JUDGMENT OF THE COURT (Second Chamber)

26 May 2005 *

In Case C-212/03,

ACTION under Article 226 EC for failure to fulfil obligations, brought on 15 May 2003,

Commission of the European Communities, represented by H. Støvlbæk and B. Stromsky, acting as Agents, with an address for service in Luxembourg,

applicant,

v

French Republic, represented by G. de Bergues, C. Bergeot-Nunes and R. Loosli-Surrans, acting as Agents, with an address for service in Luxembourg,

defendant,

* Language of the case: French.

THE COURT (Second Chamber),

composed of C.W.A. Timmermans, President of the Chamber, C. Gulmann (Rapporteur), R. Schintgen, J. Makarczyk and J. Klučka, Judges,

Advocate General: L.A. Geelhoed,
Registrar: M. Múgica Arzamendi, Principal Administrator,

having regard to the written procedure and further to the hearing on 9 September 2004,

after hearing the Opinion of the Advocate General at the sitting on 21 October 2004,

gives the following

Judgment

1 By its application, the Commission of the European Communities asks the Court to declare that, by applying:

— a prior authorisation procedure to personal imports, not effected by personal transport, of medicinal products lawfully prescribed in France and authorised under 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 (OJ, English Special Edition 1965-1966, p. 20), as amended by Council Directive 93/39/EEC of 14 June 1993 (OJ 1993 L 214, p. 22) ('Directive 65/65'), both in France and in the Member State where they are purchased;

— a prior authorisation procedure to personal imports, not effected by personal transport, of homeopathic medicinal products lawfully prescribed in France and registered in a Member State pursuant to 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 (OJ 1992 L 297, p. 8); and

— a disproportionate prior authorisation procedure to personal imports, not effected by personal transport, of medicinal products lawfully prescribed in France and not authorised in that Member State but only in the Member State where they are purchased,

the French Republic has failed to fulfil its obligations under Article 28 EC.

National regulations

2 Articles R 5142-12, R 5142-13 and R 5142-14 of the French Public Health Code, in the version in force at that time, provided:

'Article R 5142-12 — Any medicinal product for which no marketing authorisation has been issued as referred to in Article L 601 or temporary authorisation for use as

referred to in Article L 601-2(b) granted in respect of imported medicinal products ... 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) ...

...

Article R 5142-13 — 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 normal use, or for the prescribed treatment period. Where individuals import the medicinal product personally, they are exempt from requiring authorisation.

Article R 5142-14 — 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;

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

(c) the name, composition, pharmaceutical form, dosage and method of administration;

(d) the quantities imported.

The application must be accompanied by:

...

4. 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.

...

In all cases the director-general of the French Agency for the Safety of Health Products may ask the applicant to supply any supplementary information needed to evaluate the application.'

Pre-litigation procedure

3 Following a complaint, the Commission decided to examine the compatibility with Community law of the entire authorisation procedure for importation into France of medicinal products for personal use.

4 In a letter of formal notice of 9 March 2000 addressed to the French Government, the Commission informed the latter that the French regulations on the importation of medicinal products, in so far as they require a prior authorisation to be issued in respect of imports of medicinal products by individuals not effected by personal transport, might constitute a measure having equivalent effect to a quantitative restriction on imports prohibited under Article 28 EC.

5 In reply to that letter of formal notice, the French authorities submitted, in a letter of 11 May 2000, that if the control introduced by the French regulations in respect of importation of medicinal products by individuals constituted such a measure, that measure was justified by Article 30 EC since it was intended solely to guarantee the protection of health and life of humans through measures which are not disproportionate.

6 The Commission took the view that that reply was not such as to call in question the grounds for complaint put forward in its letter of formal notice and issued a reasoned opinion on 23 October 2001 calling on the French Republic to take the measures necessary to comply with that opinion within two months of its notification.

7 On 18 December 2001 the French Government sent the Commission a note enclosing a draft decree concerning importation of medicinal products for human consumption. Since that reply, in the Commission's opinion, contained nothing capable of altering its assessment, the Commission decided to bring the present action.

