European Court of Justice, 30 November 1983, Van Bennekom

PHARMACEUTICAL LAW

Defenition of medicinal product

• **Definition broader than mere presentation of product**

Substances such as the vitamin preparations at issue, which are not ‘‘indicated or recommended’’ expressly as being suitable for curing, treating or preventing an infection, may none the less constitute substances ‘‘presented for treating or preventing disease in human beings or animals’’ within the meaning of the community definition of ‘‘medicinal products’’ contained in directive 65/65.

• **External form of product relevant but not decisive**

In particular, the external form given to the product in question - such as that of a tablet, pill or capsule - may in this connection serve as strong evidence of the seller's or manufacturer's intention to market that product as a medicinal product. Such evidence cannot, however, be the sole or conclusive evidence, since otherwise certain food products which are traditionally presented in a similar form to pharmaceutical products would also be covered.

• **Substance which is endowed with properties ‘‘for treating or preventing disease in human beings or animals’’ is a medicinal product**

The second question seeks to ascertain whether a substance which may have curative or preventive properties in relation to human or animal diseases, but which is not presented as such and cannot be administered to a human being or an animal with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or animals, nevertheless falls within the definition of a medicinal product for the purposes of directive 65/65.

It is apparent in this connection that a substance which is endowed with properties ‘‘for treating or preventing disease in human beings or animals’’ within the meaning of the first part of the community definition, but which is not ‘‘presented’’ as such, falls in principle within the scope of the second part of the community definition of a medicinal product.

• **Exhaustive definition**

On the other hand, a product which is covered by neither the first nor the second part of the community definition of a medicinal product may not be regarded as a medicinal product within the meaning of directive 65/65.

Status of vitamins?

• **Classification of vitamins as medicinal product must be carried out case by case**

Inasmuch as vitamins are usually defined as substances which, in minute quantities, form an essential part of the daily diet and are indispensable for the proper functioning of the body, they may not, as a general rule, be regarded as medicinal products when they are consumed in small quantities.

Similarly, it is a fact that vitamin or multi-vitamin preparations are sometimes used, generally in large doses, for therapeutic purposes in combating certain diseases other than those of which the morbid cause is a vitamin deficiency. In such cases, it is beyond dispute that the vitamin preparations constitute medicinal products.

It is, however, apparent from the file and from the observations submitted to the court, taken as a whole, that it is impossible in the present state of scientific knowledge to state whether the criterion of concentration alone is always sufficient in order to be able to determine whether a vitamin preparation constitutes a medicinal product; still less therefore is it possible to specify the level of concentration above which such a vitamin preparation would fall within the community definition of a medicinal product.

The answer to be given to the national court should therefore be that 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 such vitamin to the extent to which they have been established in the present state of scientific knowledge.

Free movement of goods

• **Prohibition on marketing of imported vitamins in pharmaceutical form or of high concentration justified when compatible with the requirements of health protection.**

The answer to be given to the national court should therefore be that where certain vitamin or multi-vitamin preparations may (a) be regarded as medicinal products within the meaning of directive 65/65, but are not covered by the legislation on medicinal products of one or more member states, or (b) are not covered by the community definition of medicinal products, the law of a member state may prohibit the sale, or the holding in stock for the purpose of supply, of such preparations imported from another member state, in particular when they are presented in a pharmaceutical form or when they are highly concentrated. However, such rules are justified only if authorizations for marketing are granted when they are compatible with the requirements of health protection.

Source: **Eur-Lex**

European Court of Justice, 30 November 1983

(…)

