

# Prescription for change

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The regulators of the multibillion-dollar global drugs industry must sometimes feel like a barnacle on a whale: not easily able to influence the direction of travel. Yesterday's report from the Medicines and Healthcare Products Regulatory Agency (MHRA), on GlaxoSmithKline's failure to disclose adverse evidence about its antidepressant drug Seroxat, reveals again how powerless the watchdog is. It has taken four years to extract (it had to use its special powers on no less than 103 occasions) and then to analyse a million pages of evidence that confirm the drugs company failed to report the findings of Seroxat's potentially suicidal effect on young people in a "timely" manner. There was no warning of the potential problems that led to the MHRA's ban on prescribing the drug to under-18s until 2003, possibly several years after GSK first had evidence. Even so, the MHRA has reluctantly concluded that there is no case for the company to answer in law.

At about the time when the agency began its inquiry into GSK, MPs on the Commons health committee accused the MHRA of failing to hold the drugs industry to account, of a "poor history in recognising drug risks", and of "poor communication and lack of public trust". The committee also blasted the body for secrecy and even accused it of becoming too close to the industry to regulate it effectively. Yesterday the health minister Dawn Primarolo promised a tougher regulatory structure. It will tackle one of the failings exposed by the Seroxat affair by forcing drugs companies to disclose for the first time the post-licensing research that the industry does in the search for new applications for existing drugs. It was this research that first exposed the possible risks associated with prescribing Seroxat to under-18s. In fact, following a £2.5m legal action in New York, GSK began making all its clinical trial data available online. But the evidence against Seroxat only emerged after GSK had simultaneously analysed a series of nine separate trials. The regulators - and the public - need access to such costly and time-consuming meta-analyses if confidence is to be restored. But granting that is only the first necessary step.

It is not just work done after drugs are licensed that big pharma has been able to keep secret. It is commonplace, insiders say, for trials that reveal problems to be suppressed, while positive results are written up in glowing terms. A study last week suggesting that previously hyped antidepressants - including Seroxat and Prozac - often had little effect. That has increased public suspicions about the claims of the industry. The firms do now have to reveal results of the pre-licensing trials to the regulators, although that does not necessarily stop them promoting only the good bits. The health committee proposed random audits of all drug trials as a solution.

The MHRA came up against a further problem. In the Seroxat case it had the power to force GSK to disclose what it knew and when. However, the cloak of commercial confidentiality means there is no obligation to disclose this information more widely. Despite an open appeal from the MRHA chief executive, Professor Kent Woods, it seems unlikely GSK will publish the evidence on Seroxat. All we are allowed to know is that we do not know. This is not a new problem, but the government appears reluctant to address it. In an earlier report the MPs said the health department "was remarkable for its denial that any significant conflict between commercial and health objectives might arise". Nothing seems to have changed. Meanwhile, the MHRA (perhaps fearing that the drugs companies are exploiting other loopholes that it has yet to discover) appeals to doctors who work for drugs companies to recognise their ethical responsibility to report adverse findings. Desirable, of course, but when GSK still insists it did nothing wrong, and no one can review the evidence to examine its claim, much stronger medicine is required.