The action

8 By its application, the Commission refers to three situations involving personal imports, not effected by personal transport, of lawfully prescribed medicinal products. Those are imports of:

— medicinal products which, in accordance with Community law, are authorised both in France and in the Member State where they are purchased;

— homeopathic medicinal products which, in accordance with Community law, are registered in another Member State; and

— medicinal products which are not authorised in France but are authorised in the Member State where they are purchased.

9 The Commission notes that, in those three situations, a prior authorisation is required. It submits that that requirement is per se contrary to Article 28 EC in the first two situations outlined and that the authorisation procedure, as applied by the authorities concerned in the third situation, is disproportionate and therefore also contrary to that article.

The first complaint: the procedure for importation of medicinal products authorised both in France and in the Member State where they were purchased

Arguments of the parties

10 The Commission takes the view that a prior authorisation procedure imposed on the importation of medicinal products authorised both in the Member State into which they are imported and in the Member State from which they are exported, under the conditions set out in the application, constitutes a restriction on the free movement of goods between Member States contrary to Article 28 EC.

11 The French Government does not substantially challenge that assessment but is of the opinion that the Commission's analysis is based on an incorrect reading of the French regulations, which, in the circumstances to which the present complaint refers, do not lay down any prior authorisation procedure in respect of medicinal products for which a marketing authorisation has already been obtained in France.

12 The Commission counters by stating that it is calling in question, not the French regulations, but an administrative practice under which the competent authority requires import authorisations in respect of medicinal products intended for personal use and already authorised in France.

13 The French Government concedes that that administrative practice is ambiguous but notes that, in any event, that practice concerns applications from nationals of Member States in only 1% of cases.

Findings of the Court

14 It should be stated, first, that by its complaint the Commission is referring to an administrative practice requiring the issue of an authorisation in respect of personal imports, not effected by personal transport, of lawfully prescribed medicinal products and, secondly, that the French Government does not substantially deny that such a practice, were it established, would constitute a restriction contrary to Article 28 EC.

15 In respect of that administrative practice, the French Government accepts that, according to a document delivered to the Commission concerning the procedure set up by the French Agency for the Safety of Health Products ('AFSSAPS'), an import authorisation is required in respect of a certain number of products for which a marketing authorisation has already been obtained in France. However, it states that that authorisation procedure concerns, in practice, applications made by nationals of Member States in only 1% of cases.

16 That latter circumstance, however, is not such as to remove the restrictive nature of the administrative practice in question for the purpose of Article 28 EC. Rather than the absolute or relative number of authorisations granted, it is the very fact that they are required which is decisive.

17 In those circumstances, an administrative practice requiring authorisation in respect of personal imports, not effected by personal transport, of medicinal products lawfully prescribed and authorised under Directive 65/65/EEC, both in France and in the Member State where they are purchased, must be found to exist in France.

18 It follows that the Commission's first complaint must be upheld.

The second complaint: the procedure for importation of homeopathic medicinal products registered in another Member State

Arguments of the parties

19 The Commission takes the view that it is contrary to Article 28 EC to make homeopathic medicinal products falling within Article 7(1) of Directive 92/73 and registered in another Member State subject to a prior authorisation procedure.

20 The Commission submits that, where a homeopathic medicinal product is registered in a Member State, it does not, a priori, present any health risk, given that Article 7 (1) of Directive 92/73 provides that only homeopathic medicinal products with a sufficient degree of dilution to guarantee their safety may be registered, and that, in addition, the rules relating to the manufacture and control of homeopathic medicinal products have been harmonised.

21 According to the French Government, the authorisation procedure in question is in no way contrary to Article 28 EC. The Member States are free, on grounds of health protection, to require such authorisations.

22 The French Government observes that Directive 92/73 does not lay down a mutual recognition procedure, but a simple obligation for Member States to take due account of registrations or authorisations already issued by another Member State. The view cannot therefore be taken that that directive has established a sufficient degree of harmonisation of Community law to release the Member State of importation from responsibility for the patients concerned.

Findings of the Court

23 It must be stated, first, that requiring an authorisation in respect of the personal importation, not effected by personal transport, of a homeopathic medicinal product lawfully placed on the market in the Member State of exportation constitutes a restriction on the free movement of goods contrary to Article 28 EC which, however, may be justified by the need to protect the health of humans.

