OPINION OF ADVOCATE GENERAL MISCHO

delivered on 6 December 2000 [1]

1. In the application under examination, the Commission of the European Communities asks the Court to declare that, by introducing and maintaining in force Article 281g of the *Code Général des Impôts* (the General Tax Code), which provides for a rate of 2.1% for value added tax (hereinafter 'VAT') on reimbursable medicinal products, whereas other medicinal products are taxed at the rate of 5.5%, the French Republic has failed to fulfil its obligations under Article 12 of Sixth Council Directive 77/388/EEC of 17 May 1977 on the harmonisation of the laws of the Member States relating to turnover taxes — Common system of value added tax: uniform basis of assessment [2] (hereinafter the 'Sixth Directive').

2. Article 12(3)(a) of the Sixth Directive, as amended by Directive 92/111/EEC, [3] provides that:

'The standard rate of value added tax shall be fixed by each Member State as a percentage of the taxable amount and shall be the same for the supply of goods and for the supply of services. From 1 January 1993 until 31 December 1996, this percentage may not be less than 15%.

...

Member States may also apply either one or two reduced rates. These rates shall be fixed as a percentage of the taxable amount which may not be less than 5% and shall apply only to supplies of the categories of goods and services specified in Annex H.'

3. Medicinal products constitute one category of goods listed in Annex H.

4. The existence of rates of VAT lower than 5% is, none the less, allowed by Article 28(2)(a) of the Sixth Directive, as

1 — Original language: French.

2 — OJ 1977 L 145, p. 1.

3 — Council Directive of 14 December 1992 amending Directive 77/388/EEC and introducing simplification measures with regard to value added tax (OJ 1992 L 384, p. 47).

amended by Directive 92/77/EEC.[4] This provides in effect that, notwithstanding Article 12(3), during a transitional period which is still running:

'Exemptions with refund of the tax paid at the preceding stage and reduced rates lower than the minimum rate laid down in Article 12(3) in respect of the reduced rates, which were in force on 1 January 1991 and which are in accordance with Community law, and satisfy the conditions stated in the last indent of Article 17 of the second Council Directive of 11 April 1967, may be maintained.

...'

5. Under the aforementioned criteria in Article 17, these reduced rates must have been fixed 'for clearly defined social reasons and for the benefit of the final consumer'.

6. In the view of the Commission, the existence in France of two different VAT rates for medicinal products, depending on whether or not they are reimbursable by the social security authorities, is unacceptable because it does not satisfy at least one of the conditions laid down in Article 28(2)(a) of the Sixth Directive, as amended by Directive 92/77.

7. From the Commission's point of view, the situation in which not all medicinal products are subject to the same rate of VAT is at variance with Community law.

8. It submits that all medicinal products are similar products, so that the existence of two different rates of VAT is in conflict with the principle of fiscal uniformity laid down in above Article 12(3) and is contrary to the fundamental principles of the Community VAT system, fiscal neutrality and the elimination of distortions in competition.

9. The Commission accepts that the system provided by the Community directives involves some limited deviations from those principles, notably in Article 28(2)(i) of the Sixth Directive, as amended by Council Directive 96/42/EEC of 25 June 1996,[5] authorising Member States to apply a reduced rate of VAT to wood for use as firewood, and in Annex H to the Sixth Directive, as amended by Directive 92/77,

4 — Council Directive of 19 October 1992 supplementing the common system of value added tax and amending Directive 77/388 (approximation of VAT rates) (OJ 1992 L 316, p. 1).

5 — OJ 1996 L 170, p. 34.

authorising the application of a reduced rate of not less than 5%, instead of the normal rate of 15%, for the supply of housing provided as part of a social policy and for the supply of services and goods by organisations recognised as charities by Member States and engaged in welfare or social security work.

10. However, the Commission considers that the existence of these derogations laid down by the Community legislature cannot in any way be relied on by the French government to justify other derogations, such as that which it has unilaterally established.

11. The very fact that the Community legislature has intervened in order to establish derogations also proves that, in the absence of a clear legislative intention, no derogation can be accepted.