In case 227/82

Reference to the court under article 177 of the eec treaty by the arrondissementsrechtbank (district court), Amsterdam, for a preliminary ruling in the criminal proceedings pending before that court against
Leendert van bennekom, resident at Fijnaart en Heijningen, accused, represented by H. A. Bouman of the Amsterdam bar and C. T. Barbas of the Amsterdam bar,
(…)
Subject of the case
On the interpretation, on the one hand, of the term ‘‘medicinal product’’ in council directive 65/65/eec of 26 january 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (official journal, english special edition, 1965-66, p. 20) and, on the other hand, of articles 30 to 36 of the eec treaty in connection with the netherlands national legislation on medicinal products,
Grounds
1 By judgment of 12 may 1982, received by the court on 1 september 1982, the arrondissementsrechtbank (district court) amsterdam referred for a preliminary ruling under article 177 of the eec treaty a number of questions concerning the interpretation 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 1965-66, p. 20) and also of articles 30 to 36 of the eec treaty, with a view to appraising the compatibility with community law of the netherlands law on the supply of medicinal products (wet op de geneesmiddelenvoorziening).
2 The questions were raised in the context of criminal proceedings brought against mr van bennekom, who is being prosecuted in The Netherlands for possessing, for the purpose of resale, a large quantity of vitamin and multi-vitamin preparations contrary to the aforesaid netherlands law.
3 It is common ground that the preparations in question were put up in pharmaceutical form (tablets, pills and capsules) and were highly concentrated.
4 Under article 3 (5) (b) of the netherlands law on the supply of medicinal products, such products may not be marketed until they have been registered by the public authorities. Manufacturers, importers or wholesalers must, moreover, hold manufacturing, import or wholesale authorizations.
5 Those registration and authorization requirements are also laid down by community provisions on the approximation of legislative provisions relating to proprietary medicinal products.
6 Mr van bennekom, who is being prosecuted for failure to comply with either of those two requirements, contended in his defence before the netherlands courts that the preparations in question were not medicinal products but foodstuffs for the purposes of both the netherlands law and the aforesaid directive 65/65.
7 The netherlands law on the supply of medicinal products defines ‘‘ medicinal product ‘‘ as :
‘‘ Any substance or combination of substances which is intended to be used or which is in any way indicated or recommended as being suitable for :
1. Healing, treating or preventing any infection, disease, symptom, pain, wound or illness in human beings;
2. Restoring, correcting or modifying the function of bodily organs in human beings ;
3. Making a medical diagnosis by its administration to or use upon human beings. ‘‘
8 council directive 65/65 defines ‘‘medicinal product’’ in the first place as ‘‘any substance or combination of substances presented for treating or preventing disease in human beings or animals’’, and, in the second place, as ‘‘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.’’
9 In the appeal proceedings before it, the arrondissementsrechtbank amsterdam, concluding that it needed an interpretation of the community provisions, stayed the proceedings and referred the following questions to the court of justice:
‘‘1. Is it possible for substances or combinations of substances, such as vitamin preparations in certain concentrations and doses and in the form (tables, pills and capsules) referred to in the present case, which are not indicated or recommended as being suitable for treating, relieving or preventing any infection, disease or symptom, pain, wound or infirmity in human beings, to constitute substances or combinations of substances' presented for treating or preventing disease in human beings or animals' ?
2.is it possible for a substance or combination of substances, such as a vitamin or multi-vitamin preparation similar to those referred to in the present case, which may be suitable for treating or preventing disease in human beings or animals but which is not presented as such and cannot 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, to be a ' medicinal product ' within the meaning of the directive?
3. (a) on the assumption that vitamins in certain low concentrations are intended for use in foodstuffs and not as medicinal products, even though they are marketed in the form of tablets, pills or capsules, can a high(er) concentration of those vitamins, whether or not they are in that form, be sufficient for the substance to be classified as a medicinal product within the meaning of the directive?
(b)if so, on the basis of what criteria may that be established?
4. Is it permissible for netherlands law to prohibit, or to be applied in the form of a criminal penalty to, the sale or holding in stock for the purpose of supply of vitamins and vitamin preparations by the use of a definition of medicinal product which, like that contained in the wet op de geneesmiddelenvoorziening, is so wide as to

