ORDER OF THE PRESIDENT OF THE COURT
8 May 2003 *

In Case C-39/03 P-R,

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

appellant,

APPLICATION for suspension of operation of the judgment of the Court of First Instance of the European Communities (Second Chamber, Extended Composition) of 26 November 2002 in Joined Cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00 *Artegodan and Others* v *Commission*, ECR II-4945,

the other parties to the proceedings being:

Artegodan GmbH, established in Lüchow (Germany), represented by U. Doepner, Rechtsanwalt, with an address for service in Luxembourg,

* Languages of the case: German, English and French.

Bruno Farmaceutici SpA, established in Rome (Italy),

Essential Nutrition Ltd, established in Brough (United Kingdom),

Hoechst Marion Roussel Ltd, established in Denham (United Kingdom),

Hoechst Marion Roussel SA, established in Brussels (Belgium),

Marion Merrell SA, established in Puteaux (France),

Marion Merrell SA, established in Barcelona (Spain),

Sanova Pharma GmbH, established in Vienna (Austria),

Temmler Pharma GmbH & Co. KG, established in Marburg (Germany),

Schuck GmbH, established in Schwaig (Germany),

Laboratórios Roussel L^{da}, established in Mem Martins (Portugal),

Laboratoires Roussel Diamant SARL, established in Puteaux,

Roussel Iberica SA, established in Barcelona,

represented by B. Sträter and M. Ambrosius, Rechtsanwälte, with an address for service in Luxembourg,

Gerot Pharmazeutika GmbH, established in Vienna, represented by K. Grigkar, Rechtsanwalt, with an address for service in Luxembourg,

Cambridge Healthcare Supplies Ltd, established in Norfolk (United Kingdom), represented by D. Vaughan QC, K. Bacon, barrister, and S. Davis, solicitor, with an address for service in Luxembourg,

and

Laboratoires pharmaceutiques Trenker SA, established in Brussels, represented by L. Defalque and X. Leurquin, avocats, with an address for service in Luxembourg,

applicants at first instance,

THE PRESIDENT OF THE COURT

upon hearing the Advocate General, S. Alber,

makes the following

Order

1 By application lodged at the Court Registry on 3 February 2003, the Commission of the European Communities, in accordance with Article 225 EC and the first paragraph of Article 56 of the Statute of the Court of Justice, brought an appeal against the judgment of the Court of First Instance of 26 November 2002 in Joined Cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00 *Artegodan and Others* v *Commission* (ECR II-4945, 'the judgment under appeal'), by which the Court of First Instance annulled, in so far as they related to the medicinal products marketed by the applicants at first instance, Commission Decisions C(2000) 452, C(2000) 453 and C(2000) 608 of 9 March 2000 concerning the withdrawal of marketing authorisations of medicinal products for human use containing phentermine (Decision C(2000) 452), amfepramone (Decision C(2000) 453) and other 'amphetamine-like' anorectic substances, *inter alia* norpseudoephedrine, clobenzorex and fenproporex (De-

cision C(2000) 608) ('the contested decisions'). In its application, the Commission requested that the appeal be determined pursuant to an expedited procedure in accordance with Article 62a of the Rules of Procedure of the Court.

2 By separate document lodged at the Court Registry on the same day, the Commission applied to the Court under Article 242 EC for suspension of operation of the judgment under appeal.

3 Artegodan GmbH ('Artegodan') lodged its written observations on the application for interim relief on 28 February 2003. Laboratoires pharmaceutiques Trenker SA ('Trenker') and Gerot Pharmazeutika GmbH ('Gerot') lodged their written observations on 3 March 2003. Bruno Farmaceutici SpA, Essential Nutrition Ltd, Hoechst Marion Roussel Ltd, Hoechst Marion Roussel SA, Marion Merrell SA (France), Marion Merrell SA (Spain), Sanova Pharma GmbH, Temmler Pharma GmbH & Co. KG, Schuck GmbH, Laboratoires Roussel Diamant SARL, Laboratórios Roussel L^{da} and Roussel Iberica SA (together, 'Bruno Farmaceutici and Others') lodged their joint written observations on 4 March 2003. Cambridge Healthcare Supplies Ltd ('CHS') also lodged its written observations on 4 March 2003.

