Injunction impedes independent information

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(Aust Prescr 2006;29:120)

A Federal Court injunction has stopped the publication of a review criticising a medicinal product. The injunction concerns claims that the symptoms associated with tinnitus and vertigo can be relieved by a formulation of *Ginkgo biloba*.

These claims were the subject of scrutiny by AusPharm Consumer Health Watch. This is a service which was launched earlier this year to evaluate the evidence behind non-prescription products promoted to pharmacies. The aims were to help pharmacists decide whether or not to stock the products and to help consumers make an informed choice about whether or not to use the products.

The working group behind AusPharm Consumer Health Watch outlined the review process on their website.[1] These processes are similar to those used by *Australian Prescriber* when assessing new drugs, except we do not send draft reviews to the manufacturers.[2]

Although the sponsor of the product provided some supporting information, the working group concluded that there was insufficient evidence to justify promoting the product for the relief of tinnitus. This concurs with a report by the Cochrane Collaboration which concluded 'The limited evidence did not demonstrate that *Ginkgo biloba* was effective for tinnitus…'.[3]

When the company sponsoring the product received a draft copy of the review, it expressed a number of concerns. After these concerns were not addressed to its satisfaction it applied for an injunction to halt publication of the review. Ironically, although the working group's intention had been to publish a critical appraisal for consumers, the company used consumer protection legislation to contend that AusPharm Consumer Health Watch had engaged in misleading and deceptive conduct in contravention of the *Trade Practices Act 1974*, and that the publication constituted an injurious falsehood.

Justice Greenwood determined that there was a serious question to be tried as to whether the publication contravened the Trade Practices Act. He therefore granted an interim injunction[4] which was later made permanent.[5]

The 80 paragraph judgement does not imply that *Ginkgo biloba* is an effective treatment for tinnitus. The scientific evidence was not examined; the judgement was based on the process of preparing the review and the extent to which that process complied with the methodology outlined on the website of AusPharm Consumer Health Watch.[1] For example, a copy of the draft review had been sent to the Therapeutic Goods Administration (TGA) at the same time it was sent to the company. As this distribution was not mentioned on the website[1] the judge said this was a 'failure to act consistently with the expressed methodology'. Health professionals frequently ask drug companies for copies of published papers about pharmaceutical products. However, in this case, the judge said that a request which failed 'to properly describe and identify the purpose for which the papers were sought and the task and scope of the role proposed to be undertaken, was misleading'.[4]

I know of only two other cases where drug bulletins have been taken to court by drug companies. In both cases the judgements went in favour of the independent publications. For example, a Spanish judge rejected a claim that Bulleti Groc had published inaccurate information about rofecoxib.[6] The bulletin's view was later vindicated by the worldwide withdrawal of the drug for safety reasons.

Drug bulletins are usually written for health professionals, but they act in the public interest. However, in the Australian case publication was not seen to be in the public interest. The judge felt the public interest would be served by the regulatory authorities examining the evidence supporting the efficacy of *Ginkgo biloba*. Unfortunately, the Department of Health and Ageing has said that any investigation by the TGA will be commercial-in-confidence and the results will not be disclosed to the public.

The manufacturers of prescription medicines are gradually becoming more willing to allow the release of information about their products, for example the public summaries of the decisions of the Pharmaceutical Benefits Advisory Committee. The complementary medicines industry should follow this lead to increased transparency. If the company had not taken legal action, it would not have drawn international attention to questions about the effectiveness of its product.[7]

References

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