include such preparations if they are not, either alone or in combination, medicinal products within the meaning of the directive?
5. If vitamins or multi-vitamin preparations may be regarded as medicinal products within the meaning of the directive but the latter or the national legislation based thereon is drafted, interpreted or applied in one or more of the member states in such a way that those preparations do not fall within the legislation governing medicinal products which is in force there, may netherlands law prevent the sale or the holding in stock for the purpose of supply of such preparations imported from one of those member states in reliance on the wet op de geneesmiddelenvoorziening or its implementing decrees, or would that be in conflict with the treaty, in particular with article 30 thereof, and with the prohibition of restrictions on trade between the member states?
6. If the answer to the preceding questions leads to the conclusion that the definition of medicinal products in netherland law, in contrast to the definition contained in the eec directive, includes the vitamin preparations referred to in this case, with the result that they must be registered as indicated above in the same way as proprietary medicinal products and medicinal preparations, must the netherlands statutory provisions be regarded as constituting to that extent a measure having an effect equivalent to a quantitative restriction on trade within the meaning of article 30 et seq. Of the eec treaty, in view of the fact that the eec directive only contains rules concerning proprietary medicinal products?''
10 It should be observed at the outset that, whilst it is not for the court, in the context of article 177 of the eec treaty, to rule on the compatibility of national legislative provisions with the treaty, it many none the less furnish the national court with all those criteria for the interpretation of community law which may enable it to judge the issue of such compatibility.
11 As to the substantive issues, it should be stressed that directive 65/65 constitutes only the first stage in the harmonization of national laws dealing with the production and distribution of pharmaceutical products.
12 The directive is limited in its scope to '' proprietary medicinal products '' which are defined as any ready-prepared medicinal products placed on the market under a special name and in a special pack. Furthermore, '' medicinal products '' are defined as '' substances '', which in turn are the subject of closer definition. Finally, article 2 limits the scope of the directive to proprietary medicinal products for human use intended to be placed on the market in member states.
13 In view of the technicalities of the definition of medicinal products contained in directve 65/65, the court of justice can do no more than provide a number of general guidelines enabling the dividing line to be drawn between medicinal products and foods.
14 Directive 65/65 is designed to eliminate - at least in part - obstacles to trade in proprietary medicinal products within the community whilst at the same time attaining the essential objective of safeguarding public health. As a result of such harmonization recourse to article 36 of the eec treaty must gradually become unnecessary.
15 It is in the light of those considerations that replies should first be given to the first three question of the arrondissementsrechtbank amsterdam, concerning the interpretation of the directive, and then, in the alternative, should the vitamin preparations at issue prove not to be covered by the directive, to the questions concerning articles 30 et seq. Of the treaty.
First question
16 In the first question the court is asked, essentially, whether products such as the vitamin preparations at issue, which are not '' indicated or recommended '' expressly as being suitable for curing, treating or preventing an infection, may none the less be substances '' presented for treating or preventing disease in human being or animals '' within the meaning of the community definition of '' medicinal product '' in directive 65/65.
17 In order to answer this question, it should be observed that the directive, by basing itself, in the first community definition of a medicinal product, on the criterion of the product ' s '' presentation '', is designed to cover not only medicinal products having a genuine therapeutic or medical effect but also those which are not sufficiently effective or which do not have the effect which consumers would be entitled to expect in view of their presentation. The directive thereby seeks to preserve consumers not only from harmful or toxic medicinal products as such but also from a variety of products used instead of the proper remedies. For that reason, the concept of the '' presentation '' of a product must be broadly construed.
18 It is therefore necessary to take the view that a product is '' presented for treating or preventing disease '' within the meaning of directive 65/65 not only when it is expressly '' indicated '' or '' recommended '' as such, possibly by means of labels, leaflets or oral representation, but also whenever any averagely well-informed consumer gains the impression, which, provided it is definite, may even result from implication, that the product in question should, regard being had to its presentation, have an effect such as is described by the first part of the community definition.
19 In particular, the external form given to the product in question - such as that of a tablet, pill or capsule - may in this connection serve as strong evidence of the seller's or manufacturer's intention to market that product as a medicinal product. Such evidence cannot, however, be the sole or conclusive evidence, since otherwise certain food products which are traditionally presented in a similar form to pharmaceutical products would also be covered.
20 The answer to the first question should therefore be that substances such as the vitamin preparations at issue, which are not ''indicated or recommended'' expressly as being suitable for curing, treating or preventing an infection, may none the less constitute substances ''presented for treating or preventing disease in human beings or animals'' within the meaning

of the community definition of ‘‘medicinal products’’ contained in directive 65/65.

