ORDER OF THE PRESIDENT OF THE COURT OF FIRST INSTANCE
31 October 2000 *

In Case T-84/00 R,

Laboratórios Roussel Ld.ª, established in Mem Martins (Portugal),

Laboratoires Roussel Diamant SARL, established in Puteaux (France),

represented by B. Sträter, Rechtsanwalt, Bonn, with an address for service in Luxembourg at the Chambers of Bonn and Schmidt, 7 Val Sainte-Croix,

applicants,

v

Commission of the European Communities, represented by H. Støvlbæk, of its Legal Service, acting as Agent, and B. Wägenbaur, of the Brussels Bar, with an address for service in Luxembourg at the office of C. Gómez de la Cruz, of its Legal Service, Wagner Centre, Kirchberg,

defendant,

* Language of the case: German.

APPLICATION for suspension of operation of the Commission's decision of 9 March 2000 concerning the withdrawal of marketing authorisations of medicinal products for human use which contain, *inter alia*, the substance 'clobenzorex' (C(2000) 608),

THE PRESIDENT OF THE COURT OF FIRST INSTANCE
OF THE EUROPEAN COMMUNITIES

makes the following

Order

Legal background

1 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 proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 20), since amended on several occasions. Article 3 of that directive lays down the principle that no proprietary medicinal product may be placed on the market in a Member State unless an authorisation has first been issued by the competent authority 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).

2 Article 4 of Directive 65/65 states 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. Under Article 5, the authorisation is to be refused if it proves that the proprietary 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, or if the particulars and documents submitted in support of the application do not comply with Article 4. Under Article 10, as amended, the authorisation is to be valid for five years and 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.

3 The first paragraph of Article 11 provides that the competent authorities of the Member States are to suspend or revoke an authorisation to place a proprietary medicinal product on the market where that product proves to be harmful in the normal conditions of use, where its therapeutic efficacy is lacking, or where its qualitative and quantitative composition is not as declared. According to that provision, therapeutic efficacy is lacking when it is established that therapeutic results cannot be obtained with the proprietary product.

4 Under Article 21, an authorisation to market a proprietary medicinal product may not be refused, suspended or revoked except on the grounds set out in Directive 65/65.

5 The 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), as amended by Council Directive 93/39/EEC of 14 June 1993 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products (OJ 1993 L 214, p. 22), provides for a number of arbitration procedures before the Committee for Proprietary Medicinal Products (hereinafter 'the CPMP') of the European Agency for the Evaluation of Medicinal Products. Such a procedure is applied where 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 (Article 10 of Directive 75/319 as amended by Directive 93/39), where divergent decisions have been adopted concerning the grant, suspension or withdrawal of national authorisations (Article 11), in specific cases where the interests of the Community are involved (Article 12) and in the case of variations of harmonised authorisations (Articles 15, 15a and 15b). The procedures laid down in Articles 12 and 15a of Directive 75/319 are of particular relevance in the present case.

6 Under Article 12, the Member States among others may, in specific cases where the interests of the Community are involved, refer the matter to the CPMP for 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 in the context of the pharmacovigilance system provided for in Chapter Va of Directive 75/319.

7 Article 15a provides:

'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.'

Facts and procedure

8 The applicants hold marketing authorisations for medicinal products containing clobenzorex.

9 On 17 May 1995 the Federal Republic of Germany made a referral to the CPMP in accordance with Article 12 of Directive 75/319, as amended by Directive 93/39, expressing its fears as regards anorectics, which include medicinal products containing clobenzorex, liable to cause serious pulmonary artery hypertension.

10 The procedure initiated by this referral led to the adoption of Commission Decision C(96) 3608 of 9 December 1996, based on Article 14(1) and (2) of Directive 75/319, instructing Member States to vary certain clinical information which had to appear in the national authorisations to place the medicinal products in question on the market.

11 By letter of 7 November 1997 addressed to the chairman of the CPMP, the Belgian Ministry of Social Affairs, Public Health and the Environment expressed *inter alia* its fears that there was a causal link between cardiac valve disorders and the use of anorectics containing amfepramone or phentermine. It therefore requested the CPMP, pursuant to Articles 13 and 15a of Directive 75/319, to issue a reasoned opinion on the medicinal products concerned.

