

MENTAL HEALTH

UK psychiatrists question SSRI warnings for under-18s

β See related articles pages 487 and 489

Leading psychiatrists in the UK are expressing misgivings about regulatory action to curb the use of most selective serotonin reuptake inhibitors (SSRIs) to treat depression in children and adolescents.

The Royal College of Psychiatrists' (RCPsych) Faculty of Child and Adolescent Psychiatry is writing to equivalent organizations in Canada, the US and Europe to stress its concern about a recent warning from the UK Committee on Safety of Medicines (CSM) that all but one of the SSRI group of drugs should not be used to treat depression in under-18s. The faculty is also detailing its concerns to the CSM.

The CSM's advice on SSRIs followed its warning about the use of paroxetine last June when it found that the risk of suicidal thoughts and behaviour was between 1.5 and 3.2 times more likely in young patients taking paroxetine compared to placebo.

The RCPsych Faculty of Child Psychiatry Chairman Sue Bailey said they will be asking the CSM whether it is "really satisfied that this data is definite enough for absolute guidance to be given in the way it has been given."

The CSM decision has pressured other regulators to consider warnings. Health Canada is setting up an expert advisory panel of independent psychiatrists to review the safety data on SSRIs. The US Food and Drug Administration, which was scheduled to meet Feb. 2 to decide on regulatory action, says

SSRIs must be used with caution in all age groups.

In addition, new draft guidelines from the UK's National Institute of Clinical Excellence state that antidepressants are not recommended for the initial treatment of mild depression in adults "because the risk-benefit ratio is poor." NICE will publish guidelines for the treatment of depression in children next year.

Bailey said she has "grave concerns" about the CSM action. For example at least 1 drug (fluvoxamine) is being ruled out as a depression treatment for under-18s simply because efficacy has not been shown. She says this raises serious questions about other drugs as research evidence showing efficacy in children is frequently lacking.

Much larger trials are needed so the results can be stratified by age, she says. "But one consequence of this CSM decision may be that no further trials on the pharmaceutical treatment of adolescent depression will ever get through an ethics committee."

To allow clinicians to assess the evidence for themselves, CSM has released the drug company data it used to review safety and efficacy of SSRIs (www.mhra.gov.uk).

CMAJ asked John Geddes, a professor of epidemiological psychiatry at Oxford University to do just that. "I don't think that the ... analysis is up to the current best standards," he concluded. "If this was sent to a journal, it would not do well in peer review."

David Healy, a psychiatrist at



Health Canada

SSRIs and young patients: Do we know enough about safety?

the North Wales department of psychological medicine, has written on SSRI safety for several years and gave evidence to the CSM investigation. He said the trials assessed by the CSM clearly show that children taking SSRIs for depression are more likely to become suicidal than those taking a placebo.

Following the CSM warning, doctors — including Healy — have demanded compulsory disclosure of all drug company trial data. Currently, companies don't have to disclose data if they are not pursuing a product licence, and no SSRI drugs are licensed for the treatment of depression in under-18s in the UK.

GlaxoSmithKline said that of the 3 trials the CSM used to assess paroxetine only one was published (*J Am Acad Child Adolesc Psychiatry* 2001;40:762-72). The other 2 are still not in the public domain. But Healy says doctors may not be any the wiser even if the trials are published.

— Colin Meek, Scotland