JUDGMENT OF THE COURT (Sixth Chamber)

14 December 2000 *

In Case C-55/99,

Commission of the European Communities, represented by R.B. Wainwright, Principal Legal Adviser, and O. Couvert-Castéra, a national civil servant on secondment to its Legal Service, acting as Agents, with an address for service in Luxembourg at the office of C. Gómez de la Cruz, of its Legal Service, Wagner Centre, Kirchberg,

applicant,

v

French Republic, represented by K. Rispal-Bellanger, Head of Subdirectorate in the Legal Affairs Directorate at the Ministry of Foreign Affairs, and R. Loosli-Surrans, Chargé de Mission in the same directorate, acting as Agents,

defendant,

APPLICATION for a declaration that, by introducing in Decree No 96-351 of 19 April 1996 concerning the reagents mentioned in Article L.761-14-1 of the Code de la Santé Publique (Code of Public Health) (JORF, 26 April 1996,

* Language of the case: French.

p. 6386) a registration procedure for all medical reagents, and by imposing in that decree the obligation to state the registration number on the external packaging and the notice accompanying each reagent, the French Republic has failed to fulfil its obligations under Article 30 of the EC Treaty (now, after amendment, Article 28 EC),

THE COURT (Sixth Chamber),

composed of: V. Skouris, President of the Second Chamber, acting as President of the Sixth Chamber (Rapporteur), J.-P. Puissochet and F. Macken, Judges,

Advocate General: N. Fennelly,
Registrar: L. Hewlett, Administrator,

having regard to the Report for the Hearing,

after hearing oral argument from the parties at the hearing on 17 February 2000,

after hearing the Opinion of the Advocate General at the sitting on 6 April 2000,

gives the following

Judgment

1 By application lodged at the Court Registry on 18 February 1999, the Commission of the European Communities brought an action under Article 169 of the EC Treaty (now Article 226 EC) for a declaration that, by introducing in Decree No 96-351 of 19 April 1996 concerning the reagents mentioned in Article L.761-14-1 of the Code de la Santé Publique (Code of Public Health) (*Journal Officiel de la République Française*, 26 April 1996, p. 6386, hereinafter 'the contested decree') a registration procedure for all medical reagents, and by imposing in that decree the obligation to state the registration number on the external packaging and the notice accompanying each reagent, the French Republic had failed to fulfil its obligations under Article 30 of the EC Treaty (now, after amendment, Article 28 EC).

Legal background

2 The third paragraph of Article 19 of Law No 93-5 of 4 January 1993 on safety in connection with blood transfusions and medicines (JORF, 5 January 1993, p. 237) defines medical reagents as chemical or biological substances specially prepared for use *in vitro*, in isolation or in association, for medical biology analyses within the meaning of Article L.753 of the Code of Public Health. Under Article L.753 of the Code, medical biology analyses are biological examinations which contribute to the diagnosis, treatment or prevention of human diseases or which disclose any other change in physiological condition.

3 As regards the marketing of these substances, the first paragraph of Article L.761-14-1 of the Code prescribes that reagents intended for laboratories performing medical biology analyses and reagents packaged for sale to the public and intended for medical diagnosis or pregnancy testing are to be subject, before they are placed on the market, whether or not for consideration, to registration with the Agence du Médicament (Medicinal Products Agency) under conditions laid down by decree adopted in the Conseil d'État.

4 To that end, the contested decree, in the first paragraph of Article 1, makes the placing of reagents on the French market subject to their prior registration and, in subsequent articles, lays down the detailed conditions of registration.

5 In particular, Article 2 of the contested decree lists 15 items of documentation which must be included in the file of the application to the Agence du Médicament for registration, among which are all information on the diagnostic and therapeutic value of the reagent, the conditions of conservation supported by results of stability studies, and a report of analytical and clinical evaluations. Article 4 of the contested decree further requires the applicant to inform the Agence du Médicament of any change affecting the items in the registration file.

6 Under Article 3 of the contested decree, if the file defined in Article 2 is complete, the Director-General of the Agence du Médicament shall, if appropriate, after consulting the advisory committee on registration of reagents set up to advise the Minister of Health under Articles 6 and 7 of the decree, register the reagent or the range of reagents which is the subject of the application, and inform the applicant of the registration number.

7 Under Article 5(I)(11) of the contested decree, the notice accompanying each reagent must mention the registration with the Agence du Médicament.

8 Under Article 5(II)(3) of the contested decree, the registration number must appear on the primary packaging and the external packaging. However, under the second subparagraph of Article 5(II), where there is external packaging the primary packaging need not state the registration number.

9 Article 5 of the contested decree also requires the batch number of manufacture and the name and address of the distributor to be stated on the primary packaging and the external packaging (Article 5(II)(8) and (2)), and the name and address of the manufacturer, the distributor and, if any, the importer to be stated on the accompanying notice (Article 5(I)(2)).

