

Drugs firms face new laws on test results

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A major tightening of the law governing the oversight of drugs companies will be announced today when the government says GlaxoSmithKline delayed informing the authorities that a controversial drug increased the likelihood of suicide among teenagers.

The health minister Dawn Primarolo will tell MPs that new legislation will be introduced by the end of the year to ensure drugs companies pass on results of clinical trials as soon as the alarm is raised about one of their medicines.

The government is to intervene after a four-year investigation by the drug regulatory body into the way GSK withheld the full results of their trials of the antidepressant Seroxat on children.

The trial data, which was finally handed to the Medicines and Healthcare Regulatory Authority (MHRA) in May 2003, identified two problems of which the company had been aware as early as 1998:

- A higher risk of suicidal behaviour among under 18s using Seroxat rather than a placebo.
- Seroxat was ineffective in dealing with depressive illness among under 18s.

Primarolo will announce that GSK should have told the MHRA earlier than it did about the results. But GSK will not face criminal prosecutions, she will say, because the legislation in this area is insufficiently clear on whether and when drugs companies should inform the regulator.

The minister will announce that new legislation will be introduced by the end of the year placing a greater obligation on companies to disclose results of trials.

The MHRA's investigation asked whether GSK had informed the regulatory body in reasonable time. It shows that the drug company had the information about the potentially suicidal effects of Seroxat and concludes that GSK should have informed the MHRA earlier. However, it finds that the company acted within the letter of the law by withholding data that would have shown up a problem. The failure to take stronger action against GSK will anger the many critics of the regulatory body, who say it is not up to the job of policing the pharmaceutical industry.

Patients and some doctors have been urging a tough line against GSK ever since the MHRA suddenly announced, in June 2003, that doctors must not give Seroxat to children and under 18s.

The agency said it was acting within two weeks of being given the full set of data from trials of Seroxat in children. The statistics contained in those results showed that the drug was no better than a placebo in alleviating depression in children and that those on the drug were more likely to develop suicidal tendencies than those on placebo. In one of the trials, 6.5% of those taking Seroxat became suicidal compared with 1.1% in the placebo group.

A leaked internal document from GSK, dated to 1998, said the company would have to "effectively manage the dissemination of these data in order to minimise any potential negative impact".

In the United States, GSK was sued by the New York state attorney general, Eliot Spitzer, and settled for \$2.5m (£1.25m) and an agreement to publish all its trial results - negative or positive - on a publicly available database.

Critics have called for big changes to the MHRA. In its report into the influence of the pharmaceutical industry, the Commons' health select committee expressed concern that the MHRA did not get all the information it needed from manufacturers before it licensed drugs. It called for a new regime of random audits of the raw trial data collected by companies and for more staff to be employed.

GSK has always completely rejected allegations that it improperly withheld data on the drug. It said Seroxat had never been approved by EU or US regulators as a medicine for those under 18, and that the company had therefore never marketed the drug for that age section. It also said its trial results had been submitted to regulators and were presented publicly in journals and on its website.

