JUDGMENT OF THE COURT (Third Chamber)
11 December 2003 *

In Case C-122/03,

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 and C. Bergeot-Nunes, acting as Agents,

defendant,

* Language of the case: French.

APPLICATION for a declaration that, by imposing, pursuant to Article R. 5142-15 of the Code de la santé publique, on traders importing or distributing in France medicinal products which are already covered by a marketing authorisation for the French or Community market a requirement that they submit, when first so requested by the monitoring authorities, either a certified copy issued by the Agence française de securité sanitaire des produits de santé of the French marketing authorisation or of the registration of the medicinal product, or a document issued by that Agency attesting that the imported medicinal product has obtained a marketing authorisation issued by the European Community, the French Republic has failed to fulfil its obligations under Article 28 EC,

THE COURT (Third Chamber),

composed of: C. Gulmann (Rapporteur), acting for the President of the Third Chamber, J.-P. Puissochet and F. Macken, Judges,

Advocate General: L.A. Geelhoed,
Registrar: R. Grass,

having regard to the report of the Judge-Rapporteur,

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

gives the following

Judgment

1 By application lodged at the Court Registry on 19 March 2003, the Commission of the European Communities brought an action under Article 226 EC for a declaration that, by imposing, pursuant to Article R. 5142-15 of the Code de la santé publique (French Public Health Code), on traders importing or distributing in France medicinal products which are already covered by a marketing authorisation for the French or Community market a requirement that they submit, when first so requested by the monitoring authorities, either a certified copy issued by the Agence française de securité sanitaire des produits de santé (French Agency for Health Product Safety) of the French marketing authorisation or of the registration of the medicinal product, or a document issued by that Agency attesting that the imported medicinal product has obtained a marketing authorisation issued by the European Community, the French Republic has failed to fulfil its obligations under Article 28 EC.

Legal background

Community legislation

2 Article 28 EC provides that quantitative restrictions on imports and all measures having equivalent effect are to be prohibited between Member States.

3 Article 30 EC states that the provisions of Article 28 EC are not to preclude prohibitions or restrictions on imports justified *inter alia* on grounds of the protection of health and life of humans. Such prohibitions or restrictions are not, however, to constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

4 According to Article 3 of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to 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), no medicinal product may be placed on the market in a Member State unless a marketing authorisation (hereinafter 'MA') has been issued by the competent authorities of that Member State in accordance with that directive or an authorisation has been granted in accordance with Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ 1993 L 214, p. 1).

5 Article 2(1) of Council Directive 92/27/EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets (OJ 1992 L 113, p. 8) requires that particulars of *inter alia* the MA number appear on the outer packaging of medicinal products or, where there is no exterior packaging, on the immediate packaging.

National legislation

6 Article R. 5142-15 of the Code de la santé publique, as amended by Decree No 99-144 of 4 March 1999 (JORF of 5 March 1999, p. 3294, hereinafter 'the contested provision') is worded as follows:

'On request by customs officers, where a medicinal product has a Community status within the meaning of Article 4 of Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code, and in other cases in support of the customs declaration, there shall be submitted:

1. ...

2. either a certified copy issued by the Agence française de sécurité sanitaire des produits de santé of the [MA] or of the registration of the medicinal product,

3. or a document issued by the Agence française de securité sanitaire des produits de santé attesting that the imported medicinal product has obtained an [MA] issued by the European Community.'

Pre-litigation procedure

7 As it considered that the contested provision and its implementation by the French authorities were likely to constitute a measure having an effect equivalent to a quantitative restriction, prohibited by Article 28 EC, the Commission sent to the French Republic on 3 June 1999 a letter of formal notice in accordance with Article 226 EC.

8 By letter of 13 September 1999 the French authorities replied to that letter of formal notice, announcing *inter alia* their intention to adopt a new decree repealing the contested provision and to replace it with a system for monitoring the MA number appearing on the packaging of medicinal products.

9 On 31 March 2000, the French authorities notified the Commission of a draft decree amending *inter alia* the contested provision and stating that 'for medicinal products bearing the [MA] referred to in Article L. 601, or the registration referred to in Article L. 603, customs officers shall check the [MA] number or the corresponding registration number which appears on the packaging. This will be done either in the course of random checks, where the medicinal product has a Community status, or when the customs declaration is lodged in other cases'.