4 On 26 February 2003, the President of the Court decided that the appeal in the main proceedings was to be determined pursuant to an expedited procedure, in accordance with Article 62a of the Rules of Procedure. By letter of 11 March 2003, the Commission was requested to state whether, in those circumstances, it maintained its application for interim relief and, if so, to specify in summary form the serious and irreparable damage to public health which could arise if operation of the judgment under appeal were not suspended.

5 By letter of 21 March 2003, the Commission confirmed that it maintained its application for interim relief and specified its arguments. CHS submitted its observations on that letter on 31 March 2003. Bruno Farmaceutici and Others

and Trenker submitted their observations on 1 April 2003, and Artegodan on 2 April 2003. By letter of 2 April 2003, Gerot waived its right to submit observations on the Commission's letter and referred to its pleading lodged on 3 March 2003.

6 Since the parties' written submissions contain all the information necessary for deciding the application, there is no need to hear oral argument from the parties.

Legal background

7 On 26 January 1965, the Council adopted Directive 65/65/EEC 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). That directive has been amended on several occasions, in particular by Council Directive 89/341/EEC of 3 May 1989 (OJ 1989 L 142, p. 11) and Council Directive 93/39/EEC of 14 June 1993 (OJ 1993 L 214, p. 22) ('Directive 65/65'). Article 3 of Directive 65/65 lays down the principle that no medicinal product may be placed on the market of a Member State unless an authorisation has first been issued by the competent authorities of that Member State in accordance with the 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).

8 Article 4 of Directive 65/65 provides in particular that, in order to obtain a marketing authorisation as provided for in Article 3, the person responsible for placing the product on the market is to apply to the competent authority of the Member State concerned.

9 Article 5 of Directive 65/65 states:

'The authorisation provided for in Article 3 shall be refused if, after verification of the particulars and documents listed in Article 4, it proves that the medicinal product is harmful in the normal conditions of use, or that its therapeutic efficacy is lacking or is insufficiently substantiated by the applicant, or that its qualitative and quantitative composition is not as declared.

Authorisation shall likewise be refused if the particulars and documents submitted in support of the application do not comply with Article 4.'

10 Article 10 of Directive 65/65 provides that the authorisation is valid for five years and is renewable for five-year periods after consideration by the competent authority of a dossier containing in particular details of the data on pharmacovigilance and other information relevant to the monitoring of the medicinal product.

11 The first paragraph of Article 11 of Directive 65/65 provides:

'The competent authorities of the Member States shall suspend or revoke an authorisation to place a medicinal product on the market where that product proves to be harmful in the normal conditions of use, or where its therapeutic efficacy is lacking, or where its qualitative and quantitative composition is not as declared. Therapeutic efficacy is lacking when it is established that therapeutic results cannot be obtained with the [medicinal] product.'

12 Under Article 21 of Directive 65/65, a marketing authorisation for a medicinal product is not to be refused, suspended or revoked except on the grounds set out in that directive.

13 Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of medicinal products (OJ 1975 L 147, p. 1), as amended by Directive 89/341 ('Directive 75/318'), provides, in the first paragraph of Article 1, that the Member States are to take all appropriate measures to ensure that the particulars and documents which must accompany an application for authorisation to place a medicinal product on the market pursuant to points 3, 4, 6, 7 and 8 of the second paragraph of Article 4 of Directive 65/65 are submitted by the persons concerned in accordance with the annex to Directive 75/318.

14 The seventh and eighth recitals in the preamble to Directive 75/318 are worded as follows:

'[w]hereas the concepts of "harmfulness" and "therapeutic efficacy" referred to in Article 5 of Directive 65/65/EEC can only be examined in relation to each other and have only a relative significance depending on the progress of scientific knowledge and the use for which the medicinal product is intended; whereas the particulars and documents which must accompany an application for authorisation to place a medicinal product on the market [must] demonstrate that potential risks are outweighed by the therapeutic efficacy of the product; whereas failing such demonstration, the application must be rejected;

[w]hereas the evaluation of "harmfulness" and "therapeutic efficacy" may be modified in the light of new discoveries and standards and protocols must be amended periodically to take account of scientific progress'.