12 By letter of 31 August 1998, likewise addressed to the chairman of the CPMP, the Austrian Ministry of Labour, Health and Social Affairs pointed out that, in addition to phentermine and amfepramone, clobenzorex, fenbutrazate, fenproporex, mazindol, mefenorex, norpseudoephedrine, phenmetrazine, phendimetra-

zine and propylhexedrine belonged to the same group of amphetamine-related anorectics. The Austrian Ministry added that all those substances probably had the same properties and the same side-effects and requested the CPMP, pursuant to Article 15a of Directive 75/319, to issue a reasoned opinion relating to the medicinal products concerned.

13 On 31 August 1999 the CPMP gave its opinion on medicinal products containing clobenzorex, fenbutrazate, fenproporex, mazindol, mefenorex, norpseudoephedrine, phenmetrazine, phendimetrazine and propylhexedrine. It concluded that those medicinal products had an unfavourable benefit/risk balance and recommended that the authorisations to place them on the market should be withdrawn.

14 On the basis of that opinion, the Commission prepared a draft decision which was sent to the applicants amongst others on 20 January 2000. On 9 March 2000 the Commission adopted the decision concerning the withdrawal of marketing authorisations of medicinal products for human use which contain the substances 'clobenzorex', 'fenbutrazate', 'fenproporex', 'mazindol', 'mefenorex', 'norpseudoephedrine', 'phenmetrazine', 'phendimetrazine' and 'propylhexedrine' (C(2000) 608, hereinafter 'the contested decision'). Article 2 of the contested decision refers to the views expressed by the CPMP in the opinion. Article 3 provides that the Member States are to withdraw the marketing authorisations for all the medicinal products mentioned in Annex I to the contested decision within 30 days of its notification.

15 By application lodged at the Registry of the Court of First Instance on 6 April 2000, the applicants brought an action before the Court under the fourth paragraph of Article 230 EC for annulment of the contested decision or, in the alternative, its annulment in so far as it entails withdrawal of the marketing authorisations for medicinal products for human use containing clobenzorex in France and Portugal (Case T-84/00).

16 By separate document lodged at the Court Registry on the same day, the applicants brought the present application for suspension of operation of the contested decision, together with an application on the basis of Article 105(2) of the Rules of Procedure of the Court of First Instance for an urgent decision on the claim for interim relief.

17 The parties presented oral argument at the hearing on 13 April 2000, in the course of which the applicants were requested to disclose information by 27 April 2000 at the latest providing a full view of their commercial and/or industrial activities and those of the undertakings belonging to their respective groups.

18 On 18 April 2000 the President of the Court of First Instance granted the application based on Article 105(2) of the Rules of Procedure and ordered that operation of the contested decision should be suspended until the making of the order terminating the proceedings for interim relief.

19 On 27 April 2000 the applicants lodged at the Court Registry the information requested at the hearing.

Law

20 Under the combined provisions of Articles 242 EC and 243 EC and Article 4 of Council Decision 88/591/ECSC, EEC, Euratom of 24 October 1988 establishing a Court of First Instance of the European Communities (OJ 1988 L 319, p. 1), as amended by Council Decision 93/350/Euratom, ECSC, EEC of 8 June 1993 (OJ 1993 L 144, p. 21), the Court may, if it considers that circumstances so require, suspend the operation of the contested measure or prescribe any necessary interim measures.

21 Article 104(2) of the Rules of Procedure provides that applications for suspension of operation must state the circumstances giving rise to urgency and the pleas of fact and law establishing a prima facie case for the relief applied for. These conditions are cumulative, so that an application for suspension of operation must be dismissed if either of them is not fulfilled (order of the President of the Court of Justice in Case C-268/96 P(R) *SCK and FNK* v *Commission* [1996] ECR I-4971, paragraph 30). The court hearing the application will also, where appropriate, balance the competing interests (order of the President of the Court of Justice in Case C-107/99 R *Italy* v *Commission* [1999] ECR I-4011, paragraph 59; orders of the President of the Court of First Instance in Case T-191/98 R *DSR-Senator Lines* v *Commission* [1999] ECR II-2531, paragraph 22, and in Case T-222/99 R *Martinez and de Gaulle* v *Parliament* [1999] ECR II-3397, paragraph 22).