12. Nor is the Commission satisfied that the rate of 2.1% for reimbursable medicinal products really does exist for clearly defined social reasons because, behind this measure, it sees an economic objective, namely the reduction of social-security costs. However, the Commission considers that no purpose would be served by dwelling at length on this point since, in any event, Community law has not been complied with.

13. The French Government submits that the application should be dismissed on the ground that all the conditions of Article 28(2)(a) are satisfied. The rate of 2.1% existed before 1 January 1991, a fact which the Commission, moreover, does not dispute.

14. The French Government argue that reimbursable medicinal products and those which are not reimbursable are separate products, so that it is incorrect to claim that there has been an infringement of the principles invoked by the Commission, which are, admittedly, essential in the Community VAT system.

15. The rate of 2.1% does indeed exist for social reasons, because it facilitates access to healthcare for those covered by social security.

16. Regard being had to the way in which the issues in the dispute became clearer during the written procedure and the positions adopted by the parties at the hearing, it seems that its resolution turns on the question whether all medicinal products should be treated as similar products for purposes of the Community VAT system, or whether that system allows those which are reimbursable to be distinguished from those which are not.

17. The Commission acknowledges that any search in the various VAT directives for a provision clarifying the concept of similar products would prove fruitless, and it admits, in consequence, that it is acceptable to reason by analogy with other branches of Community law.

18. However, while the French Government seeks to draw analogies from 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, [6] from the Common Customs Tariff, from the case-law relating to the permissibility, for the purposes of Articles 30 and 36 of the EC Treaty (now, after amendment, Articles 28 EC and 30 EC), of a national rule prohibiting pharmacists dispensing a doctor's prescription from substituting one medicinal product for another, and from competition law, the Commission argues that the only reasoning by analogy that may legitimately be applied in this case is that drawn from the case-law of the Court on the concept of similar products within the meaning of the first paragraph of Article 95 of the EC Treaty (now, after amendment, the first paragraph of Article 90 EC).

19. It should immediately be pointed out that the Commission is in no way criticising the procedure by which the French authorities enter a medicinal product on the list of those which are reimbursable.

20. The Commission is in no way disputing that this listing is carried out pursuant to objective criteria and complies with the rules laid down by Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems. [7]

21. For the Commission, however, the classification of medicinal products into two categories cannot be in the slightest way relevant for the application of the Community VAT system, because the fact that some medicinal products are reimbursable and others are not does not lead to the conclusion that, for the purposes of that system, these are different products that may be subject to different rates of tax without any infringement of the principle of fiscal neutrality or of the prohibition of creating distortions of competition.

22. In support of its assertion that reimbursable medicinal products are different from non-reimbursable ones, with the result that the principles of the Community VAT system do not require that they be taxed at the same rate, the French Govern-

6 — OJ, English Special Edition (1965-1966), p. 20.

7 — OJ 1989 L 40, p. 8.

ment puts forward a variety of arguments to demonstrate that the category of medicinal products is, so far as Community law is concerned, far from homogeneous.

23. In my opinion, some of these arguments plainly do not bear examination and can accordingly be disposed of quickly.

24. To start with, such is the case with the argument based on Directive *65/65*. According to the French Government, the existence of different categories of medicinal products is approved by that directive, since it provides that a product may be defined as a medicinal product on the basis of various criteria, and it is true that the directive does, in admitting a product to the category of medicinal products, take into account its packaging as well as its function. That, however, does not alter the fact, emphasised by the Commission, that when the directive sets out the various cases in which, for its purposes, a product is to be considered to be a medicinal product, its objective is solely to draw a distinction between medicinal products and other products.

25. A product may be a medicinal product on various grounds, but once it is recognised as a medicinal product a single system applies to it and, in any event, nothing in the directive supports the contention that not all medicinal products are similar products for VAT purposes.

26. No more relevant is the fact, emphasised by the French Government, again on the basis of Directive *65/65*, that two medicinal products in which the active ingredients are identical may be the subject of two separate marketing authorisations.