24 In that respect, as regards homeopathic medicinal products as defined in Article 2 of Directive 92/73, that directive lays down rules for the harmonisation of the manufacture, control and inspection of those medicinal products and is designed in particular, according to the eighth and ninth recitals in the preamble thereto, to provide users with a clear indication of the homeopathic character of those products and with sufficient guarantees as to their quality and safety.

25 Moreover, the 10th and 11th recitals in that directive show that the latter lays down a distinction between, on the one hand, traditional homeopathic medicinal products placed on the market without therapeutic indications in a dosage which does not present a risk for the patient and, on the other, homeopathic medicinal products marketed with therapeutic indications or in a form which may present risks.

26 The medicinal products in the first group are, under Article 7(1) of Directive 92/73, subject to a special, simplified registration procedure. That procedure applies only if all the conditions listed in that provision are satisfied, including those relating to the absence of any specific therapeutic indication appearing on the labelling and to the degree of dilution which is to guarantee the safety of the medicinal product. In particular, the medicinal product may not contain either more than one part per 10 000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active principles whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription.

27 The homeopathic medicinal products belonging to the second group as referred to in the preamble to Directive 92/73 are, under Article 9(1) thereof, to be authorised in accordance with the rules applicable to medicinal products other than homeopathic medicinal products. For medicinal products in that group, a Member State may, under Article 9(2) of that directive, introduce or retain in its territory specific rules for the pharmacological and toxicological tests and clinical trials of medicinal products in accordance with the principles and characteristics of homeopathy as practised in that Member State.

28 The present complaint refers only to homeopathic medicinal products which have been registered in accordance with the procedure laid down by Article 7 of Directive 92/73, namely medicinal products which have been manufactured, controlled and inspected in accordance with the harmonised rules and which have a sufficient degree of dilution to guarantee their safety.

29 The French Government has not shown that, on grounds of health protection, a prior authorisation procedure is necessary in respect of personal imports, not effected by personal transport, of such medicinal products.

30 It follows that the Commission's second complaint must be upheld.

The third complaint: procedure for importation of medicinal products not authorised in France but authorised in the Member State where they were bought

Arguments of the parties

31 The Commission claims that, as regards the medicinal products referred to in this complaint, the prior authorisation procedure set up should be easily accessible, carried out within a reasonable period and lead to an import authorisation in respect of medicinal products not presenting a risk to public health. However, the procedure applied by the French authorities to personal imports of such medicinal products does not satisfy those criteria and is therefore disproportionate in relation to the objective pursued.

32 Accordingly, in the Commission's view the procedure in question is not easily accessible given that it is not straightforward for the patient concerned to gather information on the qualitative and quantitative composition of the product which is intended for importation and to supply the directions for use and the labelling of that product, which are available only in another Member State. In addition, there is no provision defining the period prescribed to AFSSAPS for processing the application for an import authorisation.

33 Further, it appears that AFSSAPS checks that the medicinal product imported contains active principles present in the composition of medicinal products already evaluated in France. That control precludes, de facto, the possibility of obtaining an authorisation in respect of a medicinal product not authorised in France.

34 The French Government claims that the prior authorisation procedure in question is justified in order to combat fraud or abuse of the system of marketing authorisations.

35 It submits, next, that the procedure in question satisfies the conditions stated by the Commission as capable of justifying the existence of a prior authorisation procedure. First, the detailed rules of that procedure are laid down in Articles R 5142-12, R 5142-13 and R 5142-14 of the Public Health Code, and, secondly, it is common ground that individuals have the opportunity to bring proceedings before the courts against decisions taken by AFSSAPS.

36 In respect of the period within which the authorisation procedure should be brought to completion, the French Government is of the opinion that a period of two months is reasonable, since that is a maximum period and, in practice, in respect of applications submitted by individuals, that period is equal to or less than 24 hours in 50% of cases and equal to or less than 72 hours in 85% of cases.