Prima facie case

Arguments of the parties

22 The applicants put forward several pleas in law to establish a prima facie case for the interim relief sought.

23 First, they submit that the Commission lacked competence to adopt the contested decision. Article 15a of Directive 75/319 does not provide a legal basis for the procedure used in the present case. Article 15a allows a Member State to initiate the procedure provided for in Articles 13 and 14 of the directive only in the case of marketing authorisations which have been granted in accordance with Chapter III of the directive. However, the authorisations in question are national

authorisations, not authorisations granted in accordance with that chapter. The fact that they were varied by the decision of 9 December 1996, following a procedure initiated under Article 12 of Directive 75/319, does not affect that conclusion. Article 15a of Directive 75/319 does not contain any reference to authorisations varied on the basis of a procedure initiated under Article 12. The applicants add that Article 15a requires suspension or withdrawal to be necessary for the protection of public health. However, that condition is not met or, at least, ceased to be met during the procedure, after it was established that the risks had not changed since the Commission's decision of 9 December 1996 and that the Belgian cases were not significant.

24 Second, the applicants contend that the procedure before the CPMP and the Commission was marked by a serious breach of the procedural rules laid down in Articles 13 and 14 of Directive 75/319 as amended, since the CPMP and the Commission did not comply at all with the time-limits prescribed by those provisions. According to the applicants, the time-limits are not designed solely to ensure that the procedure is conducted expeditiously in the interests of public health, but are also intended to protect the holders of authorisations or applicants concerned by the procedure whose financial decisions depend to a large extent on the outcome of the referral procedure. Also, the fourth subparagraph of Article 14(1) of Directive 75/319 should be interpreted as requiring the Commission to forward the draft decision to the Member States and the holders of authorisations at the same time. However, the draft decision was forwarded to the Member States on 5 January 2000, but to the holders of authorisations only on 20 January 2000. Finally, the length of the procedure shows, indirectly, that the marketing of the medicinal products in question did not entail risks to public health.

25 Third, the applicants plead that the contested decision infringes the first paragraph of Article 11 and Article 21 of Directive 65/65, Article 11 alone providing an appropriate legal basis for the withdrawal of authorisations. According to the applicants, where the Commission orders the Member States to withdraw a marketing authorisation pursuant to the procedure set out in

Articles 13 and 14 of Directive 75/319, it must comply with the conditions governing withdrawal laid down in Article 11 of Directive 65/65. In the present case, it must therefore be established that medicinal products containing clobenzorex are harmful, that they lack therapeutic efficacy or that their qualitative and quantitative composition is not as declared. However, the opinion of the CPMP, adopted by the Commission to justify the contested decision, does not contain any finding relating to those requirements. Rather, the CPMP weighed the benefits against the risks, which Article 11 of Directive 65/65 does not provide for and is therefore unlawful. Nor can the 'Note for Guidance on Clinical Investigations of Drugs Used in Weight Control', which the CPMP also considered, justify withdrawal of a marketing authorisation because it is only the specific embodiment of standards and protocols in respect of testing prescribed by Directive 75/318 which, according to the express wording of that measure, apply solely to new authorisations. Furthermore, the statements of the CPMP and the Commission regarding the efficacy of the medicinal products concerned clearly show that their negative appraisal is the result of balancing safety against the benefit which the medicinal products could provide. At the time of the earlier pharmacovigilance procedure initiated in 1996, the risks were judged to be minor in relation to efficacy. In the present case, it is clear that the negative result of the benefit/risk balance arises primarily from the fact that efficacy is now subject to a different assessment on the basis of the most recent guidelines. That balancing exercise within the framework of a pharmacovigilance procedure is clearly incorrect and constitutes a misuse of powers. The applicants add that the CPMP's scientific conclusions infringe the rule concerning allocation of the burden of proof contained in Article 11 of Directive 65/65. The effect of that provision is that the burden of proving the reasons given for withdrawal lies with the competent authorities. The CPMP expected the applicants to adduce appropriate evidence of the efficacy of clobenzorex whereas it should itself have proved the inefficacy of that substance.

