

OPINION OF ADVOCATE GENERAL

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delivered on 21 October 2004¹

I — Introduction

1. The Commission asks the Court, pursuant to Article 226 EC, to find that the French Republic has failed to fulfil its obligations under Article 28 EC in that in certain cases, in breach of Community law, it applies a (disproportionate) prior authorisation procedure to medicinal products. In the Commission's view that procedure, which is required by the French Code de la santé publique (Public Health Code), constitutes a measure having an effect equivalent to a quantitative restriction on imports, which is in breach of Article 28 EC. The prior authorisation procedure cannot be justified on the basis of Article 30 EC.

2. What is more particularly at issue here is the importation, not effected by personal transport, of certain medicinal products

lawfully prescribed for personal use by the patient. Patients importing medicinal products in accordance with a doctor's prescription ought not to encounter (disproportionate) obstacles. In its application the Commission distinguishes three instances of failure to fulfil obligations:

- (a) medicinal products authorised under Directive 65/65/EEC,² and, following its repeal, by Directive 2001/83/EC,³ both in France and in the Member State where they are purchased;
- (b) homeopathic medicinal products registered in a Member State pursuant to Directive 92/73/EEC⁴ and later pursuant to Directive 2001/83/EC;

2 — Council Directive of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 20).

3 — Directive of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67).

4 — Council Directive of 22 September 1992 widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homeopathic medicinal products (OJ 1992 L 297, p. 8).

¹ — Original language: Dutch.

- (c) medicinal products not authorised in France, but authorised in the Member State where they are purchased.

In the first two instances, according to the Commission, no authorisation procedure as such is justified. In the third instance, a prior authorisation procedure may be justified in principle on the basis of Article 30 EC, but in the Commission's view the procedure applied in France is disproportionately burdensome.

3. The action has resulted from a complaint by a Spanish manufacturer who is being prosecuted in France for sending homeopathic products to French patients without having an import authorisation issued by the French authorities. The products in question were for personal use by the addressees and were not intended to be sold on in France.

4. That complaint led the Commission to undertake a wider investigation of the French system for importing medicines for personal use, even though the complaint related only to homeopathic products. French legislation does not distinguish between homeopathic and other products.

5. The present action is not an isolated one. In two other recent cases in 2003 the Commission has summoned the French Republic before the Court for breaching Article 28 EC in respect of the severity of the procedural requirements applied in France to the importation of medicines from other Member States. In Case C-122/03⁵ the Court declared that the French Republic had failed to fulfil its obligations under Article 28 EC. Case C-263/03 is still pending.⁶

II — Legal framework

A — *European law*

6. This case, which relates to a possible breach of Articles 28 EC and 30 EC, is to be seen against the background of the system for authorising medicinal products laid down in Community legislation.

7. Under Article 3 of Directive 65/65,⁷ amended on numerous occasions, no proprietary medicinal product may be placed on

⁵ — *France v Commission* [2003] ECR I-15093.

⁶ — The Court has since handed down judgment on 12 October 2004, not published in the ECR.

⁷ — Cited in footnote 2.

the market of a Member State unless an authorisation (hereinafter referred to as a marketing authorisation) has been issued by the competent authority of that Member State. Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products⁸ extended the system by introducing, among other things, a procedure for applying for a marketing authorisation, designed in accordance with Community requirements.

8. Directive 92/73⁹ widens the scope of Directives 65/65 and 75/319 to include certain homeopathic medicinal products, as described in Article 2(1) of Directive 92/73.

9. Article 4 of that directive states: 'The supervision „measures and the sanctions provided for in ... Directive 75/319/EEC shall apply to homeopathic medicinal products ... However, the proof of therapeutic efficacy ... shall not be required for homeopathic medicinal products registered in accordance with Article 7 of this Directive or, where appropriate, admitted in accordance with Article 6(2).'

10. Article 6(1) and (2) states, in so far as is relevant here:

'1. Member States shall ensure that homeopathic medicinal products manufactured and placed on the market within the Community are registered or authorised in accordance with Articles 7, 8 and 9. Each Member State shall take due account of registrations and authorisations previously granted by another Member State.

2. A Member State may refrain from establishing a special, simplified registration procedure for the homeopathic medicinal products referred to in Article 7. ...'

11. Article 7(1) reads as follows: 'Only homeopathic medicinal products which satisfy all of the following conditions may be subject to a special, simplified registration procedure:

— ...

