

Glaxo Escapes Prosecution Over Paxil In UK

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After a four-year investigation and examining 1 million pages of evidence, the UK's Medicines and Healthcare products Regulatory Agency has decided not to pursue criminal charges against the drugmaker, although the agency did chastise Glaxo for failing to release more quickly clinical trial data about suicidal risk in youngsters.

The prospect of obtaining a criminal conviction wasn't "realistic," because the legislation in force in 2003 - when the investigation began - wasn't clear enough, especially concerning the disclosure of data and off-label use, the MHRA said in [a statement](#). Glaxo and individual Glaxo employees declined "invitations to attend interviews," the MHRA says, but did provide three written witness statements - two on behalf of the drugmaker and one on behalf of an unnamed employee.

Glaxo provided the MHRA with data from clinical trials confirming that patients under 18 had a higher risk of suicidal behaviour if they were treated with Paxil, which is known as Seroxat in the UK, than if they received a placebo; and that Seroxat was ineffective in treating depression in kids. The probe began after disclosure that Glaxo withheld clinical trial info.

"I remain concerned that GSK could and should have reported this information earlier than they did. All companies have a responsibility to patients and should report any adverse data signals to us as soon as they discover them," Kent Woods, MHRA's ceo, says in the statement. "This investigation has revealed important weaknesses in the drug safety legislation in force at the time."



Laws have subsequently been changed to require drugmakers to report adverse reactions in any clinical trial, though these rules don't apply outside of Europe - and most of Glaxo's Paxil trials were conducted in the US. The MHRA plans to press for change in law in the UK and eventually Europe to force drugmakers to report adverse clinical data no matter where trials are conducted.



“Such a course of action should be unnecessary in an industry which relies so heavily on public trust and aspires to high ethical standards. I would have thought it self-evident that such information should be made available promptly to the regulator in order that action can be taken to protect public health. However, that moral responsibility now needs to be insisted upon by the unambiguous force of law,” [Woods wrote Glaxo ceo JP Garnier.](#)