27. It does not follow that, because two proprietary medicinal products, sold under different trade marks and with different packagings, must be the subject of separate marketing authorisations, they cannot be similar products for the purposes of VAT.

28. In fact, the reason for the existence of two marketing authorisations should probably be sought in the need to verify, each time that a manufacturer proposes to market a medicinal product, exactly which product is involved and to ensure that it cannot be harmful to public health.

29. This is totally unrelated to the demands of fiscal neutrality in the Community VAT system.

30. This is even more obviously the case with the definition of a medicinal product in the Common Customs Tariff, which the

French Government cites as demonstrating that the category of medicinal products is not homogenous.

31. While, from the point of view of application of the Common Customs Tariff, both products whose curative properties are established and others for which those properties are merely claimed or assumed by virtue of the manner of their packaging and marketing are classified as medicinal products, all medicinal products fall within the same chapter heading of the Common Customs Tariff and the subheadings found there have nothing to do with reimbursement by the social security authorities.

32. Finally, the same holds true for the judgment in Joined Cases 266/87 and 267/87.[8] In that judgment, the Court accepted that: 'a national rule of a Member State requiring a pharmacist, in response to a prescription calling for a medicinal product by its trade mark or proprietary name, to dispense only a product bearing that trade mark or proprietary name may be justified under Article 36 of the Treaty on grounds of the protection of public health even where the effect of such a rule is to prevent the pharmacist from dispensing a therapeutically equivalent product licensed by the competent national authorities pursuant to rules adopted in conformity with the judgment of the Court of Justice in Case 104/75 and manufactured by the same company or group of companies or by a licensee of that company but bearing a trade mark or proprietary name applied to it in another Member State which differs from the trade mark or proprietary name appearing in the prescription'.

33. The reasoning of the Court is in effect based on the protection of public health. In accepting the restriction on the power of a pharmacist to substitute products bearing a different trade mark, the Court was in reality seeking to safeguard the power of a doctor to prescribe and to avoid the risks which could result from giving a patient a product which is not exactly the one which his doctor prescribed for him, even though the difference may only be one of appearance.

34. It seems, accordingly, difficult to argue that the Court, in so holding, made it possible to treat two products with the same active ingredients as different products for the purposes of VAT.

35. Inasmuch as its reasoning was strictly within the context of Article 36 of the Treaty, it seems to me pointless to discuss whether the Court took the view that a proprietary medicinal product marketed by a laboratory should or should not be regarded as similar to a competitor of the same kind.

8 — *The Queen* v *Royal Pharmaceutical Society of Great Britain, ex parte Association of Pharmaceutical Importers* [1989] ECR 1295, at paragraph 24.

36. The arguments which the French Government draws from Article 95 of the Treaty and from competition law are much more relevant to the question before the Court, and for that reason merit very thorough examination.

37. Concerning Article 95 of the Treaty, the Commission itself admits that reasoning by analogy, on the basis of the extensive case-law to which this article has given rise, is legitimate since, just like the Community system of VAT, Article 95 seeks to ensure fiscal neutrality and to avoid distortions of competition.

38. The Commission considers, none the less, that this line of argument offers no assistance to the French Government inasmuch as that case-law has always favoured a very broad construction of the concept of product similarity, on the ground that the concept should not be seen as depending on the criterion of strict identity, but rather on that of similarity and comparability of use. [9]

39. A fortiori, two products having the same objective characteristics should be considered to be similar products within the meaning of the first paragraph of Article 95 of the Treaty.

9 — See, for example, Case 243/84 *John Walker* v *Ministeriet for Skatter og Afgifter* [1986] ECR 875, at paragraph 11 of the judgment.

40. In fact, medicinal products are not placed on, or excluded from, the list of reimbursable products because of intrinsic differences between them.

41. On the one hand, the inclusion of a product occurs only at the request of the manufacturer, and, for a given product, a manufacturer may see no advantage in this where the placing of that product on the list would impose a number of restrictions on him. He would lose the freedom to fix the price and would be unable to advertise it to the public at large.