— there is a sufficient degree of dilution to guarantee the safety of the medicinal product ...'

8 — OJ 1975 L 147, p. 13.

9 — Cited in footnote 4.

12. Lastly, I cite Article 9:

should be allowed access to the medicinal products of their choice, provided all precautions are taken to ensure the quality and safety of the said products;

'1. Homeopathic medicinal products other than those referred to in Article 7 of this Directive shall be authorised and labelled in accordance with Articles 4 to 21 of Directive 65/65/EEC, including the provisions concerning proof of therapeutic effect and Articles 1 to 7 of Directive 75/319/EEC.

...

2. A Member State may introduce or retain in its territory specific rules for the pharmacological and toxicological tests and clinical trials of homeopathic medicinal products other than those referred to in Article 7(1) in accordance with the principles and characteristics of homeopathy as practised in that Member State. ...'

— Whereas it is desirable in the first instance to provide users of these medicinal products with a very clear indication of their homeopathic character and with sufficient guarantees of their quality and safety;

— Whereas the rules relating to the manufacture, control and inspection of homeopathic medicinal products must be harmonised to permit the circulation throughout the Community of medicinal products which are safe and of good quality;

13. The Community legislature gives the following reasons, among others, for having special rules for homeopathic medicinal products (I quote here sections from the 3rd and the 8th to 11th recitals in the preamble to Directive 92/73):

— 'Whereas, despite considerable differences in the status of alternative medicines in the Member States, patients

— Whereas, having regard to the particular characteristics of these medicinal products, such as the very low level of active principles they contain and the difficulty of applying to them the conventional statistical methods relating to clinical trials, it is desirable to provide a special, simplified registration procedure for those traditional homeopathic medicinal products which are placed on the market without therapeutic indications in a pharmaceutical form and

dosage which do not present a risk for the patient; B — *National law*

— Whereas, however, the usual rules governing the authorisation to market medicinal products should be applied to homeopathic medicinal products placed on the market with therapeutic indications or in a form which may present risks ...’.

14. The Community directives on medicinal products have now been replaced by Directive 2001/83.¹⁰ Recital (30) in the preamble refers to the importation of medicinal products for personal use. I quote: ‘In this connection persons moving around within the Community have the right to carry a reasonable quantity of medicinal products lawfully obtained for their personal use. It must also be possible for a person established in one Member State to receive from another Member State a reasonable quantity of medicinal products intended for his personal use.’

15. The directives referred to above have been transposed into French legislation in the Public Health Code. The particular sections which are relevant in the present case are Articles R 5142-12 to R 5142-15, in the version prior to the amendment of 23 January 2004.¹¹

16. Article R 5142-12 reads, in so far as is relevant here: ‘Any medicinal product for which no marketing authorisation has been issued, as referred to in Article L 601 ..., must, prior to importation into French customs territory, obtain an import authorisation from the director-general of the Agence française de sécurité sanitaire des produits de santé (French Agency for the Safety of Health Products, “AFSSAPS”) ... Such authorisation may be refused if the medicinal product presents or could present a risk to public health.

...’

17. Article R 5142-13 provides that: ‘Individuals may import medicinal products only in a quantity that is consistent with their personal therapeutic use for a treatment period of not more than three months under

¹⁰ — See footnote 3.

¹¹ — See Decree 2004-83, JORF of 27 January 2004, p. 1934.

normal use, or for the prescribed treatment period. Where individuals import the medicinal product personally, they are exempt from requiring authorisation.'

4e. Where a medicinal product is imported by an individual other than by personal transport, where appropriate the doctor's prescription drawn up in accordance with the special conditions of prescription and supply that apply under French legislation for the medicinal product in question.

18. Article R 5142-14 reads: 'Applications for an import authorisation must include:

...

a. the name or trade name and the address of the natural or legal person responsible for importation;

In all cases the director-general of the AFSSAPS may ask the applicant to supply any supplementary information needed to evaluate the application.'

b. the country of provenance and, where different, the country of origin of the medicinal product;

c. the name, composition, pharmaceutical form, dose and method of administration;

19. Article R 5142-15 specifies which documents have to be supplied to the customs authorities. These are either the import authorisation or temporary import authorisation referred to in Article R 5142-12, or a certified copy of the marketing authorisation or registration issued by the AFSSAPS for the medicinal product, or evidence of authorisation at European Community level.

d. the quantities imported.

