

JUDGMENT OF THE COURT (Fourth Chamber)

30 March 2006 \*

In Case C-495/04,

REFERENCE for a preliminary ruling under Article 234 EC from the Hoge Raad der Nederlanden (Netherlands), made by decision of 26 November 2004, received at the Court on the same day, in the proceedings

**A.C. Smits-Koolhoven**

v

**Staatssecretaris van Financiën,**

THE COURT (Fourth Chamber),

composed of K. Lenaerts, acting for the President of the Fourth Chamber, M. Ilešič and E. Levits (Rapporteur), Judges,

\* Language of the case: Dutch.

Advocate General: A. Tizzano,  
Registrar: M. Ferreira, Principal Administrator,

having regard to the written procedure and further to the hearing on 19 October 2005,

after considering the observations submitted on behalf of:

- A.C. Smits-Koolhoven, by C.H. Bouwmeester and B.S. Mulier, advocaten,
- the Netherlands Government, by H.G. Sevenster and D.J.M. de Grave, acting as Agents,
- the French Government, by G. de Bergues and C. Jurgensen-Mercier, acting as Agents,
- the Finnish Government, by A. Guimaraes-Purokoski, acting as Agent,
- the Commission of the European Communities, by K. Gross and A. Weimar, acting as Agents,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

### **Judgment**

- <sup>1</sup> The reference for a preliminary ruling concerns the interpretation of Article 7(2) of Council Directive 95/59/EC of 27 November 1995 on taxes other than turnover taxes which affect the consumption of manufactured tobacco (OJ 1995 L 291, p. 40).
- <sup>2</sup> That reference was submitted by the Hoge Raad der Nederlanden (Supreme Court of the Netherlands) in the context of proceedings between Ms Smits-Koolhoven and the Staatssecretaris van Financiën (State Secretary for Finance) concerning the levying of excise duty on herbal cigarettes.

### **Legal context**

#### *Community legislation*

- <sup>3</sup> Manufactured tobacco is subject to a harmonised Community excise duty. Directive 95/59 defines the different categories of products subject to excise duties and specifies the methods for calculating the latter.

4 Article 4(1) of that directive defines ‘cigarettes’ in the following terms:

‘The following shall be deemed to be cigarettes:

- (a) rolls of tobacco capable of being smoked as they are and which are not cigars or cigarillos within the meaning of Article 3;
- (b) rolls of tobacco which, by simple non-industrial handling, are inserted into cigarette-paper tubes;
- (c) rolls of tobacco which, by simple non-industrial handling, are wrapped in cigarette paper.

...’

5 ‘Smoking tobacco’ is defined in Article 5 of that directive.

6 Article 7(2) of the same directive provides:

‘Products consisting in whole or in part of substances other than tobacco but otherwise conforming to the criteria set out in Article 4 or 5 shall be treated as cigarettes and smoking tobacco.

Notwithstanding the first subparagraph, products containing no tobacco and used exclusively for medical purposes shall not be treated as manufactured tobacco.’

7 Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (OJ, English Special Edition 1965, p. 20), as amended by Council Directive 93/39/EEC of 14 June 1993 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products (OJ 1993 L 214, p. 22; ‘Directive 65/65’), defines ‘medicinal product’ in Article 1(2) thereof as ‘any substance or combination of substances presented for treating or preventing disease in human beings or animals’ or ‘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’.

### *National legislation*

8 Under Article 1(1)(f) of the Netherlands Law on excise duty of 31 October 1991 (Wet op de accijns, Stb. 1991, No 561), an excise duty is levied on tobacco products.

- 9 Article 64(1) of that law, which transposes the second subparagraph of Article 7(2) of Directive 95/59 into Netherlands law, provides:

‘Under conditions and limitations to be established in accordance with general administrative rules, exemption from excise duty shall be conferred in regard to the placing on the market and importation of:

...

(f) cigarettes and smoking tobacco consisting wholly of substances other than tobacco and which are clearly intended to be used for medical purposes.’

### **The main proceedings and the question referred for a preliminary ruling**

- 10 At the material time, Ms Smits-Koolhoven (the ‘appellant in the main proceedings’) sold wholesale, for retail sale, a product called ‘herbal cigarettes’. They were cigarettes without tobacco and consisting of herbs, in particular of the *Labiatae* family.
- 11 They were made of substances with no medical effect and were marketed without medical prescription but exclusively through chemists’ shops and herbalists. Each packet of cigarettes came with a sticker on it bearing the text ‘medicinal herbal cigarettes’. In addition, a leaflet presenting the cigarettes in question as an aid to

giving up smoking was included with the product. That leaflet had been authorised by the Keuringsraad Openlijke Aanprijzing Geneesmiddelen/Keuringsraad Aanprijzing Gezondheidsproducten (Council for the Monitoring of Medicinal Product Advertising/Council for the Monitoring of Health Product Advertising) (the 'KOAG/KAG'), a non-governmental agency responsible for monitoring advertising relating to medicinal and health products.