15 The provisions most directly at issue in the appeal in the main proceedings are described in the following terms in paragraphs 8 to 12 of the judgment under appeal:

'8 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 products (OJ 1975 L 147, p. 13), amended on several occasions, in particular by [Council] Directives 83/570[/EEC of 26 October 1983 (OJ 1983 L 332, p. 1)] and 93/39 (hereinafter, as amended, "Directive 75/319"), establishes, in Chapter III (Articles 8 to 15c) a procedure for the mutual recognition of national marketing authorisations (Article 9), together with Community arbitration procedures.

9 That directive expressly provides for referrals to the Committee for Proprietary Medicinal Products (hereinafter "the CPMP") of the European Agency for the Evaluation of Medicinal Products, for application of the procedure governed by Article 13, where, in the context of the procedure for mutual recognition established by Article 9, a Member State considers that there are grounds for supposing that the authorisation of the medicinal product concerned may present a risk to public health and the Member States do not reach agreement within the prescribed time-limit (Article 10 of that directive), where Member States have adopted divergent decisions concerning the grant, suspension or withdrawal of national authorisations (Article 11), and in specific cases where the interests of the Community are involved (Article 12). In addition, the directive expressly provides that the variation, suspension and withdrawal of marketing authorisations granted in accordance with the provisions of Chapter III thereof are subject to the procedures laid down in Articles 13 and 14 (Articles 15 and 15a). Finally, Article 15b provides that Articles 15 and 15a are to apply by analogy to medicinal products authorised by the Member States following an opinion of the CPMP issued prior to 1 January 1995, in accordance with Article 4 of Council Directive 87/22/EEC of 22 December 1986 on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology (OJ 1987 L 15, p. 38). The procedures established by Articles 12 and 15a of Directive 75/319 are of particular relevance in the present case.

10 Article 12 of Directive 73/319 provides:

"The Member States or the Commission or the applicant or holder of the marketing authorisation may, in specific cases where the interests of the Community are involved, refer the matter to the [CPMP] for the application of the procedure laid down in Article 13 before reaching a decision on a request for a marketing authorisation or on the suspension or withdrawal of an authorisation, or on any other variation to the terms of a marketing authorisation which appears necessary, in particular to take account of the information collected under the pharmacovigilance system provided for in Chapter Va.

The Member State concerned or the Commission shall clearly identify the question which is referred to the [CPMP] for consideration and shall inform the person responsible for placing the medicinal product on the market.

The Member States and the aforementioned person shall forward to the [CPMP] all available information relating to the matter in question."

11 Article 15a of Directive 75/319 states:

"1. Where a Member State considers that the variation of the terms of a marketing authorisation which has been granted in accordance with the provisions of this chapter or its suspension or withdrawal is necessary for the protection of public health, the Member State concerned shall forthwith refer the matter to the [CPMP] for the application of the [procedures] laid down in Articles 13 and 14.

2. Without prejudice to the provisions of Article 12, in exceptional cases, where urgent action is essential to protect public health, until a definitive

decision is adopted a Member State may suspend the marketing and the use of the medicinal product concerned on its territory. It shall inform the Commission and the other Member States no later than the following working day of the reasons for its action."

12 Article 13 of Directive 75/319 governs the procedure before the CPMP, which issues a reasoned opinion. Paragraph 5 of that article provides that the European Agency for the Evaluation of Medicinal Products is to forward the final opinion of the CPMP to the Member States, the Commission and the person responsible for placing the medicinal product on the market, together with a report describing the assessment of the medicinal product and stating the reasons for its conclusions. Article 14 of that directive governs the Community decision-making procedure. The first subparagraph of Article 14(1) provides that within 30 days of the receipt of the CPMP opinion, the Commission is to prepare a draft of the decision to be taken in respect of the application, taking into account Community law. Under the third subparagraph of Article 14(1), "[w]here, exceptionally, the draft decision is not in accordance with the opinion of the [European] Agency [for the Evaluation of Medicinal Products], the Commission shall also annex a detailed explanation of the reasons for the differences". The final decision is adopted in accordance with the regulatory procedure governed by Articles 5 and 7 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ 1999 L 184, p. 23). The Commission is assisted in that procedure by the Standing Committee on Medicinal Products for Human Use, set up by Article 2b of Directive 75/318.

...

13 All the directives relating to medicinal products for human use which govern the "decentralised Community procedure", in particular Directives 65/65, 75/318 and 75/319, have been recast in Directive 2001/83/EC 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; hereinafter, "the Code"). Even though the Code was not in force when the contested decisions were adopted, it should be taken into

account where appropriate. In so far as the Code restates in a more structured corpus, without amending them, the provisions of Directives 65/65 and 75/319, a systematic analysis of the provisions of Chapter III of Directive 75/319 is part of the scheme of that code.'

