of a medicinal product, which is based not only on the actual effects of the product but also on the effects which it seeks to produce. That leaves open the question whether that aim must derive solely from the properties of the product or whether — alternatively — it is enough for such an aim merely to be indicated by the manufacturer, although not justified by the properties of the product.

81. I should like to propose a discriminating solution. In principle, verification of therapeutic efficacy should prevent a consumer from using inappropriate medicinal products in the event of the onset or threat of a disease and the prevention or treatment thereof from being jeopardized or even frustrated. Such an approach is supported, first, by the application of the concept of 'therapeutic efficacy' which, by definition, presupposes a disease and, secondly, by the fact that the authors of the directive explicitly formulated the definition of a medicinal product in terms of a criterion of description only with reference to 'substances presented for treating or preventing disease in human beings or animals'. Medicinal products not presented for that purpose, however, cannot give rise to the risk which that machinery strives to counteract. The fact that a hair restorer such as that in issue in the present proceedings, for example, is ineffective does not constitute a danger to public health.

82. In the case of certain other products, however, which fall within the second part of the definition of a medicinal product, the fact that they are ineffective does indeed constitute a danger to public health, as is demonstrated by the *Tissier* case,[36] with regard, for example, to diagnostic products. For the purposes of the alternative part of

36 — See the judgment in *Tissier*, paragraph 27

the definition of a medicinal product under consideration, mention must also be made of narcotics, the effects of which cannot, in the interest of public health, be ignored.

83. It must be conceded that the aspect of therapeutic efficacy as understood in the foregoing considerations will not often play a part in the delimitation of cosmetic products from medicinal products. For the sake of completeness, however, it must be pointed out that in so far as a product is held out — explicitly or by implication — as possessing properties which would qualify it to be described on the basis of the above criterion as a medicinal product, it is to be classified as such if its ineffectiveness may be detrimental to public health.

84. For those reasons, the answer to the second question should also contain a part making it clear that, for the criteria arrived at,

'as a general rule only the actual properties of the product in question are relevant.

However, if the manufacturer — explicitly or by implication — holds the product out as having properties which would qualify it to be described as a medicinal product on the basis of those criteria, it constitutes a medicinal product, regardless of its actual properties, if its ineffectiveness may be detrimental to public health.'

85. *(b)* The said criteria do take into account the individual aspects of the protection of public health but they do not go beyond what is necessary for that protection, and so that interpretation is not open to doubts from the viewpoint of the free movement of goods (facilitation of trade) which is one of the preoccupations not only of the directive on proprietary medicinal products but also and more particularly of the directive on cosmetic products.

C — Conclusion

86. On the basis of all the foregoing considerations, I propose that the Hoge Raad's question should be answered as follows:

'(1) The fact that a product is not presented for treating or preventing disease in human beings or animals within the meaning of the first part of the definition set out in Article 1(2) of Directive 65/65 does not preclude its being administered to human beings with a view to restoring, correcting or modifying physiological functions and, therefore, its being a medicinal product within the meaning of that directive.

(2) (a) A product which is not presented for treating or preventing disease in human beings or animals and which, although not mentioned as being a cosmetic product in Annex I to Directive 76/768, constitutes a cosmetic product by virtue of Article 1(1) of Directive 76/768 must nevertheless not be classed as such a product but as a medicinal product within the meaning of Directive 65/65 if it may be administered to human beings with a view to restoring, correcting or modifying physiological functions.

(b) It should be determined on a case-by-case basis whether such a product is intended for the purpose of "restoring, correcting or modifying physiological functions" in human beings or animals in the light of its pharmacological properties as they are established in the present state of scientific knowledge and observed when the product is administered to the appropriate part of the human body. Consequently, a product is a medicinal product if it has an exceptional effect on physiological functions and therefore constitutes a risk to public health sufficient to justify the application of the authorization system laid down in Directive 65/65. For the purpose of this assessment, the pharmacological properties of the product in question should as far as possible be compared with those of products classed as medicinal products because they are generally accepted as such on account of their properties; they should also be compared with the properties of cosmetic products classed as such in Annex I to Directive 76/769 or, failing such classification, generally accepted as such.

(c) As far as the criteria referred to under (b) are concerned, as a general rule only the actual properties of the product in question are relevant. However, if the manufacturer — expressly or by implication — holds the product out as having properties which would qualify it to be described as a medicinal product on the basis of those criteria, it constitutes a medicinal product, regardless of its actual properties, since its ineffectiveness may be detrimental to public health.'