Second question

21 The second question seeks to ascertain whether a substance which may have curative or preventive properties in relation to human or animal diseases, but which is not presented as such and cannot be administered to a human being or an animal with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or animals, nevertheless falls within the definition of a medicinal product for the purposes of directive 65/65.

22 It is apparent in this connection that a substance which is endowed with properties ‘‘for treating or preventing disease in human beings or animals’’ within the meaning of the first part of the community definition, but which is not ‘‘presented’’ as such, falls in principle within the scope of the second part of the community definition of a medicinal product.

23 On the other hand, a product which is covered by neither the first nor the second part of the community definition of a medicinal product may not be regarded as a medicinal product within the meaning of directive 65/65.

Third question

24 In its third question, the national court, proceeding on the assumption that vitamins in low concentrations may be regarded as foodstuffs, asks in substance whether a higher concentration should lead to their being regarded as medicinal products within the meaning of the directive, and, if so, on the basis of what criteria.

25 The answer to that question must be such as to enable the national court to assess the importance of the criterion of concentration for the purpose of establishing whether a vitamin falls within the second part of the community definition of a medicinal product.

26 Inasmuch as vitamins are usually defined as substances which, in minute quantities, form an essential part of the daily diet and are indispensable for the proper functioning of the body, they may not, as a general rule, be regarded as medicinal products when they are consumed in small quantities.

27 Similarly, it is a fact that vitamin or multi-vitamin preparations are sometimes used, generally in large doses, for therapeutic purposes in combating certain diseases other than those of which the morbid cause is a vitamin deficiency. In such cases, it is beyond dispute that the vitamin preparations constitute medicinal products.

28 It is, however, apparent from the file and from the observations submitted to the court, taken as a whole, that it is impossible in the present state of scientific knowledge to state whether the criterion of concentration alone is always sufficient in order to be able to determine whether a vitamin preparation constitutes a medicinal product ; still less therefore is it possible to specify the level of concentration above which such a vitamin preparation would fall within the community definition of a medicinal product.

29 The answer to be given to the national court should therefore be that 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 such vitamin to the extent to which they have been established in the present state of scientific knowledge.

Fourth, fifth and sixth questions

30 The fourth, fifth and sixth questions ask, in substance, whether, where the certain vitamin or multivitamin preparations may

(a) be regarded as medicinal products within the meaning of directive 65/65, but are not covered by the legislation on medicinal products of one or more member states, or

(b) are not covered by the community definition of medicinal product,

The law of one member state may none the less prohibit the sale or the holding in stock for the purpose of supply of such preparations imported from another member state.

31 In this connection it is apparent from the last recital in the preamble to directive 65/65 that the directive aims to achieve only a progressive approximation of the relevant provisions laid down by law, regulation or administrative action. Therefore, whilst seeking to remove as far as possible obstacles to trade within the community in respect of the products to which it relates, the directive does not preclude as such the possibility that products not covered by its provisions may be subjected by member states to restrictions on their sale or marketing, provided always that the other provisions of community law are complied with.

32 Under article 30 of the treaty quantitative restrictions on imports and all measures having equivalent effect are prohibited in trade between member states. According to a consistent line of decisions of the court, any commercial legislation by member states which is liable to hinder trade within the community, whether directly or indirectly, actually or potentially, is to be regarded as a measure having an effect equivalent to quantitative restrictions.

33 In that light it is clear that legislation which prohibits the marketing of vitamins and vitamin preparations without prior registration with the administrative authorities constitutes a measure having an effect equivalent to a quantitative restriction on imports within the meaning of article 30 of the eec treaty, since such a measure is liable to hinder trade between member states.

34 Under article 36 of the treaty, however, ‘‘ the provisions of articles 30 to 34 shall not preclude prohibitions or restrictions on imports... Justified on grounds of... The protection of health and life of humans... ‘‘, Unless they constitute ‘‘ a means of arbitrary discrimination or a disguised restriction on trade between member states.’’