42. It is, however, entirely possible that another manufacturer might decide differently for a product which is intrinsically identical, taking the view that inclusion on the list would have advantages outweighing the accompanying constraints.

43. On the other hand, even if the manufacturers of two medicinal products which are intrinsically identical were both to seek to have them placed on the list, the rules applicable in France do not guarantee that both will be successful.

44. According to Article R 163-3 of the *Code de la Sécurité Sociale* (the Social Security Code), reimbursable medicinal products are those which bring either an improvement in the therapeutic effective-

ness or, where relevant, the secondary effect of the medical service supplied or a saving in the cost of medicinal treatment.

45. A new medicinal product which does not have new therapeutic qualities, or which is expensive, may thus be excluded from reimbursement without being intrinsically different from a reimbursable medicinal product with the same use.

46. The French Government none the less points out that, according to the case-law on the first paragraph of Article 95 of the Treaty, the similarity of products is not determined solely by reference to the intrinsic characteristics of the goods. The case-law also requires that the products should be substitutable, in the sense that they must meet the same consumer needs.

47. In its judgment in *John Walker*, cited above, the Court held that:

'... in order to determine whether products are similar it is necessary first to consider certain objective characteristics of both categories of beverages, such as their origin, the method of manufacture and their organoleptic properties, in particular taste and alcohol content, and secondly to consider whether or not both categories of beverages are capable of meeting the same needs from the point of view of consumers' (paragraph 11).

48. This capacity to meet consumers' needs seems to me to introduce a subjective element into the assessment of similarity and, in fact, the possibility cannot be discounted that even two products which are intrinsically identical may not really meet the same consumer needs, once one introduces this factor relating to the choice of the consumer, his personal perception of the use to which he can put each one of the two products, and the advantages which he can derive from each of them.

49. The position of the French Government would certainly be much stronger if the reimbursable medicinal products could be supplied by a pharmacist only on production of a doctor's prescription, while all non-reimbursable medicinal products were on open sale, that is to say, were self-medication products. That, however, is not the case.

50. In fact, the French system does contain medicinal products which are available only on prescription but none the less are non-reimbursable, for example because they have been deemed too expensive or because they are considered to be comfort medicinal products for which the social security system should not be expected to pay.

51. There are also reimbursable medicinal products which may be bought in a pharmacy without a prescription, but which will only be reimbursed if prescribed by a doctor.

52. Finally, there are medicinal products which require no prescription and the cost of which can never be reimbursed because they are not on the list of those which are reimbursable.

53. In spite of these differences, is it none the less possible to take the view, as the French Government does, that reimbursable medicinal products, as a group, cater for a need which is different from that met by non-reimbursable medicinal products?

54. The Commission replies in the negative, pointing out that a person who briefly suffers slight headaches will probably go directly to a pharmacy and request the pharmacist to sell him a medicinal product to relieve his pain, little caring whether the medicinal product is reimbursable or not, since he has no prescription.

55. Such a person may request the pharmacist to supply him with a reimbursable product, but his reason for so doing will not be because the product is reimbursable, but solely because he has already used it on prescription from his doctor and has found it to be effective. In this case, if the product is on open sale, the pharmacist will have no reason to refuse to supply it to him.

56. In practice, it may also happen that a reimbursable medicinal product, even when its reimbursement cannot be requested because there has been no prescription, turns out to be cheaper than a non-reimbursable medicinal product with the same curative powers and that the VAT rate of 2.1% is not unconnected with that difference.

57. However, the non-reimbursable medicinal product may also prove to be cheaper than the reimbursable one, in spite of the higher VAT rate which it bears. Moreover, it does not seem possible to me to base all our reasoning on these specific instances because, as a general rule, reimbursable medicinal products will still be bought on prescription and will attract full or partial reimbursement.

58. Besides, if one puts oneself not so much in the position of the individual consumer but rather in the position of the whole group of consumers who benefit from the French social-security system, one would tend more to reach a conclusion contrary to that of the Commission.