Background to the dispute

16 Artegodan, CHS, Gerot, Bruno Farmaceutici and Others and Trenker are holders of marketing authorisations, initially issued by the competent national authorities, for medicinal products containing 'amphetamine-like' anorectic agents, namely, as the case may be, amfepramone, norpseudoephedrine, clobenzorex and fenproporex or phentermine.

17 On 9 March 2000, the Commission adopted, on the basis of Article 15a of Directive 75/319, the contested decisions concerning the withdrawal of marketing authorisations of medicinal products for human use which contain phentermine (Decision C(2000) 452), amfepramone (Decision C(2000) 453) and the substances clobenzorex, fenbutrazate, fenproporex, mazindol, mefenorex, norpseudoephedrine, phenmetrazine, phendimetrazine or propylhexedrine (Decision C(2000) 608). In Article 1 of the operative part of each of those decisions, the Commission ordered the Member States to 'withdraw the national marketing authorisations provided for in the first paragraph of Article 3 of Directive 65/65... concerning the medicinal products listed in Annex I [to the decision] which contain the [substance or substances assessed]'. Article 2 of each of the contested decisions justified that withdrawal by referring to the scientific conclusions which were appended to the CPMP final opinion of 31 August 1999 on the substance or substances concerned and annexed to the respective decision (Annex II). Article 3 of each of the contested decisions required the Member States concerned to comply with the decision within 30 days of its notification.

18 The contested decisions were adopted following a reassessment of the anorectic substances to which they refer, under Article 15a of Directive 75/319, at the request of several Member States.

19 The substances in question had already been the subject of Commission Decision C(96) 3608 final/1 of 9 December 1996 concerning the placing on the market of the medicinal products for human use which contain the following substances: clobenzorex, norpseudoephedrine, phentermine, fenproporex, mazindol, amfepramone, phendimetrazine, phenmetrazine, mefenorex (hereinafter 'the decision of 9 December 1996'), subsequent to an opinion of the CPMP to which the matter had been referred under Article 12 of Directive 75/319. The decision of 9 December 1996 is expressly based on Article 14 of Directive 75/319. By that decision, in line with the CPMP opinions of 17 July 1996, the Commission instructed the Member States concerned to amend certain clinical particulars in the summaries of product characteristics approved when the marketing authorisations of the medicinal products in question were granted. It stipulated that a series of clinical particulars be included, in particular those relating to the therapeutic indications, contraindications and undesirable effects of those medicinal products.

20 A fuller account of the facts that gave rise to the dispute is to be found in paragraphs 14 to 73 of the judgment under appeal.

The judgment under appeal

21 By the judgment under appeal, the Court of First Instance annulled the three contested decisions in so far as they relate to the medicinal products marketed by the applicants at first instance, on the following grounds.

22 In the first place, the Court of First Instance upheld the plea put forward by the applicants at first instance alleging the Commission's lack of competence to take

the contested decisions. The reasoning of the Court of First Instance, set out in paragraphs 112 to 155 of the judgment under appeal, may be summarised very succinctly for the purposes of the present order.

23 The Court of First Instance first of all found that it was common ground between the parties that the marketing authorisations of the medicinal products referred to by the contested decisions had been granted, and in some cases renewed, in accordance with the national procedures applicable in the various Member States concerned, and not in accordance with the mutual recognition procedure coupled with arbitration procedures, provided for in Chapter III of Directive 75/319 (paragraph 113 of the judgment under appeal).

24 The Court of First Instance accordingly inferred that, '[l]eaving aside the decision of 9 December 1996, those authorisations were thus purely national' and that 'the suspension, variation or withdrawal of those authorisations therefore came, at the time when the contested decisions were adopted, within the exclusive competence of the Member States concerned, a competence which, following the introduction of the mutual recognition procedure by Directive 93/39, is essentially residual' (paragraph 114 of the judgment under appeal). According to the interpretation adopted by the Court of First Instance of the Community legislation, '[s]ince 1 January 1995 that exclusive competence [of the Member States] has been restricted to, first, the grant and management of marketing authorisations for medicinal products marketed solely in a single Member State and, second, the management of purely national marketing authorisations granted before that date or during the transitional period from 1 January 1995 to 31 December 1997' (paragraph 116 of the judgment under appeal).