The application must be accompanied by:

III — Procedure and scope of the dispute

...

20. After protracted correspondence and verbal consultation with the French autho-

rities concerning the alleged failure to fulfil obligations under Article 28 EC, followed by a reasoned opinion, the Commission brought the present action before the Court on 15 May 2003.¹² Following a written exchange the Court heard the parties at a hearing on 9 September 2004.

that case the Court found that the obligation under Article R 5142-15 to produce (certified copies of) certain documents amounted to a breach of Article 28 EC.¹³

21. The Commission's objections relate to the import, not effected by personal transport, of certain medicinal products for personal use. The dispute does not relate to:

- medicinal products imported for personal use, but for which the patient does not have a doctor's prescription, whereas this is required under French legislation.¹⁴

- medicinal products personally imported by a patient, for which an exemption is provided in French legislation in Article R 5142-13. The exemption does not apply, the parties concur, where a third person (such as a family member) imports the medicinal products on the patient's behalf.

- medicinal products imported by a (commercial) market operator, which were the subject of Case C-122/03. In

22. I would also make the following point. The obligations under Article R 5142-15 apply equally to personal imports other than by the patient himself and to commercial imports. As far as commercial imports are concerned, as I stated earlier, the judgment in Case C-122/03 went against the French Republic. If an intermediary imports a medicinal product on behalf of an individual, as the French Government acknowledges in its rejoinder, that intermediary must produce a copy of the authorisation. The French Government adds that it intends to remove this requirement from the legislation, and it has indeed since done so. However, I have not taken this amendment of national

¹² — There was also a discussion between the parties as to the status and method of dispatch of France's response to the reasoned opinion and as to the significance of a draft amendment to the national legislation objected to. The French Government's rejoinder, however, indicates that it does not wish to pursue this point in the present proceedings.

¹³ — Cited in footnote 5.

¹⁴ — At the hearing the Commission made it clear that such cases are not covered by the dispute.

legislation into account, since it has come too late to be relevant in the present proceedings before the Court.

restricted if their doctor has prescribed a medicinal product which they can purchase in another Member State and which offers them a better remedy for a particular complaint.

23. I have also left aside the question of whether it serves any useful purpose to establish for a second time that an old provision now amended is in breach of Community law. It is clear that the Commission is competent to do so, and that the principle of *ne bis in idem* does not stand in the way of the Commission's application, which relates to a different act — the import of medicinal products for personal use — to that in the application in Case C-122/03, which concerned imports by market operators.¹⁵

25. That does not mean that French legislation and administrative practice are necessarily in breach of Community law — we are dealing with the provision of medical services, a field in which the Member States retain a number of powers which they must be able to exercise effectively — but it might have been advisable for the Commission to scrutinise the French system in its entirety.

24. The question is rather whether there is a systematic breach of Community law by the French Republic. At first sight, French legislation and French administrative practice appear to be more concerned with protecting their own system than with giving patients the freedom to enjoy the benefits of the single market by purchasing medicinal products from another Member State. Patients who have started treatment in another country should be free to continue it in their own country. In addition, with European integration at its current stage of advancement, patients should not be

26. The effectiveness and enforceability of the national measures might also have been examined. I make this point because the present proceedings relate to a patient who obtains medicinal products from another Member State and then uses them in France. If he imports the medicinal products into France himself, he faces few obstacles under French legislation. The situation is different if he asks someone else to bring the medicinal products for him, or if he orders the products by post, by telephone or electronically, when an import authorisation is sometimes required and customs duties apply in all cases. I have doubts as to the effectiveness and enforceability of such national measures and therefore as to whether they are an appropriate means of protecting public health.

¹⁵ — See, for example, how the Court tests this principle in an action for failure to fulfil obligations: Case C-127/99 *Commission v Italy* [2001] ECR I-8305.

IV — Is there a quantitative restriction on imports or a measure having equivalent effect?

27. The Commission explains why the AFSSAPS procedure for importing medicinal products might constitute a barrier to the operation of the internal market and thus be a measure having equivalent effect within the meaning of Article 28 EC. It lists four consequences: if authorisation is refused, the medicinal product in question may not be imported; if authorisation is granted, the procedure delays importation, particularly since French legislation does not specify a period within which the AFSSAPS must give its decision; the patient importing the products has to assemble a dossier, which is burdensome; and finally, the procedure discourages patients wishing to import medicinal products. The Commission presents figures to show that such consequences actually occur.

