

Appetite suppressants: European Commission overturns appeal

● 5 appetite suppressants whose marketing authorisations were withdrawn might go back on sale.

In February 2003, we analysed a ruling by the European Court of First Instance annulling a decision by the European Commission about certain appetite suppressants (1).

In March 2000 the Commission asked Member states to withdraw the marketing authorisations for 10 amphetamine-like appetite suppressants because of their negative risk-benefit balance. The Member states did so. The manufacturers of five of these appetite suppressants (amfepramone, clobenzorex, fenproporex, norpseudoephedrine, and phentermine) then demanded that the decision be annulled (1).

In November 2002, the Court considered that the European Commission had acted outside its jurisdiction and had no authority over marketing authorisations at national level. It also considered that the Commission's decision was not based on new data additional to data supporting an earlier, less restrictive decision (simply to amend some particulars in the summaries of product characteristics) (1). In January 2003, the Court made a similar ruling on fenfluramine and dexfenfluramine (2).

The EU Court of First Instance made a definitive judgement that the European Commission acted outside its jurisdiction in ordering the withdrawal of national marketing authorisation from these appetite suppressants. The European commission then lodged an appeal against the two judgments. Its requests for a suspension of execution of these two judgments were rejected on 8 May and 20 June 2003 (3,4),

and a first ruling on the appeal was given by the Court of Justice on 24 July 2003 (5).

The ruling states that the Commission's appeal has been rejected for the following reason: "(...) without it being necessary to rule on the other pleas and arguments put forward by the Commission, the Court finds that the Court of First Instance was right to hold that the Commission lacked the competence (...)" (5).

This ruling by the Court of Justice has at least two direct consequences. Firstly, it allows drug manufacturers to re-apply to the Member states for authorisation to put their appetite suppressants back on their national markets. And secondly, in failing to reach a decision on harmonisation procedures for national marketing authorisations, the ruling leaves many questions still unanswered, in particular whether or not harmonisation should be "enforced" when Member states cannot reach agreement (5).

With the new European Directive on marketing authorisation procedures to be adopted soon, this case concerning appetite suppressants underlines the need for a very clear legal framework that will be strictly applied.

The Court has not yet delivered its ruling on the Commission's appeal over fenfluramine and dexfenfluramine.

Watch this space.

©Prescrire International

.....
Selected references from our literature search.

1- Prescrire Editorial Staff "Appetite suppressants: a revealing European Court decision" *Prescrire Int* 2003; 12 (64): 78-79.

2- Prescrire Editorial Staff "Appetite suppressants: second decision of the European court" *Prescrire Int* 2003; 12 (65): 114-115.

3- European Court of justice "Appeal - Medicinal products for human use -

Withdrawal of a marketing authorisation - Competence of the Commission - Anorectics: amfepramone, clobenzorex, fenproporex, norpseudoephedrine, phentermine - Directives 65/65/EEC and 75/319/EEC - Judgment of the Court of First Instance annulling a decision of withdrawal - Suspension of operation of a judgment of the Court of First Instance - Urgency - Absence" Order of President of the Court, 8 May 2003: 12 pages.

4- European Court of Justice "Emergency ruling - Demand for suspension of operation - Appeal - Medicinal products for human use - Withdrawal of marketing authorisation - Competence of the Commission - Serotoninergic anorectic agents: dexfenfluramine, fenfluramine - Directives 65/65/CEE and 75/319/CEE - Ruling of the Tribunal annulling a withdrawal decision - Suspension of operation of a court judgment - Urgency - Absence" Order of the President of the Court 20 June 2003: 11 pages.

5- European Court of Justice "Appeal - Directives 65/65/CEE and 75/319/CEE - Medicinal products for human use - Anorectics: amfepramone, clobenzorex, fenproporex, norpseudoephedrine, phentermine - Withdrawal of a marketing authorisation - Competence of the Commission - Conditions of withdrawal" Judgment of the Court, 24 July 2003: 12 pages.

pRESCRIRE VIEWPOINT



Translated from *Rev Prescrire* November 2003; 23 (244): 721

Cut out the bluff

The media are forever proclaiming that rising health costs are inevitable because people are living longer and getting older thanks to expensive new technologies and treatments.

Meanwhile politicians are frantically seeking ways to make up for the sickness insurance shortfall without alienating anybody, and to keep the whole economic sector afloat: the doctors, pharmacists, insurers and hospitals.

But sooner or later they will end up annoying everybody to some extent, even if it's only by exploding myths and going against ingrained habits and various vested interests, not only in the field of health itself, but also in relation to modern-day "scourges" affecting health: pollution, excessive consumption of food, alcohol and tobacco and driving, etc. To meet the escalating costs of new, supposedly innovative medicines, it is common for governments to stop reimbursing older medicines that they consider no longer useful.

We really cannot carry on lumping all drugs together: the essential, the useful, the superfluous, the outdated, those with unacceptable risk, etc.

We have to come clean.

A long-established medicine is not necessarily outmoded. If it is, and if an alternative is more

effective, then yes, let's stop reimbursing it; or rather, let's explain the facts clearly and take it off the market. Otherwise, we should pay for the service it provides at the appropriate price.

A new medicine is not automatically "innovative". And even if it is sometimes the result of a technical "innovation", it does not necessarily offer a tangible therapeutic benefit, which is after all the most important thing as far as the patient is concerned.

If a new medicine or a new treatment technique offers a genuine therapeutic benefit, let us pay a proper price for it. But if this is not the case, we should refuse to pay a high price for a service that does not offer the patient any real benefits.

Pharmaceutical firms now have to face up to the fact that it is increasingly rare for new medicines to represent a significant therapeutic breakthrough. To maintain comfortable profit margins, manufacturers tend to exaggerate the degree of innovation, the cost of the research and about the price of their new products (see pages 32-36).

If a major overhaul of the reimbursement system is envisaged, let's clean up the rules for the reimbursement of all medicines old and new; and cut out the bluff.

©Prescrire International