25 The Court of First Instance then examined whether, following their amendment pursuant to the decision of 9 December 1996, the marketing authorisations of the medicinal products in question fell within the scope of Article 15a(1) of Directive 75/319, which is the legal basis on which the Commission adopted the contested decisions. That provision refers to marketing authorisations 'granted in accordance with the provisions of [Chapter III]' of Directive 75/319. According to the Court of First Instance, it essentially provides 'that the variation,

suspension or withdrawal of such authorisations, on the initiative of a Member State with a view to the protection of public health, fall within the exclusive competence of the Commission, when adopting a decision following a CPMP opinion in accordance with the procedures laid down in Articles 13 and 14 of Directive 75/319' while, '[c]onversely, the variation, suspension and withdrawal of marketing authorisations which do not fall within the ambit of Article 15a remain, in principle, subject to the exclusive competence of the Member States' (paragraph 121 of the judgment under appeal).

26 The Court of First Instance held that, since the wording of Articles 12 and 15a of Directive 75/319 provided no clear guidance, it was necessary to consider whether, in the scheme of Chapter III of that directive, and in the light of the directive's aims, Article 15a(1), in conjunction with Article 12, can be construed as also applying to national marketing authorisations which have been harmonised under Article 12 (paragraph 125 of the judgment under appeal).

27 The Court of First Instance thus dealt with the question of which authority is competent to adopt a decision following a CPMP opinion under Article 12 of Directive 75/319, an article which does no more than provide for the application of the consultative procedure set out in Article 13 of that directive. It held in that respect that Article 12 of Directive 75/319 'is intended to apply in the residual field of exclusive competence of the Member States, or when the initial marketing authorisation of a medicinal product is granted by the reference Member State' (paragraph 142 of the judgment under appeal) and that it 'cannot be interpreted as implicitly empowering the Commission to adopt a binding decision under the procedure set out in Article 14' of that directive (paragraph 147 of the judgment under appeal), unlike Article 10(2) which, although it also refers to the consultative procedure set out in Article 13, is none the less part of a different framework, that of the mutual recognition procedure. The Court of First Instance reached these conclusions by means of an interpretative approach based in particular on the scheme of Chapter III of Directive 75/319 and its objectives.

28 The Court of First Instance however noted that the decision of 9 December 1996 had been complied with by the Member States and found, finally, that it was

necessary to consider whether, in the scheme of Chapter III of Directive 75/319, authorisations harmonised by the Member States following consultation of the CPMP under Article 12 of that directive can nevertheless be placed on the same footing as marketing authorisations granted in accordance with the provisions of Chapter III (paragraph 148 of the judgment under appeal).

29 In that regard, the Court of First Instance held that, 'in the scheme of Directive 75/319, the concept of a marketing authorisation granted in accordance with the provisions of Chapter III of that directive, referred to in Article 15a(1), cannot be interpreted as also including authorisations harmonised following consultation of the CPMP under Article 12' (paragraph 155 of the judgment under appeal).

30 The Court of First Instance accordingly concluded that the contested decisions had no legal basis and that the plea in law alleging the Commission's lack of competence was well founded.

31 In the second place, the Court of First Instance held that, even assuming that the Commission had been competent to adopt the contested decisions, they would nevertheless be flawed on the ground of infringement of Article 11 of Directive 65/65. The reasoning of the Court of First Instance on that aspect is set out in paragraphs 170 to 220 of the judgment under appeal.

32 The Court of First Instance concluded that, 'given the lack of any new scientific data or information relating to assessment of the efficacy of the substances in question, Article 11 of Directive 65/65 precluded the competent authority from revising the positive assessment of the efficacy of the substances under consideration, which had been issued in 1996', and that it followed that, 'on any view, the contested decisions are in breach of the provisions of that article' (paragraph 220 of the judgment under appeal).

The application for interim relief

33 The Commission submits that the conditions for granting suspension of operation of the judgment under appeal are met. First, the appeal in the main proceedings is not prima facie without reasonable substance. Second, compliance with the judgment under appeal before the Court delivers judgment on the appeal in the main proceedings would run the risk of causing serious and irreparable harm to public health in the Member States concerned.