26 Finally, the applicants submit that for the purposes of the evaluation at issue the CPMP used various guidelines which did not support or did not justify the requirements which the CPMP itself had set, or which could not be complied with, and thus erred in its assessment in applying those guidelines. In particular, the CPMP did not take account of the fact that it is objectively impossible for the

holder of an authorisation to provide, at the time of the adoption of new guidelines, appropriate information resulting from clinical checks corresponding to those guidelines, since several years are needed to carry out such studies. Even if it is accepted that the holder of an authorisation is under a continuous obligation to adapt its dossier to the most recent requirements, it should at least be given an appropriate period to fulfil that obligation. Also, the CPMP requested studies carried out over a minimum treatment period of one year for the medicinal products concerned by the contested decision, although that requirement does not arise from any of the guidelines referred to. In the applicants' submission, that constitutes a particularly serious error of assessment.

27 The Commission considers that a prima facie case has not been made out.

28 It submits that the decision of 9 December 1996 constitutes a marketing authorisation granted in accordance with Chapter III of Directive 75/319. It adds that that decision was adopted on the basis of Article 12 of Directive 75/319 and resulted in harmonisation of the national marketing authorisations for the medicinal products listed in the decision, which include those produced by the applicants. The decision varies, on the basis of Community law, the national marketing authorisations in such a way that, following expiry of the period set in Article 3 of the decision, the medicinal products concerned may be marketed only if their presentation includes the clinical information set out in the decision. Moreover, this harmonisation of clinical information resulted in a substantial variation of the national marketing authorisations. Authorisations must be regarded as harmonised in all the Member States where a medicinal product has been the subject of the procedures provided for in Article 12 of Directive 75/319, as is the case here by means of the decision of 9 December 1996. Finally, in the Commission's submission, the applicants' assertion that Article 15a of Directive 75/319 requires suspension or withdrawal to be necessary on grounds of protection of public health and that that condition is not met is unfounded given

that, first, in view of the wording of that provision, it is sufficient for a Member State to submit a request on grounds of protection of public health and, second, if it were to become apparent, either during or at the end of such a procedure initiated by a request in accordance with that provision that a public health risk did not exist in the form suspected by the Member State, the request would not for that reason be retroactively inadmissible.

29 The contested decision is therefore not vitiated by any procedural defect. With regard to the applicants' argument that the time-limits laid down in Articles 13 and 14 of Directive 75/319 were not complied with, the Commission observes that the delays were due to the large number of medicinal products under examination in the present case and the fact that that examination was particularly thorough. Nor did those delays cause the applicants any prejudice. As to the applicants' argument that the Commission infringed Article 14(1) of Directive 75/319 because it did not forward the draft decision simultaneously to the Member States and the holders of authorisations, the Commission contends that that provision does not lay down any obligation to notify the draft decision to holders of authorisations. Finally, with regard to the applicants' argument that the length of the procedure shows that the Commission and the CPMP did not discover any significant public health risk, the Commission points out that the CPMP found that the medicinal products concerned by the contested decision lacked the necessary therapeutic efficacy for the treatment of obesity and took account of that fact in the context of its benefit/risk analysis.

30 The Commission also denies that the contested decision is unlawful on the ground that the conditions in Article 11 of Directive 65/65 are not satisfied. The CPMP clearly established that medicinal products containing clobenzorex lack the necessary therapeutic efficacy. Accordingly, the benefit/risk assessment was unfavourable. The Commission adds that the CPMP was not only entitled to rely

on the guidelines but also required to carry out a benefit/risk analysis with regard to clobenzorex in the light of scientific knowledge.

31 Finally, as to the applicants' argument that the CPMP erred in its assessment in applying the various guidelines, the Commission observes that the CPMP found in its opinion, which was the basis for the contested decision, that, in the light of scientific knowledge as reflected for example in the guidelines, medicinal products containing clobenzorex lacked the necessary therapeutic efficacy to treat obesity and consequently had an unfavourable benefit/risk balance.