28. In itself the Commission's argument is perfectly sound. The requirement of prior authorisation for the import, not effected by personal transport, of medicinal products from another Member State is, of itself, a measure having equivalent effect within the meaning of Article 28 EC. The French Government does not contest the Commission's argument on this point, but claims that the Commission's view is based on an incorrect reading of the French legislation.

29. The French Government draws a distinction between medicinal products for which a marketing authorisation has been granted in France (the situation described in point 2 under (a)) and medicinal products not authorised on the market in France (the situation described in point 2 under (c)).

30. Let us take the latter situation first. In view of the provisions of Article R 5142-12 et seq., there is no doubt that prior authorisation is required for the import, not effected by personal transport, of medicinal products from another Member State. The French Government does not contest this, but refers to what happens in practice. In practice, it argues, there is no question of a measure having equivalent effect, since, in the case of import for personal use, the prior authorisation procedure is almost only ever used for imports by residents of non-member countries (frequently Americans who are in France temporarily). The Commission, on the other hand, argues that the small number of applications for authorisation to import from other Member States is evidence of the deterrent nature of the legislation. The French Government contests that view, claiming that only very few people need personal imports of medicinal products from other countries. There is also the following consideration: in its defence the French Government also refers to the procedure for those with a serious or rare illness, in which case the AFSSAPS grants a temporary authorisation provided that a number of special conditions are met. The Commission

attributes little importance to this special procedure, given that it is accessible only to a very small number of patients and even then under very restrictive conditions.

31. However that may be, the statutory requirement to apply for authorisation when an individual wishes to purchase a medicinal product in another Member State is only too obviously, in my view, a measure having equivalent effect within the meaning of Article 28 EC. I make no statement as yet as to whether that measure is justified.

32. That brings me to the second situation. According to the French Government, prior authorisation is not required if a marketing authorisation has already been granted for the medicinal product in France. It refers in particular to Articles R 5142-12 and R 5142-13 of the Public Health Code, and to the reference in the first of those two articles to Article L 601. A standard letter from the AFSSAPS also refers those concerned to those provisions. I share the French Government's view that Articles R 5142-12 and R 5142-14 do not apply to imports of medicinal products authorised in France.

33. However, the obligations laid down in Article R 5142-15 do present an obstacle. As the French Government also acknowledges in its rejoinder, if an intermediary imports a

medicinal product on an individual's behalf, that person must submit a certified copy of the authorisation to the customs authorities. This requirement applies even if the person importing the medicinal product is a member of the patient's family. It is clear to me that the obligation for individuals (other than the patient) to submit a certified copy of the authorisation to the customs authorities is a very onerous requirement for those persons.

34. The parties' views also differ on administrative practice. The Commission states that the barrier to trade is presented not just in law, but also in administrative practice. In its rejoinder the French Government qualifies the Commission's view on this point, stating that individuals who themselves purchase medicinal products in other Member States are not required to submit certified copies of the marketing authorisation to the customs authorities upon import. The arguments that the Commission uses to try to show that impossible demands are made of patients therefore have no factual basis, according to the French Government. I do not find this a cogent defence, since the obligation to submit certified copies does apply to all other individuals who import medicinal products not for themselves, but none the less for personal use. The requirement therefore also applies indirectly to patients, if they are not themselves able to collect medicinal products from another Member State, for example.

35. The following point should also be made. The French Government acknowledges that a document which it forwarded to the Commission concerning practice in the AFSSAPS appears to have given rise to a degree of ambiguity. That document contains a non-exhaustive list of medicinal products requiring the intervention of the AFSSAPS. The list includes medicinal products that are authorised in France.

36. I therefore conclude that even in the case of imports of medicinal products which have a marketing authorisation in France, French legislation (Article R 5142-15 of the Public Health Code) provides for a measure having equivalent effect within the meaning of Article 28 EC. Administrative practice is also such as to make the personal import of medicinal products into France more difficult.