- 12 No excise duty was paid on those cigarettes. The authorities claimed in a letter sent to the appellant in the main proceedings on 20 July 1995 that, so far as the collection of excise duty is concerned, the herbal cigarettes must be regarded as cigarettes and, consequently, as tobacco products, and that those cigarettes were not eligible for the exemption under Article 64(1)(f) of the Netherlands Law on excise duty as they were not intended to be used for medical purposes.
- 13 As a result, the appellant in the main proceedings was subject to a tax adjustment for the period from 1 August 1995 to 15 June 1999 as to excise duty on the tobacco products.
- 14 Since her objection was rejected, the appellant in the main proceedings appealed before the Gerechtshof te Leeuwarden (Leeuwarden Court of Appeal). In a judgment of 5 August 2002, that court upheld the adjustment relating to excise duty on the tobacco products.
- 15 Considering that the Gerechtshof te Leeuwarden had accepted an overly restrictive interpretation of the concept of 'medical purposes' referred to in Article 64(1)(f) of the Netherlands Law on excise duty, the appellant in the main proceedings brought

an appeal on a point of law before the Hoge Raad der Nederlanden, which decided to stay the proceedings and refer the following question to the Court of Justice for a preliminary ruling:

‘Do herbal cigarettes of the type in issue in the present case, which it is established do not contain any substances having a medicinal effect, but which, with the approval of the [KOAG/KAG], are sold as “Medicinal herbal cigarettes” as an aid to giving up smoking, come under the exemption for which Article 7(2) of ... Directive 95/59 ... provides for products which are used exclusively for medical purposes?’

### **The question referred for a preliminary ruling**

<sup>16</sup> In the question referred for a preliminary ruling, the national court is essentially asking whether Article 7(2) of Directive 95/59 must be interpreted as meaning that cigarettes without tobacco which do not contain substances having a medical effect but which are presented and marketed as an aid to giving up smoking are ‘used exclusively for medical purposes’ within the meaning of the second subparagraph of that provision.

<sup>17</sup> The first point to be noted here is that Directive 95/59 was adopted as part of a policy designed to harmonise the structures of excise duty on manufactured tobacco, to ensure that competition in the different categories of manufactured tobacco belonging to the same group was not distorted (Case C-216/98 *Commission v Greece* [2000] ECR I-8921, paragraph 18). In order to ensure that it is applied in a uniform fashion, the terms in that directive must be interpreted independently on the basis of the wording of the provisions in question and the purpose of the



directive (see, to that effect, Case C-389/02 *Deutsche See-Bestattungs-Genossenschaft* [2004] ECR I-3537, paragraph 19).

- 18 Against that background, attention should be drawn to the fact that the first subparagraph of Article 7(2) of Directive 95/59 seeks to lay down the general rule that products which, although consisting in whole or in part of substances other than tobacco, nevertheless conform to the other criteria for cigarettes and smoking tobacco set out in Article 4 or Article 5 of that directive are to be treated as cigarettes and smoking tobacco. In accordance with the second subparagraph of Article 7(2) of the same directive, the only products which are not covered by that rule are those which, firstly, do not contain tobacco and, secondly, are 'used exclusively for medical purposes'. Consequently, that subparagraph distinguishes between two kinds of products not containing tobacco, depending on whether they are used for such purposes or not, and only the first kind is covered by the derogation.
- 19 It is therefore necessary to determine the criteria which enable products which are used exclusively for medical purposes to be distinguished from those which are not used for such purposes or which are not used exclusively for such purposes.
- 20 From the order for reference, the national court seems to be hesitating between two criteria, namely the composition of the cigarettes and their presentation. Although the absence of substances having a medical effect in the cigarettes at issue tends to indicate that they are not to be used exclusively for medical purposes, their presentation would argue in favour of acknowledging that they are.
- 21 The criterion of a product's composition can be considered to be relevant and, therefore, appropriate to the determination of whether it is used for medical purposes. A product containing substances the combustion and inhalation of which produce medical effects on the human body can be objectively distinguished, by those effects, from a product which does not contain any such substances.

