

Case T-123/03

Pfizer Ltd

v

Commission of the European Communities

(Medicinal products for human use — Initiation, under Article 30 of Directive 2001/83/EC, of the procedure under Article 32 of that directive — Application for annulment — Measure against which an action may be brought — Preparatory measure — Inadmissible)

Order of the Court of First Instance (Fourth Chamber), 2 June 2004 II - 1633

Summary of the Order

Actions for annulment — Actionable measures — Concept — Measures producing binding legal effects — Preparatory measures — Decision of the Commission to refer a matter to the Committee for Proprietary Medicinal Products for a reasoned opinion — Measures constituting a preliminary stage in a consultative procedure — Excluded
(Art. 230 EC; European Parliament and Council Directive 2001/83, Art. 30)

Only measures which produce binding legal effects capable of affecting an applicant's interests by bringing about a significant change in his legal position are acts or decisions against which an action for annulment may be brought under Article 230 EC. In the case of acts or decisions adopted by a procedure involving several stages, and particularly where they are the culmination of an internal procedure, it is only those measures which definitively determine the position of the institution upon the conclusion of that procedure which are open to challenge, and not intermediate measures whose purpose is to prepare for the final decision. It would be otherwise only if the acts or decisions adopted in the course of the preparatory proceedings not only bore all the legal characteristics of measures against which action may be brought, but in addition were themselves the culmination of a special procedure distinct from that intended to permit the institution to take a decision on the substance of the case.

Therefore, the decision of the Commission to refer a matter to the Committee for Proprietary Medical Products under Article 30 of Directive 2001/83 setting out a Community code relating to medicinal products for human use in order to obtain a reasoned opinion, such as that on harmonising the summaries of a product's characteristics, is not an actionable measure. Such a decision does not definitively determine the position of the institution, any more than it represents the culmination of a special procedure distinct from that intended to result in a decision on that harmonisation. The measure does no more than set in motion a consultative procedure, and merely represents a preliminary stage in that procedure.

(see paras 21-23, 26)