10 In a letter of 10 July 2000 addressed to the French authorities, the Commission intimated that it considered that the contested provision as amended by the draft decree represented a satisfactory response to the objections raised in the letter of formal notice, and requested the French authorities to adopt the amended version as soon as possible.

11 In a letter of 4 December 2000, the French authorities stated that they did not consider it necessary to adopt the new Article R. 5142-15 of the Code de la santé publique separately from other provisions that were under preparation relating to parallel importing of medicinal products.

12 As it considered that the breach of Community law remained unremedied the Commission sent a reasoned opinion to the French Republic on 29 December 2000 requesting it to adopt the measures necessary to comply with the opinion within two months of its notification.

13 By letter of 18 March 2001, the French authorities replied that the draft decree relating to imports of medicinal products for human use was practically finalised and would be considered by the French Conseil d'État as soon as the Conseil de la concurrence (Competition Council) had given its opinion. They stated again that they considered it pointless and technically problematic to adopt the new version of the contested provision separately from other provisions relating to parallel importing of medicinal products.

14 At a meeting held on 23 January 2002, the French authorities informed the Commission that the draft decree relating to imports of medicinal products for human use had been sent to the relevant ministers for signature on 10 August 2001, but that it had still not been signed.

15 In those circumstances, the Commission decided to bring the present action.

Substance

16 The Commission claims that the contested provision is capable of hindering, directly or indirectly, actually or potentially, intra-Community trade and that it therefore constitutes a measure having an effect equivalent to a quantitative restriction, prohibited by Article 28 EC.

17 The Commmission observes first of all that, as regards the period before the products are imported, the requirement under the contested provision to submit documents necessitates an administrative involvement with the French authorities, thereby hindering the import of medicinal products in France.

18 In relation, next, to the actual importation of the products, the Commission claims, first, that the requirement to submit 'on request by customs officers' either a certified copy of the MA or of the registration of the medicinal product, or a document attesting that the imported medicinal product has obtained an MA issued by the European Community, imposes an obligation on importers and distributors permanently to retain the necessary documents. Secondly, the number and volume of the necessary documents could give rise to transport difficulties at all statges of import and distribution.

19 The Commission argues lastly that the French authorities have put forward no justification in support of the contested provision. Even supposing that the contested provision could have been prompted by the objective of protecting health and life of humans, it would not comply with the requirements of Article 30 EC. If the objective of the contested provision were to enable the competent authorities to verify that a French or Community MA has been obtained, it could be attained as effectively by a system which is less of an obstacle to intra-Community trade, for example by checking the number on the external packaging of the medicinal product, as the draft decree amending the provision in issue stipulated.

20 The French Government states in response that the draft decree amending the provision in issue was ultimately not adopted. It explains that on the change in government, the draft was the subject of new discussions with the trade. Following those discussions, a fresh draft decree was prepared. While it differs in some ways from the previous draft, the substance of the provision amending the provision in issue nevertheless remains unchanged.

21 Before being signed and publicised, the new draft decree will require to be considered again by the Conseil d'État, and the matter will be brought before it in

June 2003. The French Government has given assurances that it will strive to ensure that this decree is adopted as swiftly as possible.

22 The French Government does not dispute the failure to fulfil its obligations and the Commission's action must therefore be held to be well founded.

Costs

23 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 (Third Chamber),

hereby:

1. **Declares that by imposing, pursuant to Article R. 5142-15 of the Code de la santé publique, on traders importing or distributing in France medicinal**

products which are already covered by a marketing authorisation for the French or Community market a requirement that they submit, when first so requested by the monitoring authorities, either a certified copy issued by the Agence française de securité sanitaire des produits de santé of the French marketing authorisation or of the registration of the medicinal product, or a document issued by that Agency certifying that the imported medicinal product has obtained a marketing authorisation issued by the European Community, the French Republic has failed to fulfil its obligations under Article 28 EC;

2. Orders the French Republic to pay the costs.

Gulmann Puissochet Macken

Delivered in open court in Luxembourg on 11 December 2003.

R. Grass V. Skouris

Registrar President