

Press release

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GSK investigation concludes

The MHRA has concluded its four year investigation into Glaxosmithkline and its anti-depressant drug Seroxat. The investigation focused on whether GSK had failed to inform the MHRA of information it had on the safety of Seroxat in under 18's in a timely manner. The investigation was undertaken with a view to a potential criminal prosecution for breach of drug safety legislation. It was the largest investigation of its kind in the UK, and included the scrutiny of over 1 million pages of evidence.

The decision taken by Government Prosecutors, based on the investigation findings and legal advice, is that there is no realistic prospect of a conviction in this case, and that the case should not proceed to criminal prosecution. The legislation in force at the time was not sufficiently strong or comprehensive as to require companies to inform the regulator of safety information when the drug was being used for, or tested outside its licensed indications.

GSK provided the MHRA with data from clinical trials in May 2003, confirming that patients under 18 had a higher risk of suicidal behaviour if they were treated with Seroxat than if they received a placebo; and that Seroxat was ineffective in treating depressive illness in under 18's. Acting upon this information the MHRA immediately reviewed the data and published advice to all doctors that Seroxat should not be used in under 18's. The investigation arose from concern that GSK had held the information for some time before this and failed to disclose it.

Professor Kent Woods, MHRA Chief Executive, said: "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. This investigation has revealed important weaknesses in the drug safety legislation in force at the time. Subsequent legislation has partially addressed the problem, but we will take immediate steps to ensure the law is strengthened further, so that there can be no doubt as to companies' obligations to report safety issues."



NOTES TO EDITORS

1. See website homepage www.mhra.gov.uk to download full report and related documents