V — Presence of justification under Article 30 EC

A — Introductory remarks

37. It is argued that the import restrictions in the present case are justified on the grounds of protection of public health. The Court has consistently held that the health and life of humans rank foremost among the

property or interests protected by Article 30 EC and it is for the Member States, within the limits imposed by the Treaty, to decide what degree of protection they intend to assure and in particular how strict the checks to be carried out are to be.¹⁶ However, the manner in which the Member States protect public health is subject to the principle of proportionality, as is clear from recital (30) in the preamble to Directive 2001/83, which recognises the right of a resident of a Member State to obtain a reasonable quantity of medicinal products for his or her personal use from another Member State.

38. I agree with the Commission that if the French authorities have authorised a medicinal product in France, they cannot subsequently invoke a risk to public health if that product is imported by individuals from another Member State and the conditions are present for normal use. The Commission rightly refers here to the judgment in *Commission v Germany*,¹⁷ in which the Court held that the prescription of a medicinal product by a doctor in another Member State must be regarded as providing a guarantee equivalent to that which would result from the prescription of a medicinal product by a doctor in the State of importation. It also makes no difference in principle

16 — See, for example, the judgment referred to by the Commission in Case C-62/90 *Commission v Germany* [1992] ECR I-2575, paragraph 10.

17 — Cited in footnote 16, paragraph 15 et seq.

whether a medicinal product is purchased by the patient himself in another Member State, or whether it is sent to him by post.¹⁸

B — Medicinal products authorised both in France and in the Member State in which they are purchased

39. I attach great importance to the principle of mutual recognition — or, in other words, mutual trust — which forms the starting point for Community legislation on medicinal products. If a medicinal product has been tested and subsequently authorised in one Member State, other Member States cannot simply carry on imposing restrictions on imports of that product from that Member State. As the Court has held in its case-law, 'the Member States must rely on trust in each other to carry out inspections on their respective territories. ... A Member State may not unilaterally adopt, on its own authority, corrective or protective measures designed to obviate any breach by another Member State of rules of Community law.'¹⁹

40. In assessing whether there are any justifying grounds, I shall take account of the three cases of failure to fulfil obligations which the Commission distinguishes in its application.

41. As I stated in point 36 above, the barrier to trade stems from the provisions of Article R 5142-15. Under that article persons, other than the patient, who import medicinal products into France for personal use are required, when first requested to do so by the supervisory authorities, to submit either a certified copy, issued by the AFSSAPS, of the French marketing authorisation or of the medicinal product's registration, or a document issued by the AFSSAPS showing that the European Community has granted a marketing authorisation for the medicinal product imported.

42. In Case C-122/03 the Commission argued that this obligation, in so far as it is imposed on market operators, is not justified by any compelling reason of public interest and, even if there were such justifying grounds, it still constitutes a disproportionately severe barrier to trade. The French Government did not contest that view.

43. In my opinion it is clear that that argument also applies in the case of imports of medicinal products for personal use. If, indeed, an undertaking transporting medic-

¹⁸ — With due regard for the conditions referred to in the judgment in Case C-322/01 *Deutscher Apothekerverband* [2003] ECR I-14887.

¹⁹ — See Case C-5/94 *Hedley Lomas* [1996] ECR I-2553, paragraphs 19 and 20.

inal products commercially cannot always be required to carry certified copies, that requirement certainly cannot be imposed on an individual importing medicinal products into France for personal use. In other words, by enforcing a rule such as Article R 5142-15 for medicinal products authorised pursuant to Directive 65/65 (and subsequently, following its repeal, Directive 2001/83) both in France and in the Member State in which they are purchased, the French Republic has failed to fulfil its obligations under Article 28 EC.

which are placed on the market without therapeutic indications in a form and dosage which do not present a risk for the patient. The directive is necessary because of the wide variations in the status of alternative medicines in the Member States, among other things.

46. The question which the Court now has to answer is what significance the existence of a simplified registration procedure for certain safe, traditional homeopathic medicinal products has for the obligations that may be imposed for the import of such products for personal use.

C — Homeopathic medicinal products registered in a Member State

44. This instance must be assessed in the light of the provisions of Directive 92/73 and the objectives pursued by the Community legislature in that directive, as stated in the preamble. There are two distinct objectives, in my view. First, it is desirable for the patient to be able to choose to have certain medicinal products, and he must therefore be properly informed. Second, the quality and safety of the products must be properly guaranteed.

47. According to the Commission, prior authorisation for personal imports of homeopathic medicinal products already registered in a Member State is manifestly unjustified. As a subsidiary plea, the Commission objects to the methods involved in the French procedure, as the information supplied to the Commission indicates that the therapeutic effect of the medicinal products is examined, which under Directive 92/73 is not required for homeopathic products.