- 22 Consequently, to ascertain whether a product is capable of being used for medical purposes, it is necessary to examine whether that product contains substances the combustion and inhalation of which produce scientifically recognised medical effects of a curative or preventive nature.
- 23 It is common ground that the cigarettes at issue in the main proceedings do not contain any such substances.
- 24 However, the appellant in the main proceedings claims that, even though lacking substances producing medical effects, the herbal cigarettes concerned in the main proceedings are used exclusively for medical purposes since smoking those cigarettes helps overcome addiction to tobacco.
- 25 To accept that argument is none the less tantamount to conceding that any cigarette not containing tobacco and, therefore, capable of being consumed as a substitute is used exclusively for medical purposes, which would clearly be contrary to the objective and scheme of the second subparagraph of Article 7(2) of Directive 95/59, as explained in paragraph 18 of this judgment. That argument thus cannot be accepted.
- 26 In those circumstances, it is therefore necessary to examine whether the presentation of the cigarettes can be considered to be relevant to the determination of whether the cigarettes are used exclusively for medical purposes and, thus, to establish whether the method of presentation can constitute a criterion enabling cigarettes with such a purpose to be distinguished from products which do not have that purpose or do not have that exclusive purpose.

- 27 The appellant in the main proceedings maintains, in that connection, that it should be conceded that the cigarettes in question are used exclusively for medical purposes since they are presented, with the KOAG/KAG's authorisation, as having curative or preventive properties, marketed as a medicinal product and perceived to be a medicinal product by the averagely well-informed consumer.
- 28 That argument cannot be accepted, because the fact that such cigarettes are used for medical purposes cannot be inferred only from their presentation, the method used to market them, or the public's perception of them without rendering meaningless the general rule set out in the first subparagraph of Article 7(2) of Directive 95/59. Changing a product's presentation or the method used to market it would be enough for it to be covered by the derogation provided for in the second subparagraph of that provision, with the result that otherwise identical products would be subject to differing treatment so far as excise duty was concerned.
- 29 In addition, Directive 95/59 can be distinguished, by its objective and by the wording of the second subparagraph of Article 7(2) thereof, from Directive 65/65. Article 1(2) of the latter lays down two alternative and complementary definitions of medicinal products relating, on the one hand, to medicinal products 'by virtue of their presentation' and, on the other hand, to medicinal products 'by virtue of their function' (see Case 227/82 *Van Bennekom* [1983] ECR 3883, paragraph 22, and Case C-219/91 *Ter Voort* [1992] ECR I-5485, paragraph 11).
- 30 In the first place, the objective of Directive 65/65, which essentially seeks to protect consumers by ensuring that public health is safeguarded, warrants such a wide

definition, which gives that directive a broad scope. As the Court stated in paragraph 17 of *Van Bennekom*, the criterion of the ‘presentation’, which stems from the first subparagraph of Article 1(2) of the directive in question, is designed to catch not only medicinal products having a genuine therapeutic or medical effect but also those which are not sufficiently effective or do not have the effect which consumers would be entitled to expect from the way in which they are presented, in order to protect the consumer not only from harmful or toxic medicinal products, but also from a variety of products used instead of the proper remedies. The objective of Directive 95/59, recalled in paragraph 17 of this judgment, is completely different and does not warrant such a broad definition.

31 In the second place, the second subparagraph of Article 7(2) of Directive 95/59, since it lays down an exception to the general rule, must be interpreted restrictively, and cannot be applied to products when only their presentation suggests that they are used for a medical purpose, unless that is supported by objective characteristics linked to the properties of those products.

32 It follows that considerations linked to the presentation, marketing or perception of a product are not, by themselves, enough to qualify that product for the derogation laid down in the second subparagraph of Article 7(2) of Directive 95/59.

33 The fact that the presentation of the cigarettes in issue is authorised by the KOAG/KAG cannot alter that assessment. When that authority, which is responsible for ensuring, in a context of self-regulation, that the rules for good conduct on the advertising of medicinal and health products are observed, approves a specific form of advertising, that approval does not entail verification of use there may be of the product exclusively for medical purposes and it is not conclusive as to the assessment of the curative or preventive characteristics of a product.

34 It follows from the foregoing that cigarettes which do not contain substances having a medical effect cannot be regarded as being used for medical purposes.

35 Having regard to all those considerations, the answer to the question referred must be that Article 7(2) of Directive 95/59 must be interpreted as meaning that cigarettes without tobacco which do not contain substances having a medical effect but which are presented and marketed as an aid to giving up smoking are not 'used exclusively for medical purposes' within the meaning of the second subparagraph of that provision.

### **Costs**

36 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Fourth Chamber) hereby rules:

**Article 7(2) of Council Directive 95/59/EC of 27 November 1995 on taxes other than turnover taxes which affect the consumption of manufactured tobacco must be interpreted as meaning that cigarettes without tobacco which do not contain substances having a medical effect but which are presented and marketed as an aid to giving up smoking are not 'used exclusively for medical purposes' within the meaning of the second subparagraph of that provision.**

[Signatures]