Facts and pre-litigation procedure

10 Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ 1983 L 109, p. 8), applicable at the material time, requires Member States to communicate immediately to the Commission any draft technical regulation and provides for a procedure for informing the other Member States and time-limits for submitting any observations on the draft communicated.

11 In accordance with that directive, the French authorities on 19 January 1995 informed the Commission of a draft decree, which was to become the contested decree, stating that pursuant to Article 9(3) of the directive, for urgent reasons relating to the protection of public health, they were obliged to introduce the measures laid down by that draft decree immediately.

12 After accepting on 23 January 1995 the French Government's recourse to the urgent procedure, while reserving its assessment of the compatibility with Community law of the draft notified, the Commission informed the French authorities by letter of 6 April 1995 of the problems it considered the adoption of the draft decree notified would raise with respect to free movement of goods, and made certain criticisms relating in particular to the provisions of the draft on the introduction of a registration procedure for all reagents, the obligation to indicate the registration number on the external packaging, and the absence of a rule on mutual recognition of checks carried out in other Member States.

13 Since the contested decree was subsequently adopted without the French Government taking account of its comments, the Commission, repeating its criticisms and still of the opinion that the provisions of the contested decree to which those criticisms related constituted measures having equivalent effect to quantitative restrictions, contrary to Article 30 of the Treaty, on 15 April 1997 sent the French Government a letter of formal notice requesting it to submit its observations.

14 Since the French authorities' reply of 3 July 1997 was not regarded as satisfactory by the Commission, a meeting took place between it and the French authorities, but the problems which had been raised were not settled.

15 In those circumstances, the Commission on 10 August 1998 sent the French Republic a reasoned opinion, calling on France to take the measures necessary to comply with the reasoned opinion within two months from its notification.

16 In reply to the reasoned opinion, the French authorities, by letter of 19 October 1998, informed the Commission that the contested decree was being amended to include a provision for mutual recognition of evaluations of reagents carried out in other Member States or countries of the European Economic Area.

17 As the French authorities' reply did not mention any other changes of the kind sought, the Commission brought the present action.

Subject-matter of the dispute

18 In view of the French Government's undertaking to include in the contested decree a mutual recognition provision, the Commission in its application expressly abandons its complaint on that point. However, it makes two other complaints against the French Republic. It submits that, first, the introduction of

a registration procedure applicable to all reagents without any distinction according to the seriousness of the disease they may detect or the reliability they must guarantee for public health and, second, the obligation to state the registration number on the external packaging and the notice accompanying each reagent constitute measures having equivalent effect to quantitative restrictions.

19 In its defence, the French Government does not dispute that those two requirements are capable of constituting measures of equivalent effect. It submits, however, that they are justified by the contested decree's objective of the protection of public health and are proportionate to the aim pursued.

20 Since the Commission, in its reply, does not dispute that the contested decree pursues an objective of the protection of public health, the issue of the dispute is confined to whether the provisions at issue comply with the principle of proportionality. The Commission considers that they do not constitute measures which are necessary and appropriate for attaining the objective of protection of public health.

Substance

The registration procedure introduced by the contested decree

21 The Commission submits that the registration procedure prescribed by the contested decree is disproportionate because, first, it imposes a single system of registration prior to placing on the market on all reagents, without distinguishing

according to the seriousness of the diseases they are intended to detect or the level of risk any unreliability might present for public health, and, second, it requires the manufacturers, importers or distributors to produce, in order to make up the registration file, documentation which includes items of unnecessary information.

22 As regards the introduction of a single registration procedure applicable to all reagents, the Commission submits that in order to determine whether the contested decree breaches the principle of proportionality account should be taken of the system established by Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ 1998 L 331, p. 1), which, as may be seen from the 22nd recital in its preamble, distinguishes between reagents which are liable to create a direct risk to patients' health in the event of failure and those which are not. The Commission states that, although that directive did not yet apply when the contested decree was adopted, its provisions are a useful factor of assessment and may be referred to, as the Court did in Case C-350/97 *Monsees* v *Unabhängiger Verwaltungssenat für Kärnten* [1999] ECR I-2921, paragraph 30, concerning another directive, to show that other less restrictive measures exist.

23 On that basis, the Commission concludes that the French system of registration might be justified with respect to certain reagents capable of detecting the serious diseases such as AIDS and some forms of hepatitis listed in Annex II to Directive 98/79, but that it is in any event not justified for all reagents.

24 The Commission further stated at the hearing that about 60% of the reagents available on the Community market present no direct risks to health, for example tests for chloresterol, allergies, salmonella and diabetes. In its opinion, the fact

that Directive 98/79 lays down, for most *in vitro* diagnostic medical devices, an obligation on the manufacturer to make a declaration shows that alternative measures exist which are less restrictive of trade than the French registration system.