59. One would, indeed, reach the conclusion that this group has a specific need, namely that of having available a full selection of medicinal products capable of satisfying the demands of quality medicine to deal cost-effectively with the full range of illnesses, a need to be addressed by recourse to a strictly defined pharmacopoeia, as expressed by the list of reimbursable medicinal products. The suitability of these medicinal products to the needs, thus defined, of social-security beneficiaries as a group means that they would be medicinal products corresponding to a specific consumer need, and would require to be distinguished from other medicinal products whose reimbursement would not be justified in terms of satisfying that need.

60. Considered from this point of view, the question whether there is a distinction capable of being taken into account within the framework of the Community VAT system could be answered in a manner which recognises the validity of the French Government's contentions.

61. This approach can be supported by analogy with Community competition law, which is the last of the French Government's arguments. Indeed, as the French Government has quite rightly pointed out, the Commission in its decision in *Glaxo/Wellcome*, [10] concerning the notification of a concentration, accepted that the market in reimbursable medicinal products can be distinguished from the market in those which are non-reimbursable. According to paragraph 8 of that decision, '[a] distinction may also be made between medicines which are wholly or partially reimbursed under the health insurance system and medicines which are not reimbursed'.

62. Once the markets for these two categories of medicinal products can be regarded as distinct, it becomes difficult to see how different rates of VAT could lead to distortions of competition.

63. Although the Commission invokes the penultimate recital in the preamble to the First VAT Directive, [11] which states that the Community VAT system must 'result in neutrality in competition, in that within each country similar goods bear the same tax burden', I am not persuaded that the system of two rates applied by the French Republic does indeed adversely affect neutrality in competition.

64. Even if there are reimbursable medicinal products on open sale in pharmacies, a medicinal product can be reimbursed only

10 — Decision of 28 February 1995 (Case No IV/M. 555) (OJ 1995 C 65, p. 3).

11 — First Council Directive 67/227/EEC of 11 April 1967 on the harmonisation of legislation of Member States concerning turnover taxes (OJ, English Special Edition 1967, p. 14).

if it has been prescribed by a doctor. In other words, products which are in fact reimbursable can be obtained by a consumer only if he consults a doctor and the doctor considers it useful to prescribe them for him.

65. There are therefore indeed two categories of goods, separated by the barrier of a medical prescription.

66. One of those categories possesses an intrinsic advantage, that of giving the right to reimbursement. The consumer, via his prescribing doctor, seeks in preference medicinal products within that category, not because they attract a reduced rate of VAT, but because they will ultimately cost him little or nothing. The higher rate of VAT applied to non-reimbursable medicinal products is thus not, in itself, capable of leading to an increase in the consumption of reimbursable medicinal products at the expense of non-reimbursable medicinal products.

67. To sum up, as the two categories of medicinal products are not in a competitive relationship in which taxation could play a determinant role, and because they are not substitutable at the consumer's free choice, I conclude that they are not similar goods.

68. The measure criticised by the Commission, in my opinion, thus satisfies the second condition in Article 28(2)(a) of the Sixth Directive, as amended by Directive 92/77.

69. There remains the question whether the third condition imposed by that provision is satisfied, namely that the reduced rate has been adopted for clearly defined social reasons and for the benefit of the final consumer.

70. On that issue, the Commission, as I have already noted, has hardly been expansive, in my view rightly so. It seems indeed difficult to deny that there are social reasons here, since the cost of medical treatment prescribed by a doctor is reduced for the patient. Moreover, the final consumer certainly benefits from the low rate of VAT since, in general, he will not obtain full reimbursement of the amount which he has spent.

71. While it cannot be denied that the general body of those entitled to social security benefits, and likewise all of those liable to pay contributions, also benefit from this measure, that cannot be a sufficient ground on which to conclude that the third condition is not also satisfied.

Conclusion

72. In the light of all of the above considerations, I propose that the Court should:

— dismiss the application;

— order the Commission to pay the costs.