

## Case T-85/00 R

Laboratórios Roussel Ld.<sup>a</sup> and Roussel Iberica SA

v

Commission of the European Communities

(Proceedings for interim relief — Withdrawal of marketing authorisations for medicinal products for human use containing the substance ‘fenproporex’ — Directive 75/319/EEC — Urgency — Balancing of interests)

Order of the President of the Court of First Instance, 31 October 2000 . . . II-3616

### Summary of the Order

1. *Applications for interim measures — Suspension of operation of a measure — Conditions for granting — Urgency — Serious and irreparable damage — Decision withdrawing marketing authorisation for a medicinal product*  
(Art. 242 EC; Rules of Procedure of the Court of First Instance, Art. 104(1) and (2))
2. *Applications for interim measures — Suspension of operation of a measure — Conditions for granting — Balancing of all the interests involved — Decision withdrawing marketing authorisation for a medicinal product*  
(Art. 242 EC; Rules of Procedure of the Court of First Instance, Art. 104 (1) and (2))

1. The damage which might be occasioned by the immediate operation of a decision of the Commission concerning the withdrawal of marketing authorisations for certain medicinal products is serious and irreparable, for the holder of a marketing authorisation for a medicinal product concerned, where it is shown, first, that the complete withdrawal from the market of the medicinal product in question entails the risk that substitute medicinal products will very probably take its place and that it will be impossible for the holder of the authorisation to restore confidence in the product even if the statements that the product withdrawn presents a danger to patients are subsequently disproved and, second, that if the decision were to be annulled by the court hearing the main application, the financial damage suffered by the holder because of a fall in sales as a result of loss of confidence in the product could not be quantified sufficiently completely.

(see paras 42-44)

2. Where, on an application for suspension of the operation of a measure, the judge hearing the application balances the various interests involved, he 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.

In the context of an application for suspension of the operation of a Commission decision concerning the withdrawal of marketing authorisation for certain medicinal products, while the requirements of the protection of public health must unquestionably be given precedence over economic considerations when balancing the competing interests, mere reference to the protection of public health cannot exclude an examination of the circumstances of the case, in particular of the relevant facts.

The balance of interests favours suspension of the operation of such a decision where, first, it appears highly probable that its operation would entail the definitive loss of the applicant's position in the market even if the court hearing the main application were to annul the decision and, second, the Commission has not been able to

show why the protective measures contained in a previous decision based on identical data, and consisting solely in a change to the compulsory information which must be included in national authorisations, have proved

to be insufficient to protect public health.

(see paras 46-51)