25 The French Government submits, first, that it is for the Commission to establish that the provisions at issue of the contested decree are disproportionate, and that, since Directive 98/79 was not yet in force when that decree was adopted, it may not be used as a factor in assessing whether those provisions are proportionate from the point of view of Community law.

26 The Government submits, second, that in the absence of harmonising rules on reagents it is for the Member States to choose the level of protection of public health. In those circumstances, a Member State is not required to distinguish between two classes of reagents according to whether or not they present a direct risk to health in the event of failure. The Government adds that, of the diseases or conditions which require merely a medical response, some, such as pregnancy, may have consequences for life and health as serious as those of AIDS or certain forms of hepatitis if they are not detected in good time, so that the division of reagents into two categories as suggested by the Commission is not correct. The Government refers here to pregnancy testing, which, if it is not reliable, may have serious consequences for the life of the mother and the foetus, if the results given do not make it possible to take the appropriate precautions or follow the treatment which is necessary in certain pregnancies involving risks.

27 In view of the arguments of the parties, and in order to determine whether the provisions at issue comply with the principle of proportionality, it must be

recalled that according to settled case-law, with respect to products liable to create a danger to health, in the absence of harmonising rules it is for the Member States to decide on their intended level of protection of human health and life and on whether to require prior authorisation for the marketing of such products (see Case C-400/96 *Harpegnies* [1998] ECR I-5121, paragraph 33).

28 The Member States also have that power with respect to reagents, which, while presenting no danger themselves, are liable, if only indirectly, to expose the health or life of humans to danger if their diagnostic performance is not reliable. Member States are therefore authorised in principle to introduce a prior registration procedure for those products, which will by its nature be less strict than prior authorisation before placing on the market.

29 Nevertheless, the principle of proportionality which underlies the last sentence of Article 36 of the EC Treaty (now, after amendment, Article 30 EC) requires that the power of the Member States to impose restrictions in trade in products from other Member States should be limited to what is necessary to attain the objectives of protection being legitimately pursued (see, to that effect, *Harpegnies*, paragraph 34).

30 Moreover, in proceedings for failure to fulfil an obligation, it is for the Commission to prove the allegation that the obligation has not been fulfilled and to place before the Court the information needed to enable it to determine whether the obligation has not been fulfilled (see Case C-159/94 *Commission* v *France* [1997] ECR I-5815, paragraph 102).

31 In this respect, without there being any need to consider whether Directive 98/79 may usefully be referred to in ascertaining whether the contested decree is proportionate from the point of view of Community law, it must be stated that the Commission has done no more than repeat the distinction drawn in that directive, without supporting its criticism of the contested decree with detailed reasons or information to enable the Court to determine whether the application of the decree to all reagents means that it is disproportionate. It has merely adduced some examples, summarised in paragraph 24 above, which in its opinion show that there are reagents for which the requirement of prior registration as prescribed by the contested decree is unnecessary.

32 As regards those examples, the French Government has refuted the Commission's arguments, first, by pointing out the absence of harmonising rules in the matter and, second, by showing that there are reagents, such as pregnancy tests, which, although — as the Commission itself states — not belonging to the category of those which present a direct risk to patients, are nevertheless liable to create danger to the life and health of humans if they are not reliable. Besides pregnancy tests, that conclusion applies also to other tests, including those mentioned as examples by the Commission and referred to in paragraph 24 above.

33 As to the Commission's assertion at the hearing that the prior registration procedure is unnecessary for at least 60% of reagents, it has not identified clearly the reagents which are said not to require prior registration. By merely stating that, for reagents which do not present a direct risk to health, registration under the contested decree could be replaced by a declaration to the authorities by the manufacturer or distributor of such reagents, in the same way as provided for by Directive 98/79, the Commission has not shown that, in the absence of harmonisation, the registration prescribed by the contested decree is unnecessary. Finally, the Commission has not produced any other information to show that the provisions of that decree are not proportionate.

34 As well as the complaint concerning the obligation of prior registration for all reagents, the Commission also submits that some of the conditions of registration are unnecessary. It submits in particular that by requiring the production of needless documentation for making up the registration file the contested decree breaches the principle of proportionality. That applies to the obligation to communicate all information on the therapeutic value of all reagents, which is rather within the competence of the doctor, on the results of stability tests, which are not necessary in the case of inorganic reagents, and on the report on analytical and clinical evaluations where the reagents have already been the subject of large-scale published studies, and to the obligation to update the file if there is a change which affects the items in it.