45. Directive 92/73 provides for a special, simplified registration procedure for traditional homeopathic medicinal products

48. The French Government takes the view that the Commission has misinterpreted the provisions of Article 7(1) of Directive 92/73. A sufficient degree of dilution is an essential condition for the registration of a homeo-

pathic medicinal product. On the other hand, the directive does not stipulate that, if a product has such a degree of dilution, it must be registered. In addition, according to the French Government, Community legislation does not provide for the mutual recognition of the registration of homeopathic medicinal products. Article 6(1) of Directive 92/73 merely requires Member States to take due account of registrations and authorisations previously granted by another Member State. The French Government refers to Article 9(2) of that directive, which allows a Member State to retain in its territory specific rules for the pharmacological and toxicological tests and clinical trials of certain types of homeopathic medicinal products in accordance with the principles and characteristics of homeopathy as practised in that Member State. Article 9(2) does not, incidentally, apply to the medicinal products referred to in Article 7(1) of Directive 92/73.

49. The Commission makes its position clear on this point. First of all, a homeopathic medicinal product with a sufficient degree of dilution does not have to be registered. What is more important, however, is that the personal importation of homeopathic products should not be subject to the same stringent requirements as is the marketing of such products. The provisions of Article 9(2) of Directive 92/73 do not apply. In conclusion, the Commission analyses Article R 5142-12 et seq. of the Public Health Code in order to demonstrate that the French

authorities also assess the effectiveness of homeopathic products. The Code does not distinguish between homeopathic and other medicinal products. The Commission also bases its argument on the information supplied by the French authorities in conjunction with the AFSSAPS.

50. In its rejoinder the French Government points out that the AFSSAPS does not reassess homeopathic medicinal products, but merely carries out administrative checks on the active principles of the product in order to make sure that active principles which are prohibited in France do not enter the country. In support of its position, the French Government referred at the hearing to the case-law of the Court, and in particular to the recent judgment in *Schreiber*,²⁰ in which the Court vindicated, on the basis of Article 30 EC, a system requiring prior authorisation for the marketing of blocks of red cedar wood with natural moth-deterrent properties.

51. This exchange of views calls for a close examination of the particular rules that apply to homeopathic medicinal products.

52. On the one hand, the special simplified registration procedure provided for in

²⁰ — Case C-443/02 [2004] ECR I-7275.

Article 7(1) of Directive 92/73 allows greater flexibility for the marketing of homeopathic medicinal products. The position is that, provided that they fulfil certain criteria, such medicinal products are deemed not to present any substantial risks to public health, and the checks that have to be carried out prior to admission onto the market may therefore be limited. It would be inconsistent with that situation if such medicinal products could not then be freely transported to the territory of other Member States for personal use. In addition, it flows from Directive 92/73 that certain tests may not be demanded for the purpose of registration. It would undermine the aim of the simplified procedure if such tests could be demanded for imports from another Member State.

53. On the other hand, Directive 92/73 has produced only a limited degree of harmonisation and/or coordination of national legislation. The directive recognises the differences in Member States' approaches to homeopathic medicine, as is clear from, *inter alia*, Article 9(2). It might be inferred from Article 6(1) that a Member State does not have to recognise a registration or authorisation granted in another Member State, but simply has to take due account of it.

54. In my view it is fundamental that the directive distinguishes two types of homeo-

pathic medicinal products. First, there are the medicinal products referred to in Article 7 of Directive 92/73. As I said, those medicinal products are deemed not to present any substantial risks to public health, and a simplified procedure is used for their registration in a Member State. Once registered in a Member State, they may, in principle, move freely within the Community. Given the small degree of risk to public health I attach no importance to the fact that Article 6(1) merely requires due account to be taken of registration. For this type of homeopathic medicinal products the directive, seen in terms of the free movement of goods, relaxes the rules governing medicinal products. It would be inconsistent with the common market if the personal import of such harmless products were subject to any form of restriction. Under Article 9 of the directive, on the other hand, other homeopathic medicinal products are covered by the normal authorisation rules, although Article 9(2) accords special recognition to the differences between the Member States. From the point of view of the free movement of goods, therefore, the rules here are more stringent.

