Press and Information Division

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Judgment of the Court of Justice in Case C-39/03 P

Commission v Artegodan GmbH and 15 Others

THE COURT CONFIRMS THE CFI'S ANNULMENT OF THE COMMISSION'S DECISIONS ORDERING THE WITHDRAWAL OF MARKETING AUTHORISATIONS FOR ANTI-OBESITY DRUGS

The Commission lacked the competence to adopt the decisions in question.

Under Community law, in order to be placed on the market, medicinal products for human use must have a marketing authorisation issued by the competent authority of the Member State concerned. A 1993 , amending a 1975 directive, established a mutual recognition procedure for national marketing authorisations and provided the possibility to seek an opinion from the Committee for Proprietary Medicinal Products (the CPMP), for example in cases involving a Community dimension. The directive also states that where a Member State considers that the variation of the terms of a marketing authorisation granted under the directive, or its suspension or withdrawal, is necessary for the protection of human health, it must immediately refer the matter to the CPMP. The CPMP then issues a reasoned opinion, following which the Commission is to prepare a decision.

Artegodan and 15 other pharmaceutical companies hold national marketing authorisations (in Austria, Belgium, Denmark, France, Germany, Italy, Luxembourg, Portugal, Spain and the United Kingdom) for drugs containing amphetamine-like anorectics (amfepramone, clobenzorex, fenproporex, norpseudoephedrine and phentermine). Those substances accelerate the feeling of satiety and have been used in a number of Member States for many years in the treatment of obesity.

In 1996, following a referral by Germany, the CPMP issued an opinion on various anorectics. By a decision of 1996, in accordance with that opinion, the Commission instructed the

1 Council Directive 93/39/EEC of 14 June 1993, amending 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.

Member States concerned to amend certain clinical particulars required under the marketing authorisations of those drugs.

By three decisions of 9 March 2000, the Commission ordered the withdrawal of marketing authorisations of medicinal products for human use which contain, *inter alia*, the anorectics referred to above. In three opinions given in 1999, the CPMP had found that those substances lacked efficacy according to the new scientific criterion of long-term efficacy of anti-obesity drugs.

The marketing authorisations of the drugs in question were accordingly suspended or withdrawn by the competent authorities of the Member States.

The pharmaceutical companies concerned sought annulment of those Commission decisions before the Court of First Instance. On 26 November 2002 the CFI annulled the decisions on the ground that the Commission lacked the competence to adopt .

The Commission lodged an appeal against that judgment before the Court of Justice on 3 February 2003, and the Court dealt with the case by way of an expedited procedure.

The Court has dismissed the appeal.

The Court first noted that **the marketing authorisations** in question were initially granted under **purely national** procedures and not pursuant to the 1975 directive.

The Court found that the amendment of certain terms of the national marketing authorisations by the 1996 Commission decision was not equivalent to an authorisation granted under the procedure laid down in the 1975 directive. It follows that those authorisations could not be withdrawn by a decision taken under the procedure laid down in the directive for authorisations granted under that directive. **The Commission therefore lacked the competence to adopt the decisions at issue and they had to be annulled**.

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2 See Press Release No 94/02.