

# Tests showed some children could become suicidal

- [Sarah Boseley](#)
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On May 21 2003, representatives of Britain's biggest pharmaceutical company handed a document to officials of the drug regulatory body that was to spark a four-year criminal investigation. It was proof that GlaxoSmithKline's bestselling antidepressant, Seroxat, could make depressed children feel suicidal.

Not only did Seroxat make some children feel like killing themselves, but it worked no better than a placebo, the document showed. The regulators, the Medicines and Healthcare Products Regulatory Authority (MHRA), could hardly believe it. "The information was received almost incidentally, at the end of a meeting which had been convened to consider the broader question of the safety of Seroxat in adults," said MHRA chief executive Kent Woods.

GSK had passed the information to MHRA officials because, it said, it was considering applying for a licence to treat children suffering from obsessive compulsive disorder. "On pointing out these data, GSK indicated this safety signal was something the agency might wish to bear in mind when considering the application for use in children which GSK was proposing to submit in late June 2003," says the MHRA's summary of its investigation, published yesterday.

Seroxat had no licence of any sort for use in children - notably, GSK had not applied to market it for depression even though it had carried out studies between 1994 and 2002. But in 1999, about 32,000 Seroxat prescriptions were written for children in the UK. By 2003, the MHRA estimates that 7,000-8,000 children were taking the drug.

Within two weeks of obtaining GSK's full analysis, the MHRA had instructed all doctors not to prescribe Seroxat to children. It then launched a criminal investigation of GSK for allegedly withholding safety data from the regulator.

The MHRA made clear yesterday it was convinced GSK was aware of the dangers of Seroxat to children some time before the company told the regulator. But not only was it unable to prosecute GSK under the existing laws, it was also prevented from revealing what it had discovered under secrecy rules related to the commercial confidentiality arrangements.

So at the end of an investigation in which the MHRA's investigators negotiated on 103 occasions with GSK lawyers over obtaining documents and accumulated 1m pages of evidence, the situation remains as it was in 2003. Nobody outside GSK and the MHRA officially knows who knew what and when.

GSK's critics say there was evidence of a problem it should not have ignored as early as 1989. Two trials showed the drug failed to have any effect in depressed children.

The company kept these results to itself. A leaked internal document dated October 1998 suggested the company should "effectively manage the dissemination of these data in order to minimise any potential negative commercial impact".

According to Professor David Healy, an expert on psychological medicine at Cardiff University, GSK and the other companies making this type of drug knew from 1989 that there were issues around suicidality - a seminal paper was published in February 1990.

GSK says it first became aware there might be a genuine problem after a meta-analysis of all its nine trials involving children was finished in October 2002, "but it was not clear-cut so the analysis continued into early 2003," said its spokeswoman.

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