35 It is only when community directives, in pursuance of article 100 of the treaty, make provision for the full harmonization of all the measures needed to ensure the protection of human and animal life and institute community procedures to monitor compliance therewith

that recourse to article 36 ceases to be justified. It is, however not in dispute that such is not the case with the directives dealing with pharmaceutical products. It is therefore necessary to consider whether measures which restrict the marketing of vitamins may be justified by article 36 of the treaty.
36 As the court has had occasion to affirm in its judgment of 14 july 1983 (officier van justitie v sandoz, case 174/82, (1983) ecr 2445), the excessive consumption of vitamins over a prolonged period may have harmful effects, the extent of which varies according to the type of vitamin, there being generally a greater risk with vitamins soluble in fat than with those soluble in water. It is further apparent that it is principally in high concentrations that vitamins constitute a serious risk to health. According to the observations submitted to the court, however, scientific research does not appear to be sufficiently advanced to be able to determine with certainty the critical quantities and the precise effects.
37 In a consistent line of decision the court has stated that, in so far as uncertainties persist in the present state of scientific research, it is for the member states, in the absence of harmonization, to decide what degree of protection of health and life of humans they intend to ensure, having regard however to the requirements of the free movement of goods within the community.
38 Those principles also apply to substances such as vitamins which are not as a general rule harmful in themselves but may have special harmful effects if taken to excess. In view of the uncertainties inherent in scientific assessment, national rules which subject vitamin or multi-vitamin preparations presented in pharmaceutical form or having a high degree of concentration to the procedures laid down by directive 65/65 are therefore justified in principle within the meaning of article 36 of the treaty on grounds of the protection of public health, even if the various member states have adopted different solutions in that regard.
39 Nevertheless, the principle of proportionality which underlies the last sentence of article 36 of the treaty requires that the power of the member states to prohibit imports of the products in question from other member states should be restricted to what is necessary to attain the legitimate aim of protecting health. Accordingly, national rules imposing such restrictions are justified only if authorizations for marketing are granted when they are compatible with the requirements of health protection.
40 In this connection it is for the national authorities to demonstrate in each case that their rules are necessary to give effective protection to the interests referred to in article 36 of the treaty and, in particular, to show that the marketing of the product in question creates a serious risk to public health.
41 The answer to be given to the national court should therefore be that where certain vitamin or multi-vitamin preparations may
(a) Be regarded as medicinal products within the meaning of directive 65/65, but are not covered by the legislation on medicinal products of one or more member states, or
(b) Are not covered by the community definition of medicinal products,
The law of a member state may prohibit the sale, or the holding in stock for the purpose of supply, of such preparations imported from another member state, in particular when they are presented in a pharmaceutical form or when they are highly concentrated. However, such rules are justified only if authorizations for marketing are granted when they are compatible with the requirements of health protection.

Decision on costs

Costs
42 The costs incurred by the governments of the member states and by the commission of the european communities, which have submitted observations to the court, are not recoverable. As these proceedings are, in so far as the parties to the main proceedings are concerned, in the nature of a step in the proceedings before the national court, the decision on costs is a matter for that court.

Operative part

On those grounds,
The court (fifth chamber),
In answer to the questions submitted to it by the arrondissementsrechtbank, amsterdam by judgment of 12 may 1982, hereby rules :
1. Substances, such as the vitamin preparations at issue, which are not ‘‘ indicated or recommended ‘‘ expressly as being suitable for curing, treating or preventing an infection, may none the less constitute sub stances ‘‘ presented for treating or preventing disease in human beings or animals ‘‘ within the meaning of the community definition of ‘‘ medicinal product ‘‘ contained in directive 65/65.
2. A product which falls neither under the first nor the second part of the community definition of ‘‘ medicinal product ‘‘ cannot be considered a medicinal product within the meaning of directive 65/65.
3. 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.
4. Where certain vitamin or multi-vitamin preparations may
(a) be regarded as medicinal products within the meaning of directive 65/65, but are not covered by the legislation on medicinal products of one or more member states, or
(b)are not covered by the community definition of medicinal products,
The law of a member state may prohibit the sale, or the holding in stock for the purpose of supply, of such preparations imported from another member state, in particular when they are presented in pharmaceutical form or when they are highly concentrated. However, such rules are justified only if authorizations for marketing are granted when they are compatible with the requirements of health protection.