CSM takes small step towards openness

Jacqui Wise *London*

The Committee on Safety of Medicines is to publish edited minutes of its meetings on its website, including details of any members who declared links with pharmaceutical companies. Its decision to adopt a more open approach to the public follows a ruling by Michael Buckley, the health service ombudsman, in August.

The committee is one of the independent advisory bodies that give advice to the Medicines Control Agency on whether a particular drug should receive a licence in the United Kingdom.

The ombudsman's ruling resulted from a complaint made by Charles Medawar, director of the consumer lobby group Social Audit, who had asked the committee for information which he said should have been made available to him under the government's Code of Practice on Access to Government Information.

In particular, he wanted the names of committee members who had declared conflicts of interest at meetings when the class of antidepressant drugs known as selective serotonin reuptake inhibitors was being discussed. He also asked for copies of the minutes of committee meetings held during 1998. The committee refused to give Mr Medawar the information he requested and passed

him on to the Medicines Control Agency.

The agency eventually provided Mr Medawar with some anonymised data from their records but withheld much of the information requested, citing exemptions from the code of practice.

After a 16 month battle for information Mr Medawar took his case to the ombudsman, who ruled that there was no reason to justify withholding most of the information requested. However, he allowed that when relevant regulatory action was ongoing the information should be released only once the action was complete. The ombudsman also strongly criticised the agency for the long delay in dealing with Mr Medawar's requests.

One of the surprising things to come out of the case is that the Committee on Safety of Medicines, unlike the Medicines Control Agency, is not obliged to comply with the Code of Practice on Access to Government Information.

Mr Medawar said last week that the committee had lost sight of its original remit: "The [committee] has emerged as an almost uniquely unaccountable quango." He added that when it was originally set up, following the recommendations of the Sainsbury Commission, it was intended to be "a stalwart, independent, competent guardian of

Two women in London participate in the Global Embrace, a worldwide walk held last Saturday in 1500 cities in 86 countries, to promote the World Health Organisation's campaign for "active ageing." Today there are 590 million people worldwide aged over 60; in 25 years, that figure will reach 1.2 billion.

the public interest" but had become instead a committee that did nothing more than give advice to the licensing authority.

Mr Medawar had originally criticised the committee for accepting as valid the main conclusions of a study conducted on paroxetine (Seroxat) which had been jointly conducted by someone who was then a member of the committee and an employee of the manufacturer of the drug. Their study was later published in a journal edited by the same committee member, who also had personal interests in the manufacturer of the drug.

Details of Mr Medawar's concerns were published in the *International Journal of Risk and Safety in Medicine* and can be found on the Social Audit web-

site (www.socialaudit.org.uk).

Dr Andrew Herxheimer, emeritus fellow at the UK Cochrane Centre, said that the committee's move to publish minutes on the web was a step in the right direction. But he said that it was worrying that the committee was not even subject to basic citizen's charter standards on giving out information.

He strongly criticised members of the committee for not being prepared to justify any of their decisions. "They had no willingness to respond to specific criticisms of the trial [of paroxetine]. That is against the public interest," he said.

The Committee on Safety of Medicines website is www.open.gov.uk/mca/csm/home.htm □

Scientists who do not publish trial results are "unethical"

Gavin Yamey *BMJ*

Failure to report the results of randomised trials constitutes scientific and ethical misconduct, Dr Iain Chalmers, director of the UK Cochrane Centre, told a press conference in London last week. Dr Chalmers and the editors of the *BMJ* and the *Lancet* called for an international register of all clinical trials to be established.

Dr Chalmers said that "prospective registration and public access to the results of all randomised trials should be required by organisations responsible for protecting the public." These organisations should include drug licensing authorities and research ethics committees.

Trials should be registered, he argued, to inform patients, clinicians, and other decision makers about trials in which they could participate, to prevent costly research duplication and to promote multi-centre trial collaboration. "A substantial problem remains," he said, "because studies with

disappointing or negative results are less likely to be submitted for publication." He presented several examples of such biased underreporting of research.

A randomised trial of the class I antiarrhythmic drug lorcinide in patients with acute myocardial infarction, carried out in 1980, remained unreported for 13 years. The increased death rate in the lorcinide group was thought to be a chance finding, and the use of class I antiarrhythmic drugs generally increased.

"At the peak of their use in the late 1980s," said Dr Chalmers, "it has been estimat-

ed that class I antiarrhythmic drugs given to people with heart attacks were causing between 20 000 and 70 000 premature deaths every year in the United States alone. This yearly total of deaths is of the same magnitude as the total number of Americans who died in the Vietnam war."

Dr Chalmers welcomed the launch of an online register of randomised controlled trials (www.controlled-trials.com) but warned that the comprehensive registration of planned, ongoing, and unpublished controlled trials is unlikely to happen "unless there is legal clout." □