34 In order to establish a prima facie case for its application for interim relief, the Commission puts forward arguments relating, first, to the reasoning of the Court of First Instance on the Commission's lack of competence to adopt the contested decisions and, second, to the interpretation by the Court of First Instance of the conditions for withdrawal of marketing authorisations laid down in the first paragraph of Article 11 of Directive 65/65.

35 In order to establish the urgency of its application for interim relief, the Commission submits that compliance with the judgment under appeal before judgment is delivered in the main proceedings would run the risk of causing serious and irreparable harm to public health in the Member States concerned.

36 It should be recalled that, according to Article 60 of the Statute of the Court of Justice, an appeal against a judgment of the Court of First Instance is not generally to have suspensory effect. However, pursuant to Article 242 EC, the Court may, if it considers that circumstances so require, order that application of the judgment under appeal be suspended.

37 Furthermore, it follows from Article 83(2) of the Rules of Procedure that the grant of interim relief pursuant to Article 242 EC is conditional on the existence of circumstances giving rise to urgency and of pleas of fact and law establishing a prima facie case for such a measure.

38 It is necessary to ascertain whether those conditions are fulfilled in the present case.

39 As regards whether pleas establishing a prima facie case for suspending the operation of the judgment under appeal have been put forward, suffice it to state that the appeal brought against it raises fundamental questions, which the Court will have to decide in the context of the appeal in the main proceedings, concerning, first, the respective powers of the Commission and the Member States in the context of the Community legislation applicable to marketing authorisations for medicinal products for human use and, second, the interpretation of the conditions for withdrawal of marketing authorisations for medicinal products laid down in Article 11 of Directive 65/65 and the limits of review by the Courts in the light of the assessment of those conditions.

40 The pleas in law put forward by the parties to the appeal relating to those various questions show that there is a major legal disagreement whose resolution is not immediately obvious, so that the appeal is not prima facie without reasonable substance. Accordingly, the application for interim relief cannot be dismissed on that ground (see, to that effect, orders in Case C-345/90 P-R *Parliament* v *Hanning* [1991] ECR I-231, paragraphs 29 and 30, and Case C-180/01 P-R *Commission* v *NALOO* [2001] ECR I-5737, paragraphs 49 and 51).

41 As regards the condition relating to urgency, it is to be remembered that the purpose of the procedure for interim relief is to guarantee the full effectiveness of the definitive future decision, in order to ensure that there is no lacuna in the legal protection provided by the Court of Justice (see, in particular, orders in Case 27/68 R *Renckens* v *Commission* [1969] ECR 255, 276; Case C-399/95 R *Germany* v *Commission* [1996] ECR I-2441, paragraph 46; Case C-393/96 P(R) *Antonissen* v *Council and Commission* [1997] ECR I-441, paragraph 36, and *Commission* v *NALOO*, paragraph 52). For the purpose of attaining that objective, urgency must be assessed in the light of the need for an interlocutory order in order to avoid serious and irreparable damage to the party seeking the interim relief (see orders in Case C-65/99 P(R) *Willeme* v *Commission* [1999] ECR I-1857, paragraph 62, and *Commission* v *NALOO*, paragraph 52).

42 It is for the party claiming serious and irreparable damage to establish its existence (see orders in Case C-329/99 P(R) *Pfizer Animal Health* v *Council* [1999] ECR I-8343, paragraph 75, and *Commission* v *NALOO*, paragraph 53). While it is not necessary for it to be absolutely certain that the damage will occur, a sufficient degree of probability being enough, the applicant is none the less required to prove the facts which are considered to found the prospect of such damage (order in *Commission* v *NALOO*, paragraph 53).

43 In the present case, it is clear that the Commission has not established that suspending operation of the judgment under appeal is necessary for the full effectiveness of the definitive future decision which will be given on the appeal, if the appeal is allowed.

44 The urgency claimed by the Commission results exclusively from the alleged risk for public health arising from the fact that, in response to the judgment under appeal, the Member States could reactivate the marketing authorisations for the medicinal products covered by the contested decisions, so that those medicinal products could be prescribed to patients and taken by them. Those medicinal products run the risk of exposing patients to serious undesirable effects.

45 It should be noted first of all that, as the Commission stated in its application and in its reply to a question from the Court, the undesirable effects of the medicinal products in question are those which are mentioned in the summaries of product characteristics as amended by the decision of 9 December 1996 and that the case file shows that those medicinal products are dispensed on prescription under a doctor's supervision.