Findings of the President of the Court

32 As regards the question of a prima facie case, the pleas raised by the applicants do not prima facie appear to be entirely unfounded. First, it appears that the competence of the Commission to adopt the contested decision depends on the nature of the decision of 9 December 1996, which is open to debate. Second, the Commission has not adduced convincing evidence to explain why that decision and the contested decision reached diametrically opposed results. The pleas raised by the applicants therefore deserve detailed consideration, a consideration which, however, in fact and in law, goes beyond the scope of the present interim proceedings.

33 In those circumstances, the condition requiring a prima facie case to be made out is satisfied here (order of the President of the Court of First Instance in Case T-308/94 R *Cascades* v *Commission* [1995] ECR II-265, paragraphs 49 and 50).

Urgency

Arguments of the parties

34 The applicants submit that if operation of the contested decision is not suspended they will suffer serious and irreparable damage.

35 Withdrawal of the marketing authorisations for the medicinal products in question would have the consequence of obliging doctors to resort to competing products. The applicants state that, even if the withdrawal of the authorisations were annulled, it would not be possible to reintroduce the medicinal products concerned under the same conditions, since it would prove very difficult and often impossible to re-establish in the market medicinal products which had been absent for a long time. They add that this difficulty in re-establishing products in the market is due to the fact that it is not easy to persuade doctors to prescribe preparations which have already been withdrawn from the market, particularly where they have been withdrawn following a pharmacovigilance procedure.

36 The applicants then submit that, if the contested decision were to be implemented, that would entail the medicinal products concerned being absent from the market for a long time. The applicants therefore risk suffering serious long-term harm which could not be compensated by damages and would substantially exceed the loss of turnover incurred in the course of the proceedings before the Court of First Instance.

37 The Commission maintains that the condition relating to urgency is not fulfilled.

38 First, the possibility of a marketing authorisation being withdrawn is one of the normal business risks of any pharmaceutical undertaking. It is for the undertaking concerned to protect itself against the financial consequences of such a withdrawal by an appropriate policy, such as product diversification and adequate turnover.

39 Second, from the initiation of the procedure under Article 15a of Directive 75/319 and, in any event, from the time at which the final opinion of the CPMP of 31 August 1999 was drawn up, the applicants could have expected the Member States to be asked by the Commission, in the form of a decision, to withdraw marketing authorisations for medicinal products containing clobenzorex.

40 Finally, it cannot be determined from the documentation produced by the applicants whether their survival would be threatened by withdrawal of the marketing authorisations for their medicinal products.

Findings of the President of the Court

41 It is settled case-law that the urgency of an application for suspension of the operation of a measure 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 suspension. In this connection, it is enough, particularly where damage depends on the occurrence of a number of factors, for that damage to be foreseeable with a sufficient degree of probability (see, *inter alia*, the order of the Court of Justice in Case C-280/93 R *Germany* v *Council* [1993] ECR I-3667, paragraphs 32 and 34, and the order of the President of the Court of First Instance in Case T-65/98 R *Van den Bergh Foods* v *Commission* [1998] ECR II-2641, paragraph 62).

42 In the present case, immediate operation of the contested decision means the complete withdrawal from the market of the medicinal products referred to in Article 1 of the decision. It therefore means that, if operation of the contested decision is not suspended, substitute medicinal products, the existence of which is acknowledged by the parties, will very probably take the place of the products withdrawn. The confidence of consumers, doctors and pharmacists in a medicinal product is particularly sensitive to statements that the product presents a danger to patients' health. Even if those statements are subsequently disproved, it is often impossible to restore confidence in the withdrawn product, other than in special cases where the qualities of the medicinal product are especially valued by users and there is no perfect substitute product, or where the manufacturer enjoys an exceptionally good reputation, so that it cannot be said that he will be unable to repossess the market shares he held before withdrawal. However, such circumstances are not present here.

