

Watchdog voices dismay at failure to police industry

Legal loophole to be tightened after GSK prosecution foiled

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- [Sarah Boseley](#) and [David Leigh](#)
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Various pills. Photograph: Getty Images

The head of Britain's drug regulatory body appealed to pharmaceutical companies yesterday to recognise they have an ethical duty to alert consumers to the dangers of their products.

Speaking in the wake of a failed attempt to prosecute the UK's biggest drug company, GlaxoSmithKline, for allegedly hiding negative trial results, Kent Woods, chief executive of the Medicines and Healthcare Products Regulatory Authority, implicitly acknowledged the difficulties of policing the multibillion-pound pharmaceutical industry.

He could see little alternative to the present reliance on drug companies, first to look for problems and then to tell the regulator about them.

GSK could not be prosecuted for concealing results which proved the antidepressant Seroxat caused children to become suicidal because the

law only obliges companies to hand over safety data from trials when drugs are being licensed. That loophole will now be closed.

Woods said yesterday he could not rule out the possibility that other companies were sitting on unpublished data that could cause them commercial damage.

"I think there is a tension between marketing considerations and the ethical dimension of making health products," he said. "We have to look again at that. The pharmaceutical industry has to look again at that. You could even say there is a positive disincentive to explore the data as fully as it could be explored."

He said the conduct and analysis of clinical trials was increasingly complex and it was not possible for MHRA staff to know more than the company chose to tell them. "We seem to be producing a more and more elaborate legal framework to cover every possible eventuality. You can keep elaborating the larger framework as much as you like, but there will be gaps," he said.

There was also pressure on regulatory bodies to streamline their activities and license drugs faster, which was at odds with attempting tougher policing of the companies.

Woods said: "I really feel there is an ethical obligation that pharmaceutical companies ought to recognise and it seems to have been lost. Twenty years ago I was a prescribing doctor and I took it for granted that if there was information relevant to the drug I was going to prescribe, then it would be available. We're talking about something which has direct relevance to health and safety."

GSK conducted nine trials of Seroxat in children between 1994 and 2002. The two earliest, in depressed children, showed clearly that the drug was not effective.

But it was not until May 2003 that the company showed the MHRA an analysis of all nine trial results which proved that the drugs were ineffective and that children were more likely to become suicidal if they took them.

GSK says it had the report from October 2002 but was still analysing it until early 2003. Critics say it must have been clear there were safety issues much earlier.

Dr Tim Kendall, joint director of the National Collaborating Centre for Mental Health, which produced NHS guidelines on the use of the drugs,

said the need to change the law revealed the inadequacies of drug regulation.

"It is an absolute indictment of the current way regulation is happening that we can still have a drug company withholding data which shows a seven-fold in risk because of the drug since 1999," he said.

Seroxat is licensed for adults but not for children, even though doctors were prescribing it for up to 8,000 under-18s by 2003. Doctors can prescribe unlicensed drugs on their own responsibility.

Woods administered a stern rebuke to GSK's chief executive, Dr Jean-Pierre Garnier, in a letter sent yesterday, informing him of the forthcoming legislation.

"Such a course of action should be unnecessary in an industry which relies so heavily on public trust and aspires to high ethical standards," he wrote.

" 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."

Drug secrecy rules prevent the MHRA from revealing the full details of what it discovered during its investigation, in which GSK - following negotiations each time with its lawyers - handed over 103 documents.

GSK's officers refused to be interviewed under caution, but three witness statements were made, two from the company and one from an individual.

Yesterday, Woods challenged GSK to allow him to release everything into the public domain because of the legitimate interest in the case.

"This of course requires your consent. GSK has regularly asserted that it has nothing to hide in this matter, and so I should be grateful if you could confirm in writing your consent to the release," he wrote to Garnier.

GSK said the disclosure "is something we are looking at. It is under review."

In a statement, the company rejected any suggestion that it withheld information. "We firmly believe we acted properly and responsibly in first carrying out this important clinical trials programme and then informing the regulatory agencies when we identified a potential increased risk of

suicidal thinking and behaviour in patients under 18," said Dr Alastair Benbow, GSK's medical director for Europe.

Mind, the mental health charity, called for the legislation to be passed quickly. "There can be no excuses from the pharmaceutical industry," said Paul Farmer, Mind's chief executive.

"The public must be able to have trust and confidence in the medicines they are taking. We need to be sure that the tragedies associated with Seroxat can never happen again."

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