Drug makers accused of trying to hide test results

Tom Whipple Science Editor

Pharmaceutical companies are lobbying to block the public release of clinical trial data in a move that campaigners say puts patient safety at risk.

A European transparency initiative is proposed to ensure that when regulators approve new drugs the full data from the trials would be publicly released, rather than just a summary published in a medical journal.

The proposal comes after high-profile cases in which independent researchers found that drugs such as Tamiflu or the antidepressant Seroxat were more dangerous or less effective than pharmaceutical companies had claimed.

In the case of Seroxat, a GlaxoSmith-Kline drug, the full study reports had been restricted. When researchers accessed the papers, they found that the drug was linked to self-harm and suicide in teenagers — even though the drug company's summary of the research had said that it was safe and effective.

Campaigners have said that while all companies are ostensibly on board with the reforms, some are now asking to be allowed to redact so much data before the release that it would effectively lead to the removal of all useful information.

The pharmaceutical companies say that they are doing this to ensure that details of patients involved in the trial remain confidential.

Other scientists argue that the approach effectively renders the whole exercise pointless.

"Healthcare professionals cannot reliably inform patients of the potential benefits and potential harms of medicines when the underlying clinical trial data is kept secret," said Peter Doshi, from the University of Maryland school of pharmacy, who has campaigned for the release of all data. "Without raw data, we are left vulnerable to trusting at face value journal articles that may, in truth, be little more than marketing dressed up as peer-reviewed science."

Tom Jefferson, a British researcher based in Rome who works for the respected Cochrane Collaboration, a volunteer health organisation, said that there was a moral, as well as a practical, necessity to change the regulations. He said that the transparency initiative would be undermined if much of the data were redacted.

"If you carry out an experiment on a human you have certain responsibilities," Mr Jefferson said. "One of those is that you shouldn't suppress data."

Both scientists said that it should be possible to make the patients anonymous without rendering the research useless. "Journals have articles ten to fifteen pages long," Mr Jefferson said. "The underlying data set is tens of thousands of pages long. This means they can present the product in the best possible light — which is what they've been doing. We've got abundant, overwhelming evidence this is the case."

Research released this year showed that when industry sponsors medical trials of its own drugs they are backed 97 per cent of the time.

This is why the European Medicines Agency, a London-based umbrella organisation for national regulators, is working to introduce a voluntary code for the release of all data as drugs come to market, so that other researchers can reassess it as necessary.

Researchers involved in the discussions have told *The Times* that several companies want a strict approach to make this data so anonymous that, when applied to real-world examples, such as the Tamiflu research, it removes virtually all the information.

A spokesman for the European Federation of Pharmaceutical Industries and Associations said it was working to "balance responsible reporting for public health benefit and safeguarding patient confidentiality".

Professor Doshi said that it was imperative that the data remained usable. "After years, we finally have a system that's soon to go live and make trial data public," he said. "But at the last minute, there's a move that could render the system useless."

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Bad medicine

Seroxat

"Study 329" has taken on a totemic status in the battle for transparency. This trial in the 1990s by Smithkline Beecham, now GSK, into the antidepressant paroxetine, also known as Seroxat, helped to establish a drug that made the company billions. The trial showed that the side effects of the drug were minimal. It transpired, though, that the study had been ghostwritten and had downplayed serious risks of the drug, which was also shown to be ineffective for adolescents.

Tamiflu

The British government spent half a billion pounds stockpiling the antiviral Tamiflu as preparation for a potential flu pandemic, but it emerged that most of the trials into the drug were never made public. It was also claimed that Tamiflu prevented pneumonia — but an analysis of the full data, eventually released, showed that many of these pneumonia cases had never been verified, and where they had there was no significant effect.