

Antidepressant linked to suicide risk in adults

- Top-selling drug already banned for children
- Minister announces move towards talking therapies

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Britain's bestselling antidepressant, Seroxat, can cause adults as well as children to become suicidal, according to the manufacturer, GlaxoSmithKline.

GSK, which for years denied there was a problem with the drug, has sent a letter to all doctors in Britain warning of the potential risk in some adult patients. The company has reanalysed data from the clinical trials of the drug and found that significantly more adults who were given Seroxat became suicidal than those given a placebo. Seroxat has been banned from use in children by the UK drug regulator for the same reason. The revelation came as the health secretary, Patricia Hewitt, declared the end of the "Prozac nation" yesterday, launching a programme to cut the numbers of patients on drugs such as Prozac and Seroxat and extend counselling to the thousands of people with mild to moderate depression and anxiety.

"Millions of people suffer from mild to moderate mental health problems and treating them takes up about a third of GPs' time," she said in a speech to the National Mental Health Partnership's conference. "Too many people are prescribed medication as a quick-fix solution."

Talking therapies worked just as well as drugs and people preferred them, she said. Two centres dedicated to counselling and psychotherapy will open in Doncaster and Newham as "demonstration sites" with the intention of extending access to talking therapies across the UK.

Seroxat is the biggest-selling SSRI (selective serotonin reuptake inhibitor) in Britain. In 2003 doctors wrote 19m prescriptions for the drug for patients with anxiety and depression. But concerns about the drug and others in its class have been growing.

GSK's letter to doctors is the result of a reanalysis of its trials requested by the US drug regulator, the food and drug administration, which is reviewing SSRIs. Seroxat is given to patients not only for depression and anxiety but, for a range of other problems defined by psychiatrists as separate conditions, such as panic disorder, generalised anxiety disorder and obsessive compulsive disorder. The analysis has found that patients taking the drug for those conditions may also have an increased risk of suicidal thinking and behaviour. But the clearest findings come from trials of the drug in people who were depressed. In those, says the letter, the frequency of suicidal behaviour was higher in patients on Seroxat than those who, without knowing it, were on a placebo. The numbers were small - 11 out of 3,455 on Seroxat and one out of 1,978 on placebo - but the difference was statistically significant, meaning it was unlikely to have occurred by chance.

Because of the small numbers, GSK says the findings should be interpreted with caution.

It adds that "all of the reported events of suicidal behaviour in the adult patients ... were non-fatal suicide attempts, and the majority of those attempts were in younger adults aged 18 to 30". But the data does suggest "that the higher frequency observed in the younger adult population across psychiatric disorders may extend beyond the age of 24".

GSK says in the letter that it "continues to believe that the overall risk:benefit of paroxetine (Seroxat) in the treatment of adult patients" with depression and other disorders "remains positive", but it warns that young adults particularly should be carefully monitored on the drug.

David Healy, professor of psychiatry and director of the north Wales department of psychological medicine, who has for years called for warnings about the suicide risk of SSRIs, said yesterday that GSK had been in possession of the statistics it was now making public for at least 15 years. "Seroxat has a severe withdrawal syndrome, which seems to me to be worse than for other drugs in the group, and the withdrawal syndrome in its own right is linked to people becoming suicidal," he said.

GSK yesterday rejected any accusation of dragging its feet on the data on suicidal behaviour in depressed adults. It had taken advice from experts who had suggested new ways of looking at the information, a spokeswoman said. The analysis, completed recently, had been forwarded to US and UK authorities.