55. To sum up, the homeopathic medicinal products referred to in Article 7 of Directive 92/73 are deemed not to present any substantial risks to public health. Rules hindering the importation of such homeopathic medicinal products after they have been registered in a Member State are

therefore in breach of Community law. The Commission's allegation of failure to fulfil obligations is therefore established, in my view.

— where there is no risk to public health, the decision given must be affirmative for the person concerned;

D — Medicinal products not authorised in France, but authorised in the Member State in which they are purchased

— these requirements must be formalised in national legislation.

56. The Commission has adopted a more qualified approach here: a Member State may make the importation of such medicinal products for personal use subject to a specific prior procedure in order to prevent circumvention of its marketing authorisation mechanism for medicinal products.

58. The French rules do not fulfil those requirements, in the Commission's view. First of all, the procedure is not easily accessible, since the person concerned has to supply a lot of information, including information on the composition of the product, which is by definition located in other Member States. Furthermore, there is no fixed period for the decision by the AFSSAPS, and lastly, there is no guarantee of a positive decision, given that the AFSSAPS examines whether a medicinal product contains active principles that are already authorised in France. Such practice, it is argued, makes it impossible to obtain authorisation for a medicine that is not on the market in France.

57. Such a procedure must fulfil the following requirements, according to the Commission:²¹

- the procedure must be easily accessible;
- the procedure must be rapid and must produce a decision within a reasonable period having regard to the circumstances;

59. The French Government contests the Commission's view. It argues that the procedure is necessary in order to combat fraud and to prevent circumvention of the marketing authorisation mechanism. It contends that the procedure is accessible, since only information that the AFSSAPS itself cannot obtain has to be provided. It is

²¹ — It refers here to the Court's judgment in Case C-344/90 *Commission v France* [1992] ECR I-4719, concerning national rules which made the use of food additives subject to authorisation.

relevant here that Article 105 et seq. of Directive 2001/83 provide for the rapid exchange of information between the offices responsible for authorising medicinal products in the Member States. In addition, the procedure is not delayed if the information is incomplete. In its reply the Commission rejects France's position, pointing out that it cannot be inferred from Article R 5142-14.

60. The periods within which the AFSSAPS gives its decisions are appropriate, according to the French Government. The maximum period is two months, but in practice the AFSSAPS delivers its decisions within one to three days. The person concerned has the option of appealing to the courts.

61. I feel it is appropriate to begin by saying something about the possibilities of fraud or of circumvention of the scheme of the directive, which has allowed the Member States to retain the power to determine which medicinal products can be marketed in their territory. In its observations the Commission rightly draws a clear distinction between the marketing of medicinal products and importation for personal use. It is consistent with the progressive harmonisation that is taking place in the pharmaceutical field and with patients' interest in having freedom of choice that they should also be able to purchase medicinal products in other Member States. I would point out

here that the Court too sees advantages in patients having alternatives when purchasing medicinal products, such as being able to order medicinal products over the internet.²² I would also refer to the case-law in the field of consumer protection. When assessing whether the consumer needs protection, the Court generally takes into account the presumed expectations of an average consumer who is reasonably well informed and reasonably observant and circumspect.²³ It seems to me that such a consumer must, in principle, be deemed capable of purchasing medicinal products in other Member States and using them as prescribed by a doctor.

62. It is not in the interests of public health for a Member State to impose very severe restrictions on imports for personal use. Doctors and pharmacists established in other Member States must also be deemed to be mindful of the interests of the patient's health. The authorities in one Member State must have confidence in what happens in another Member State: that is the starting point of Community legislation. Allowing individuals to purchase medicinal products in other countries brings with it certain risks, of course. I refer here to the judgment in *Deutscher Apothekerverband*,²⁴ in which the Court points out that it may be more difficult

22 — *Deutscher Apothekerverband*, cited in footnote 18, paragraph 113.

23 — See the Court's settled case-law, as summarised in Case C-210/96 *Gut Springenheide and Tusky* [1998] ECR I-4657, paragraph 31.

24 — Cited in footnote 18, paragraph 119.

to check in an appropriate and responsible manner whether the doctors' prescriptions are authentic. There is also, according to the Court, a real possibility that the labelling on a medicinal product purchased in a Member State other than that in which the purchaser is resident will not be written in the purchaser's own language. However, those risks are not such that a procedure should actually deter people from purchasing medicinal products in another Member State, it seems to me. That would be contrary to the fundamental assumption of mutual trust.

could also have the effect of undermining the financial balance of the national marketing authorisation mechanism. That possibility — in relation to cross-border sales of medicinal products — was examined in *Deutscher Apothekerverband*,²⁶ but does not arise in the present case.