46 Next, it is important to note that it is common ground between the parties that the resumption of the marketing of the medicinal products in question does not follow automatically from the judgment under appeal, but requires a positive decision to that effect (see, in that respect, paragraph 19 of the judgment under

appeal), and that, pursuant to the judgment under appeal, the competence to take any decision relating to the marketing authorisations for the medicinal products in question lies with the Member States.

47 It is clear from the observations of the parties that, as a result of the judgment under appeal, the competent national authorities immediately took up the files on the marketing authorisations for the medicinal products in question with a view to adopting the decisions which they judged appropriate. It is thus apparent from the documents annexed to the observations of Bruno Farmaceutici and Others that, in France, the Agence sanitaire des produits de santé, by letter of 6 February 2003, informed certain of the applicants at first instance that it was contemplating the definitive withdrawal of the marketing authorisations. In Germany, according to the same parties' observations, the medicinal products in question are the subject of a pharmacovigilance procedure and, according to Trenker's observations, a new national evaluation procedure of the medicinal products concerned is underway there. Trenker's observations, substantiated by documents annexed to them, show that the Belgian authorities have not adopted any measures designed to reactivate the marketing authorisations held by that undertaking. Similarly, Gerot and Trenker assert in their observations that, at least in respect of the medicinal products which they marketed, marketing is still prohibited in Austria. Finally, CHS referred to information from which it emerges that, in the United Kingdom, the Medicines Control Agency stated that there was no new safety issue which would debar it from reinstating the marketing authorisation for medicinal products containing amfepramone or phentermine.

48 The Commission does not, however, dispute the capacity of the competent authorities of the Member States to take those decisions on the basis of their own assessment, but rather expresses the fear that those authorities may succumb to pressure from the undertakings concerned.

49 Since those assertions are not substantiated, they cannot suffice to establish the urgency claimed. Moreover, and since the Commission's argument should be understood as the expression of a fear that the national authorities may adopt decisions without taking account of all the relevant information, suffice it to state that the Commission has not, in its observations, referred to any obstacle which

would prevent it from supplying to those authorities any information at its disposal which might prove useful in the assessment of the marketing authorisations for the medicinal products in question.

50 Without prejudging the reply which the Court might give to the question of competence in the context of the appeal in the main proceedings, it must be stated that the Commission has not established that the situation arising from the judgment under appeal produces a risk of serious and irreparable harm to public health, since national authorities specialising in public health, which they are responsible for protecting, remain empowered to take any decisions relating to the marketing authorisation of the medicinal products in question under their own responsibility and on the basis of their own assessment.

51 Admittedly, that competence of the national authorities, which stems from the interpretation of the Community legislation adopted by the Court of First Instance in the judgment under appeal, is the subject of a disagreement which the Court will have to resolve in the decision which it will give on the appeal. That situation does give rise to some uncertainty both for the national and Community authorities and for the parties concerned. However, the need to bring that situation of legal uncertainty to an end as soon as possible was taken into consideration in the decision of the President of the Court that the appeal in the main proceedings is to be heard by means of an expedited procedure, in accordance with Article 62a of the Rules of Procedure, which must ensure that the appeal is swiftly decided.

52 There can accordingly be no question of a risk of serious and irreparable damage if the operation of the judgment under appeal is not suspended as requested.

53 In those circumstances, it must be found that the Commission has not succeeded in establishing that the condition relating to urgency, imposed by Article 83(2) of the Rules of Procedure, is met in the present case.

54 Since it has been established that the condition relating to urgency is not fulfilled, it is not necessary to examine the parties' pleas in law relating to the balancing of

the interests at stake (see, to that effect, orders in Case C-364/99 P(R) *DSR-Senator Lines* v *Commission* [1999] ECR I-8733, paragraph 62, and Case C-399/02 P(R) *Marcuccio* v *Commission* [2003] ECR I-1417, paragraph 36).

55 It follows from the foregoing that the application for suspension of the operation of the judgment under appeal must be dismissed.

On those grounds,

THE PRESIDENT OF THE COURT

hereby orders:

1. The application for interim relief is dismissed.

2. Costs are reserved.

Luxembourg, 8 May 2003.

R. Grass
Registrar

G.C. Rodríguez Iglesias
President