

French guidelines are withdrawn after court finds potential bias among authors

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The highest administrative court in France has ruled that guidelines issued by the French Health Authority must be withdrawn immediately because of potential bias and undeclared conflicts of interest among the authors. Other guidelines are also being reviewed and will be withdrawn if similar problems emerge, the authority has said.

The French Council of State (Conseil d'Etat) made the ruling on 27 April, two years after doctors with the non-profit organisation Formindep (Formation Indépendante) charged that the guideline development process for the authority's guidelines on type 2 diabetes and Alzheimer's disease "contravened national law on conflicts of interests and the agency's own internal rules."

In a news release issued on 20 June Formindep stated that it had examined the diabetes and Alzheimer's disease guidelines "because of the large number of patients affected. However, . . . the group considers that most if not all of [the authority's] guidelines may not stand up to legal scrutiny for similar reasons."

Formindep, which is based in Roubaix, near the Belgian border, and which "promotes independent medical education and information," went to the court after the authority refused to withdraw the guidelines. Formindep charged that the chairpersons of both working groups had "major" financial conflicts of interest and that four members of the type 2 diabetes working group failed to file any public statement on conflicts of interest.

The French Health Authority states on its website that it is an "independent public body with financial autonomy" that develops guidelines on the basis of "rigorously acquired scientific expertise."

Laurent Degos, director of the authority at the time, told the court that it had not violated its own ethics policies, as the group can allow experts with minor and major conflicts of interest in

cases of "overriding scientific or technical interest of his or her expertise." He said that the authority made its choice knowingly and had "disclosed on its website with full transparency."

Philippe Foucras, Formindep's founder and president, told the *BMJ* that he and his colleagues uncovered undeclared conflicts of interest by searching Medscape, Google, and Google Scholar.

After the court ruled that the diabetes guidelines must be withdrawn, the authority announced on 18 May that it would also withdraw its Alzheimer's disease guideline. The authority's newly appointed president, Jean-Luc Harousseau, announced that all professional treatment guidelines issued since 2005 would be reviewed for the appropriate management of conflicts of interest, and other guidelines would be withdrawn if necessary.

Dr Foucras said in the news release that the outcome of the two year legal case is "an important step towards a recognition and proper management of the major risk to public health from conflicts of interests. In the wake of the French scandal over Mediator [benfluorex, an appetite suppressant marketed as an antidiabetes drug that is believed to have led to the deaths of 500 to 2000 people (*BMJ* 2010;341:c6882, doi:10.1136/bmj.c6882)], the impact of conflicts of interests on public health in France can no longer be ignored."

Formindep told the *BMJ* that although it did not evaluate the content of the recommendations, its analysis was conducted "in parallel to a thorough scientific review of these recommendations made by the independent drug bulletin *Prescrire*, which strongly rejected the two recommendations on the basis of . . . lack of scientific evidence" to support glitazones (now banned from the French market) for diabetes and cholinesterase antagonists for Alzheimer's disease.

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