37 So far as concerns the burden imposed on applicants in relation to information, the French Government submits that the French authorities require individuals to supply information only to the extent to which those authorities, having carried out research or taken up the relevant contacts, do not have information on the medicinal product concerned.

Findings of the Court

38 By the present complaint, the Commission is referring to the importation into France of medicinal products not authorised in that Member State but already authorised in the State where they were purchased, which are lawfully prescribed and are intended for personal use.

39 Whereas, under Article R 5142-13 of the Public Health Code, the French regulations exempt from authorisation importation of such medicinal products when they are transported personally by persons who use them, that is not the case when the importation by those persons of the same medicinal products is not effected by personal transport.

40 In respect of the latter imports, the general rules on import authorisations laid down in Articles R 5142-12 and R 5142-14 of the Public Health Code generally apply.

41 The fact that Article L 601-2 of the Public Health Code set up a procedure of temporary authorisation for use applying to patients suffering from serious or rare diseases is not relevant in this case in view of the limited scope of application of that procedure.

42 Although the Commission does not dispute, in this case, that the authorities concerned are free to require an authorisation for the imports covered by this complaint, it rightly claims, however, that it is disproportionate to apply the same authorisation procedure to those imports as it does to medicinal products imported for commercial purposes.

43 Although grounds of health protection may justify restrictions on the free movement of goods between Member States, such measures must comply with the principle of proportionality. They must be confined to what is actually necessary to ensure the safeguarding of public health; they must be proportionate to the objective pursued, which could not have been attained by measures which are less restrictive of intra-Community trade (see Case C-192/01 *Commission* v *Denmark* [2003] ECR I-9693, paragraph 45).

44 The French Government has not demonstrated the need to make the imports in question, which would be exempt from requiring authorisation if they had been effected by personal transport, subject to the authorisation procedure applied to commercial imports.

45 So far as concerns the imports referred to by the present complaint, it is for the French authorities to adopt an authorisation procedure adapted to the specific nature of those imports and the restrictive effects on intra-Community trade of which do not go beyond what is necessary to attain the objective pursued (see, concerning a specific procedure relating to parallel imports of medicinal products, the judgment of 12 October 2004 in Case C-263/03 *Commission* v *France*, not published in the ECR, paragraphs 19 and 20).

46 That procedure must be easily accessible and capable of being brought to completion within a reasonable period (see *Commission* v *France*, paragraph 21).

47 Since it has not laid down those specific rules, the French Republic has not fulfilled its obligations under Article 28 EC.

48 Under those circumstances, the present complaint must also be upheld.

49 Having regard to all of the foregoing considerations, it must be held that, by applying:

— a prior authorisation procedure to personal imports, not effected by personal transport, of medicinal products lawfully prescribed in France and authorised under Directive 65/65, both in France and in the Member State where they are purchased;

— a prior authorisation procedure to personal imports, not effected by personal transport, of homeopathic medicinal products lawfully prescribed in France and registered in a Member State pursuant to Directive 92/73; and

— a disproportionate prior authorisation procedure to personal imports, not effected by personal transport, of medicinal products lawfully prescribed in France and not authorised in that Member State but only in the Member State where they are purchased,

the French Republic has failed to fulfil its obligations under Article 28 EC.

Costs

50 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Commission has applied for costs and the French Republic has been unsuccessful, the latter must be ordered to pay the costs.

On those grounds, the Court (Second Chamber) hereby:

1. **Declares that, by applying:**

— **a prior authorisation procedure to personal imports, not effected by personal transport, of medicinal products lawfully prescribed in France and authorised under 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, as amended by Council Directive 93/39/EEC of 14 June 1993, both in France and in the Member State where they are purchased;**

— **a prior authorisation procedure to personal imports, not effected by personal transport, of homeopathic medicinal products lawfully prescribed in France and registered in a Member State pursuant to 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; and

— a disproportionate prior authorisation procedure to personal imports, not effected by personal transport, of medicinal products lawfully prescribed in France and not authorised in that Member State but only in the Member State where they are purchased,

the French Republic has failed to fulfil its obligations under Article 28 EC;

2. Orders the French Republic to pay the costs.

[Signatures]