43 Moreover, if the contested decision were to be annulled by the Court of First Instance and the applicants thus authorised to resume marketing their medicinal products, the financial damage suffered by them because of a fall in sales as a result of loss of confidence in their products could not in practice be quantified sufficiently completely for the purposes of making reparation.

44 Accordingly, the damage which immediate operation of the contested decision could cause would be serious and irreparable.

Balancing of interests

45 Since the applicants have established the existence of serious and irreparable damage, it is necessary to balance, on the one hand, the applicants' interest in

obtaining suspension of operation of the contested decision and, on the other hand, the interest of the Community in the immediate withdrawal of the marketing authorisations for the medicinal products in question and, more generally, in the protection of public health.

46 In undertaking that examination, the judge hearing the application for interim relief must determine whether later annulment of the contested measure by the Court when ruling on the main application would allow the situation which would have been brought about by the immediate operation of the measure to be reversed, and, conversely, whether suspension of operation of the measure would prevent it from being fully effective in the event of the main application being dismissed (see, in particular, the order of the President of the Court of Justice in Joined Cases 76/89 R, 77/89 R and 91/89 R *RTE and Others* v *Commission* [1989] ECR 1141, paragraph 15, the order of the Court of Justice in Case C-180/96 R *United Kingdom* v *Commission* [1996] ECR I-3903, paragraph 89, and the order of the President of the Court of First Instance in Case T-41/97 R *Antillean Rice Mills* v *Council* [1997] ECR II-447, paragraph 42).

47 In the present case the balance of interests favours suspension of operation of the contested decision.

48 It appears highly probable that the operation of the contested decision would entail the definitive loss of the applicants' position in the market, even if the court hearing the main application were to annul the decision.

49 In opposition to the commercial interests of the applicants, the Commission submits that suspension of operation of the contested decision could harm public health. On this point, it must be emphasised that in principle the requirements of the protection of public health must unquestionably be given precedence over economic considerations (order in *United Kingdom* v *Commission*, cited above, paragraph 93; judgment in Case C-183/95 *Affish* v *Rijksdienst Keuring Vee en Vlees* [1997] ECR I-4315, paragraph 43; order of the Court of First Instance in Case T-136/95 *Industria del Frio Auxiliar Conservera* v *Commission* [1998]

ECR II-3301, paragraph 58; and order of the President of the Court of First Instance in Case T-70/99 R *Alpharma* v *Commission* [1999] ECR II-2027, paragraph 152).

50 However, it must be noted that in this context the mere reference to the protection of public health cannot exclude an examination of the circumstances of the case, in particular of the relevant facts.

51 In the present case, the Commission has indeed established that there is uncertainty as regards the risks associated with medicinal products containing clobenzorex, even if those risks are slight. Nevertheless, although the decision of 9 December 1996 and the contested decision are based on identical data, the measures taken by the Commission in 1996 and 2000 for the protection of public health with respect to those risks differ fundamentally. In those circumstances, the Commission was obliged to show that the protective measures in the decision of 9 December 1996 proved to be insufficient to protect public health, so that the protective measures it adopted in the contested decision were not manifestly excessive. However, the Commission has not been able to show this.

52 Moreover, the fact that the health risks which determined the adoption of the contested decision had already been taken into account in the Commission's decision of 9 December 1996 and had resulted in a change to the compulsory information concerning medicinal products supplied on prescription indicates that implementation of the contested decision is not urgent.

53 It follows from all the foregoing considerations that the conditions for the grant of the suspension of operation sought are satisfied.

On those grounds,

THE PRESIDENT OF THE COURT OF FIRST INSTANCE

hereby orders:

1. Operation of the Commission Decision of 9 March 2000 concerning the withdrawal of marketing authorisations of medicinal products for human use which contain the substances 'clobenzorex', 'fenbutrazate', 'fenproporex', 'mazindol', 'mefenorex', 'norpseudoephedrine', 'phenmetrazine', 'phendimetrazine' and 'propylhexedrine' (C(2000) 608) is suspended in relation to the applicants.

2. Costs are reserved.

Luxembourg, 31 October 2000.

H. Jung

Registrar

B. Vesterdorf

President