35 The French Government, on the other hand, submits that the documentation required and the obligation to update the file are necessary because they enable unreliable or ineffective reagents to be detected. The documentation, combined with the obligation to update the file, makes it possible to establish a data bank which is updated regularly with a view to permanent 'reacto-vigilance', allowing products which prove less reliable or less effective to be withdrawn or substituted following checks by sampling or in the light of inconsistencies in the file. The Government states that, although not all reagents are tested before registration, the information in the file constitutes the basis for carrying out checks or rechecks for long-term surveillance of the market in reagents.

36 On this point, it must be held that the Commission has not produced evidence to show that the documentation required and the updating of the registration file are unnecessary.

37 With respect to the documentation for establishing the therapeutic value of reagents, the Commission has done no more than state that that value appears to

belong rather to the province of the doctor. With respect to the results of stability tests, it says, without further explanation, that those studies are not necessary for inorganic reagents. With respect to the report of analytical and clinical evaluations, it merely observes that Directive 98/79 adopted a different solution.

38 As to the obligation to update the file in the event of a change affecting the items in it, the Commission has not adduced any arguments to show that that obligation is of no relevance for the evaluation of reagents.

39 Accordingly, since the Commission has not put before the Court evidence from which it could conclude that the registration system for reagents under the contested decree is disproportionate, the complaint in this respect must be rejected.

The obligation to state the registration number on the external packaging and to mention the registration on the notice accompanying each reagent

40 The Commission submits that the obligation for the manufacturers, importers or distributors to indicate the registration number on the external packaging and the notice accompanying each reagent is not appropriate with regard to the aim pursued, since merely stating the registration number on that packaging and

notice does not guarantee that the reagent complies with public health requirements, nor does it provide users with information concerning actual verification that there is no risk to health. Since the sole function of indicating the registration number is, according to the Commission, to provide users with information relating to the fulfilment of an administrative formality, the obligation in question is disproportionate, having regard to the objective of the protection of public health.

41 The French Government argues that the measure is proportionate on the basis of the requirement for reagents to be traceable. It submits that the obligation to indicate the registration number makes it possible, where appropriate, to identify products causing incidents, to contact the manufacturer, distributor or importer, and if need be to ensure that the products concerned are withdrawn from the market. The Government also said at the hearing that such an obligation is necessary to remove all risk of confusion where the same reagent is placed on the market in successive periods under the same or a similar name and, although presenting the same characteristics, has better efficacy and reliability because of scientific and technical developments.

42 It is settled case-law that a national provision which has, or is likely to have, a restrictive effect on the importation of products is compatible with the Treaty only to the extent that it is necessary for the effective protection of the health and life of humans. A national provision cannot therefore benefit from the derogation in Article 36 of the Treaty if the health and life of humans may be protected just as effectively by measures which are less restrictive of intra-Community trade (see Case C-473/98 *Kemikalieinspektionen* v *Toolex Alpha*, [2000] ECR I-5681, paragraph 40).

43 Mentioning the registration, in particular by stating the registration number, merely guarantees the user that the reagent has been registered with the

competent authorities, and does not provide any additional information which might effectively protect public health. By contrast, the other requirements of Article 5 of the contested decree, namely that the name and address of the distributor and the batch number of manufacture must appear on both the external packaging and the primary packaging of the reagent itself, while the name and address of the manufacturer, distributor and, if any, the importer must appear on the accompanying notice, constitute measures which are sufficient to ensure that reagents are traceable.

44 As to the French Government's argument on the risk of possible confusion between different versions of reagents marketed under the same or similar names, the obligation to state the batch number laid down by Article 5(II)(8) of the contested decree constitutes a measure which is sufficient to avert such a risk.

45 In view of the existence of less restrictive means, the obligation at issue does not therefore comply with the principle of proportionality.

46 In those circumstances, by imposing in the contested decree the obligation to state the registration number on the external packaging and to mention that registration on the notice accompanying each medical reagent, the French Republic has failed to fulfil its obligations under Article 30 of the Treaty. The remainder of the application is dismissed.

Costs

47 Under the first subparagraph of Article 69(3) of the Rules of Procedure, where each party succeeds on some and fails on other heads the Court may order that the costs be shared or that the parties bear their own costs. Since the Commission and the French Republic have each been unsuccessful on one head, they must be ordered to bear their own costs.

On those grounds,

THE COURT (Sixth Chamber),

hereby:

1. Declares that, by imposing in Decree No 96-351 of 19 April 1996 concerning the reagents mentioned in Article L.761-14-1 of the Code de la Santé Publique the obligation to state the registration number on the external

packaging and to mention that registration on the notice accompanying each medical reagent, the French Republic has failed to fulfil its obligations under Article 30 of the EC Treaty (now, after amendment, Article 28 EC);

2. Dismisses the remainder of the application;

3. Orders the French Republic and the Commission of the European Communities to bear their own costs.

Skouris Puissochet Macken

Delivered in open court in Luxembourg on 14 December 2000.

R. Grass V. Skouris

Registrar For the President of the Sixth Chamber