64. It is also not in the interests of public health for strict conditions to be imposed on personal imports for personal use. This would not be the case only if the import of certain medicinal products presented the risk of spreading a disease not already present in a country.

63. I would also point out that it is, in certain circumstances, conceivable that the personal importation of medicinal products from other Member States could undermine the operation of a national marketing authorisation mechanism. Such circumstances led to the judgment in *Ortscheit*,²⁵ which concerned a prohibition of advertising for medicinal products not authorised in Germany. The Court held that if medicinal products which were not authorised in Germany could be advertised there, there would be a danger that manufacturers would obtain authorisation for their medicinal products in a Member State imposing fewer requirements and then import them into Germany on the basis of individual orders which they would have encouraged by advertising campaigns. Such a circumstance

65. That brings me to the requirements formulated by the Commission. First of all, the final requirement, that the criteria should be formalised in legislation, is of primary importance in my view. Only if there is legislation spelling out the requirements applicable can individuals know what those requirements are. Flexible administrative practice makes no difference here, nor can it redeem legislation that is in breach of Community law. What is more, the French Government has not been able to demonstrate that its administrative practice is flexible.

25 — Case C-320/93 [1994] ECR I-5243, in particular paragraph 19.

26 — Cited in footnote 18, paragraphs 122 and 123

66. The other three requirements which the Commission formulates are essentially an expression of the general obligation arising from Article 10 EC for the Member States to implement Community law conscientiously and effectively. The statutory authorisation procedure must offer legal certainty to individuals wishing to import medicinal products:

- first, they must have easy access to the procedure and be able to obtain a decision quickly;
- second, the substantive criteria applied by the national authority must be clear. Authorisation should be refused only if there is a risk to public health.

67. The wording of Article R 5142-12 et seq. of the French Public Health Code bears out the Commission's view. Individuals importing medicinal products have to provide details of their name, composition, pharmaceutical form, dose and the administrative background. I consider it acceptable for such information to be required for imports from non-member countries, but the requirement is manifestly disproportionate for imports from another Member State in which the medicinal products are authorised. Where the AFSSAPS does not already have this information at its disposal, it can easily

obtain it from the relevant agency in the other Member State. I would refer here to Article 105 of Directive 2001/83. There is no need to examine how this requirement for the applicant is applied in practice. The same is true of the period for delivering a decision: French legislation does not provide any guarantee that it will be delivered rapidly.

68. That brings me to the substantive criteria which the AFSSAPS may use under French legislation, and on this point I am not so convinced by the Commission's argument. In itself Article R 5142-12 offers sufficient guarantee that authorisation may be refused only if the medicinal product presents or could present a risk to public health. The article states this explicitly. I understand the Commission's argument to be that the AFSSAPS's administrative practice may also result in a refusal which is contrary to that article. In so far as that actually occurs, the French Republic is here too in breach of its Community obligations.

69. However, I do not feel it necessary to examine this last point, since the Commission has demonstrated sufficiently clearly on the other points that, by applying the prior authorisation procedure under the Public Health Code to medicinal products not authorised in France but authorised in the Member State in which they are purchased, the French Republic has failed to fulfil its obligations.

VI — Conclusion

70. In the light of the foregoing I propose that the Court:

(1) declare that the French Republic has failed to fulfil its obligations under Article 28 EC in relation to a number of requirements applied under the French Code de la santé publique to imports, not effected by personal transport, of medicinal products for personal use. The requirements in question are as follows:

- in the case of medicinal products authorised both in France and in the Member State in which they are purchased, the obligation set out in Article R 5142-15 to submit, upon importation into French territory and when first requested to do so by the supervisory authorities, the documents referred to in that article.
- in the case of the homeopathic medicinal products referred to in Article 7 of Council Directive 92/73/EEC of 22 September 1992 widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homeopathic medicinal products, the obligation set out in Article R 5142-12 to obtain an import authorisation prior to importation into French customs territory.
- in the case of medicinal products not authorised in France, but authorised in the Member State in which they are purchased, the obligation set out in Articles R 5142-12 and R 5142-14 to obtain an import authorisation prior to importation into French customs territory;

(2) order the French Republic to pay the costs.